Supported by an independent educational grant from Arcutis Biotherapeutics, Inc., AbbVie, Endo Pharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs, LLC, La Roche-Posay (a L'Oreal brand), Ortho Dermatologics, a division of Bausch Health, and Regeneron Pharmaceuticals and Sanofi Genzyme.

A SUPPLEMENT TO

cutis®

CUTANEOUS MEDICINE FOR THE PRACTITIONER

REFERENCED IN *INDEX MEDICUS*

VOL. 109 | NO. 6S | JUNE 2022 | mdedge.com/dermatology

INNOVATIONS IN DERMATOLOGY SPRING ABSTRACT COMPENDIUM

ACNE & ROSACEA

ABSTRACT 01

Acne Excoriée: Diagnostic Overview and Treatment Options

McKayla Poppens[1], Kyle Cheng[1]

[1]Division of Dermatology, Department of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA

CORRESPONDING AUTHORS:
McKayla Poppens, mpoppens@mednet.ucla.edu
Kyle Cheng, kylecheng@mednet.ucla.edu

BACKGROUND: Psychocutaneous diseases are primary psychiatric conditions with skin manifestations frequently encountered in dermatology. Acne excoriée (AE) is an excoriation disorder that involves a conscious, repetitive, and uncontrollable urge to excoriate (pick, scratch, gouge, lance, dig, rub, or squeeze) acne lesions, leading to self-injury and scarring, as well as to significant distress or functional impairment. The primary pathophysiological source is psychological, not skin based. People afflicted by skin-picking disorders often spend hours per day picking their skin, causing social and work impairment, avoidance of activities that expose picked areas, and negatively affecting their self-esteem. Recognition of psychological behaviors related to acne can be challenging and management difficult due to patient denial and refusal of treatment.
OBJECTIVE: To conduct a review of existing literature on the pathogenesis, diagnosis, and management for AE.
METHODS: A literature review via PubMed was conducted to collate relevant articles. Key terms such as "acne excoriée"; "excoriation disorder"; "skin-picking disorder"; and combinations thereof with "epidemiology"; "pathogenesis"; "presentation"; "management"; "treatment"; "pharmacotherapy"; "medication"; and "psychotherapy" were used to identify relevant articles and reports.
RESULTS: Acne excoriée is a profound psychological disorder that may cause severe reduction in quality of life. Additional research is needed to elucidate the epidemiology and risk factors for AE. This disorder is underrecognized often due to patient discomfort in initiating conversation about their skin-picking behaviors and lack of clinician query. For a patient presenting to a dermatologist with atypical acne or acne that is nonresponsive to treatment, self-excoriation habits should be assessed using a validated screening tool and the DSM-5 criteria for excoriation disorder. In addition to conventional acne therapy, psychotherapy (cognitive behavioral therapy, habit reversal training, and online self-help platforms) and pharmacotherapy (N-acetylcysteine 1200 to 3000 mg/day or oral naltrexone 50 mg/day) have proven beneficial to treat underlying cognitive and behavioral components of the disorder to reduce long-term damage to the skin. Regular medical check-ups can be advantageous to closely monitor treatment adherence and progress.
CONCLUSIONS: Psychotherapy and psychiatric pharmacotherapy are critical adjuvants to traditional acne treatments in patients with AE who otherwise may suffer with this disorder for decades.

TABLE 1. DSM-5 diagnostic criteria for excoriation (skin-picking) disorder.

1	Recurrent skin picking resulting in lesions.
2	Repeated attempts to decrease or stop skin picking.
3	The skin picking causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
4	The skin picking is not attributable to the physiologic effect of a substance (e.g. cocaine) or another medical condition (e.g. scabies).
5	The skin picking is not better explained by symptoms of another mental disorder (e.g. delusions or tactile hallucinations in a psychotic disorder, attempts to improve a perceived defect or flaw in appearance in body dysmorphic disorder, stereotypes in stereotypic movement disorder, or intention to harm oneself in non-suicidal self-injury).

FUNDING SOURCES: None.
DISCLOSURES: None declared.

ABSTRACT 02

Efficacy and Safety of Tazarotene Lotion, 0.045% in the Treatment of Truncal Acne Vulgaris

Leon H Kircik, MD

Department of Dermatology, Mt. Sinai School of Medicine, New York City, NY, USA; Derm Research PLLC, Louisville, KY, USA

BACKGROUND: Although truncal acne is thought to have the same pathophysiology as facial acne, a recent review determined that treatment response may differ based on body area involvement. (Poli F, et al. *J Eur Acad Dermatol Venereol*, 2020) Traditionally, prescribers have relied on oral therapies for the management of truncal acne (Del Rosso. *J Drugs Dermatol, 2007*), possibly because oral therapy has been considered more convenient than topical application of medication to the chest and back. A lotion formulation may be particularly well suited for the treatment of truncal acne. Tazarotene lotion, 0.045% is FDA approved for treatment of acne vulgaris in individuals 9 years of age or older.
OBJECTIVE: This open-label, 12-week pilot study was designed to investigate the efficacy and safety of tazarotene lotion for the treatment of truncal acne.
RESULTS: A total of 19 subjects ranging in age from 12 to 58 years completed the 12-week study. There were significant reductions in truncal Investigator's Global Assessment (IGA; the primary endpoint) at each of the study follow-up visits. At week 12, 89% of subjects were clear or almost clear, as assessed by truncal IGA score. There were significant reductions in inflammatory, noninflammatory, and total lesion counts from baseline to week 12. Treatment with tazarotene lotion 0.045% was well tolerated, with erythema, dryness, peeling, oiliness, pruritis, and burning generally rated as trace or mild. Most subjects (64% or more) rated the lotion as "Good" or "Excellent" in general and in comparison to prior medications.
CONCLUSIONS: Tazarotene lotion, 0.045% is effective and well tolerated for the management of truncal acne. Further study is warranted.

ABSTRACT 03

Preference and Tolerability of Two Topical Acne Formulations: Tretinoin 0.05% Lotion Versus Cream

Zoe D Draelos, MD[1]; Nicole Rawnsley, PharmD[2]; Emil A Tanghetti, MD[3]

[1]Dermatology Consulting Services, PLLC, High Point, NC; [2]Ortho Dermatologics, Bridgewater, NJ*; 3Center for Dermatology and Laser Surgery, Sacramento, CA

*Ortho Dermatologics is a division of Bausch Health US, LLC

Contact author info:
Zoe D. Draelos, MD
2444 North Main Street
High Point, NC, 27262
Phone 336-841-2040
zdraelos@northstate.net

BACKGROUND: Vehicle optimization represents an opportunity to maximize patient preference and adherence across topical therapy formulations (Eastman et al. 2014). Topical retinoids, such as tretinoin, are a mainstay of acne treatment, but associated cutaneous irritation and drying may lead to poor adherence (Zaenglein et al. 2016; *Sevimli Dikicier* 2019). As both active and inactive ingredients can contribute to tolerability, tretinoin 0.05% lotion (Altreno) was formulated using a polymeric honeycomb matrix, allowing for efficient and uniform delivery of micronized tretinoin and moisturizing/hydrating ingredients (Kircik et al. 2019).
OBJECTIVE: To compare participant preference and tolerability of two tretinoin 0.05% formulations: a lotion and a frequently dispensed generic cream (TARO).
METHODS: In this single-center, double-blinded, split-face study, females ≥18 years old with acne were randomized to apply lotion or generic cream once daily to the right or left cheek for 2 weeks. Assessments were conducted immediately after first use (at the research site) and after 2 weeks. The investigator assessed erythema, scaling, skin dryness, softness, smoothness, radiance, and brightness on a 5-point scale (0=none, 4=severe). Participants completed a 16-item facial marketing questionnaire on their impression of the products or their skin on a 9-point scale (1=agree completely, 9=disagree completely) for each cheek.
RESULTS: A total of 25 adult Caucasian females were enrolled and completed the study. While there were no significant differences in investigator assessments at baseline, after 2 weeks of use, there was a significant increase in erythema, scaling, and dryness on the cream-treated side of the face vs lotion (122-144% increase; $P<0.01$ each). Further, the lotion-treated side demonstrated significantly enhanced softness, smoothness, radiance, and brightness vs cream (~40% improvement; $P<0.01$ each). After 2 weeks of use, average impression rating scores were improved for lotion vs cream on all 16 questionnaire items (range: 1.64-3.60 vs 4.16-7.32; $P<0.05$ on 15/16 items). More participants agreed (rating score 1-3) that the lotion was gentle, comfortable/soothing, spreadable, absorbent, not sticky, and left minimal white residue vs cream (range: 72-92% vs 8-36%). Agreement scores on skin sensation (eg, soft, not dry, less dull) were similarly higher for lotion vs cream. Overall, approximately 70% of participants preferred to take lotion home over cream both after first use and 2 weeks of use.
CONCLUSIONS: Investigator-assessed irritation and skin appearance were significantly worse after 2 weeks of treatment with a generic cream compared to tretinoin 0.05% lotion. Participants also significantly preferred product and skin attributes with lotion vs cream. Though generic topicals are commonly prescribed, these results demonstrate the importance of a well-designed vehicle formulation on tolerability and patient preference.
FUNDING: Ortho Dermatologics.

REFERENCES:

Eastman, W. J., S. Malahias, J. Delconte and D. DiBenedetti (2014). "Assessing attributes of topical vehicles for the treatment of acne, atopic dermatitis, and plaque psoriasis." *Cutis* 94(1): 46-53.

Kircik, L. H., Z. D. Draelos and D. S. Berson (2019). "Polymeric Emulsion Technology Applied to Tretinoin." *J Drugs Dermatol* 18(4): s148-154.

Sevimli Dikicier, B. (2019). "Topical treatment of acne vulgaris: efficiency, side effects, and adherence rate." *J Int Med Res* 47(7): 2987-2992.

Zaenglein, A. L., A. L. Pathy, B. J. Schlosser, A. Alikhan, H. E. Baldwin, D. S. Berson, W. P. Bowe, E. M. Graber, J. C. Harper, S. Kang, J. E. Keri, J. J. Leyden, R. V. Reynolds, N. B. Silverberg, L. F. Stein Gold, M. M. Tollefson, J. S. Weiss, N. C. Dolan, A. A. Sagan, M. Stern, K. M. Boyer and R. Bhushan (2016). "Guidelines of care for the management of acne vulgaris." *J Am Acad Dermatol* 74(5): 945-973 e933.

ABSTRACT 04

Improvements in Acne and Skin Oiliness with Tazarotene 0.045% Lotion in Acne Patients with Oily Skin

Emil A Tanghetti, MD[1]; Michael Gold, MD[2]; Neil Sadick, MD[3,4]; Fran E Cook-Bolden, MD[4,5]; Leon H Kircik, MD[6-8]; Linda Stein Gold, MD[9]; Stephen K Tyring, MD, PhD[10]; James Q Del Rosso, DO[11-13]; Nicole Rawnsley, PharmD[14]; Eric Guenin, PharmD, PhD, MPH[14]

[1]Center for Dermatology and Laser Surgery, Sacramento, CA; [2]Tennessee Clinical Research Center, Nashville, TN; [3]Sadick Dermatology, New York, NY; [4]Weill Cornell Medical College, New York, NY; [5]Fran E. Cook-Bolden, MD, PLLC; [6]Indiana University School of Medicine, Indianapolis, IN; [7]Physicians Skin Care, PLLC, Louisville, KY; [8]Icahn School of Medicine at Mount Sinai, New York, NY; [9]Henry Ford Hospital, Detroit, MI; [10]University of Texas Health Science Center, Houston, TX; [11]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV; [12]Advanced Dermatology and Cutaneous Surgery, Maitland, FL; [13]Touro University Nevada, Henderson, NV; [14]Ortho Dermatologics*, Bridgewater, NJ. *Ortho Dermatologics is a division of Bausch Health US, LLC.

BACKGROUND: Excessive sebum production—which is associated with larger pore size—is a factor in acne development. The topical retinoid, tazarotene (TAZ), may reduce apparent facial pore size (0.1% cream). A lower-dose 0.045% TAZ lotion has also demonstrated efficacy in reducing acne lesions and acne-induced sequalae such as hyperpigmentation.

OBJECTIVES: To evaluate efficacy, changes in skin oiliness, and safety with TAZ 0.045% lotion in participants with moderate-to-severe acne and oily skin.

METHODS: In two phase 3, double-blind, 12-week studies (NCT03168334; NCT03168321), participants aged ≥9 years with moderate-to-severe acne were randomized 1:1 to once-daily TAZ 0.045% lotion or vehicle lotion (N=1,614). This pooled, post hoc analysis comprised participants categorized by baseline self-reported skin oiliness on the Acne Quality of Life questionnaire item 19 (scored from 0 [extremely oily] to 6 [not at all oily]); only participants scoring 0–2 (oily skin; n=736) were analyzed. Coprimary endpoints were inflammatory/noninflammatory lesion counts and treatment success (≥2-grade reduction from baseline in Evaluator's Global Severity Score [EGSS] and score of 'clear' or 'almost clear'). Changes in skin oiliness, treatment-emergent adverse events (TEAEs), and cutaneous safety/tolerability were also evaluated.

RESULTS: In oily-skin participants, TAZ provided greater least-squares mean percent reductions from baseline to week 12 in inflammatory/noninflammatory lesions vs vehicle (-57.0% vs -48.4%; -55.9% vs -42.1%; $P<0.001$, both). Treatment success rates were higher for TAZ vs vehicle (29.8% vs 19.2%; $P<0.01$). Most participants reported skin oiliness improvements to "moderately" or "low/not" oily with TAZ and vehicle (71.4% and 71.1%); more participants, however, reported improvements to "low/not" oily skin with TAZ than vehicle (35.0% vs 28.6%). TEAE rates with TAZ in oily-skin participants were similar to the overall population. While there were transient increases in the severity of cutaneous safety/tolerability assessments with TAZ, the percentage of participants reporting "none" was generally similar to baseline for most assessments by week 12.

CONCLUSIONS: Tazarotene 0.045% polymeric emulsion lotion demonstrated efficacy and safety in the treatment of moderate-to-severe acne in patients with oily skin. Nearly three-fourths of patients had skin oiliness reductions, with over a third reporting low/not oily skin by week 12.

FUNDING: Ortho Dermatologics

ABSTRACT 05

Efficacy and Safety of Triple-combination Clindamycin Phosphate 1.2%/Benzoyl Peroxide 3.1%/Adapalene 0.15% Polymeric Mesh Gel in Pediatric Participants

Lawrence F Eichenfield, MD[1]; Linda Stein Gold, MD[2]; Leon H Kircik, MD[3,4,5]; William P Werschler, MD[6]; Kenneth Beer, MD[7]; Zoe D Draelos, MD[8]; Emil A Tanghetti, MD[9]; Kim Papp, MD, PhD,[10,11]; Hilary Baldwin, MD[12,13]; Edward Lain, MD, MBA[14]; Neil Sadick, MD[15,16]; Nicole Rawnsley, PharmD[17]; Eric Guenin, PharmD, PhD, MPH[17]

[1]Departments of Dermatology and Pediatrics, University of California, San Diego School of Medicine and Rady Children's Hospital, San Diego, CA; [2]Henry Ford Hospital, Detroit, MI; [3]Indiana University School of Medicine, Indianapolis, IN; [4]Physicians Skin Care, PLLC, Louisville, KY; [5]Icahn School of Medicine at Mount Sinai, New York, NY; [6]University of Washington School of Medicine, Seattle, WA; [7]University of Miami Miller School of Medicine, Miami, FL; [8]Dermatology Consulting Services, PLLC, High Point, NC; [9]Center for Dermatology and Laser Surgery, Sacramento, CA; [10]Probity Medical Research, Waterloo, ON, CA; [11]K. Papp Clinical Research, Waterloo, ON, CA; [12]The Acne Treatment and Research Center, Brooklyn, NY; [13]Robert Wood Johnson University Hospital, New Brunswick, NJ; [14]Austin Institute for Clinical Research, Austin, TX; [15]Department of Dermatology, Weill Cornell Medical College, New York, NY; [16]Sadick Dermatology, New York, NY; [17]Ortho Dermatologics, Bridgewater, NJ*

*Ortho Dermatologics is a division of Bausch Health US, LLC

BACKGROUND: Acne is common in adolescence, with near-universal prevalence during teenage years (Yentzer et al. *Cutis* 2010). Acne in adolescents has profound

psychosocial impacts (Nguyen et al. *Clin Cosm Invest Dermatol* 2016), and younger age is associated with greater acne severity (Tan et al. *J Cutan Med Surg* 2008). In a phase 2, double-blind, 12-week study (NCT03170388), clindamycin phosphate (CLIN) 1.2%/benzoyl peroxide (BPO) 3.1%/adapalene (ADAP) 0.15% (IDP-126) polymeric mesh gel—the first fixed-dose triple-combination topical formulation in development for acne—was well tolerated and demonstrated superior efficacy to vehicle and all three component dyad combination gels (Stein Gold L, et al. *AJCD* 2022).

OBJECTIVES: This post hoc analysis investigated efficacy and safety of IDP-126 in children and adolescents with acne.

METHODS: Participants aged ≥9 years with moderate-to-severe acne (N=740) were equally randomized to once-daily IDP-126, vehicle, or 1 of 3 dyad combination gels: BPO/ADAP; CLIN/BPO; or CLIN/ADAP. Efficacy outcomes comprised changes in inflammatory/noninflammatory lesion counts and treatment success (≥2-grade reduction from baseline in Evaluator's Global Severity Score and a score of 0=clear or 1=almost clear). Treatment-emergent adverse events (TEAEs) were also assessed. Data were analyzed for pediatric participants aged 9-17 years (n=394).

RESULTS: At week 12, pediatric participants treated with IDP-126 experienced significantly greater least-squares mean percent reductions from baseline versus vehicle in inflammatory (78.3% vs 45.1%%; *P*<0.001) and noninflammatory lesions (70.0% vs 37.6% *P*<0.001). Lesion reductions were also 9.2-16.6% greater with IDP-126 than with any of the dyad combinations. A significantly greater percentage of participants achieved treatment success with IDP-126 (55.8%) than with vehicle (5.7%; P<0.001) or any of the dyad combinations (range: 30.8-33.9%; *P*<0.01, all). Efficacy of IDP-126 in pediatric participants was similar to the overall study population (lesion reductions: inflammatory, 76.4%; noninflammatory, 71.0%; treatment success, 52.5%). In pediatric participants, TEAE rates were highest with IDP-126 and BPO/ADAP. The most common treatment-related TEAEs across treatment groups were pain and dryness at the application site (up to 11.9% and 6.7%, respectively); most related TEAEs were of mild-to-moderate severity. The rates of related TEAEs in pediatric participants were similar to the overall population.

CONCLUSIONS: Treatment with IDP-126, triple-combination CLIN 1.2%/BPO 3.1%/ADAP 0.15% gel, was well tolerated in children and adolescents with acne. Over half of pediatric participants achieved treatment success, with lesion reductions of at least 70% after 12 weeks of once-daily use, similar to the overall study population. To our knowledge, such improvements have not been observed with any FDA-approved topical acne treatment, though study populations may differ.

FUNDING: Ortho Dermatologics

AESTHETICS

ABSTRACT 06

Enhanced Uptake of 2% Salicylic Acid Following 1440-nm Non-Ablative Fractional Diode Laser Treatment

Jordan V. Wang, MD, MBE, MBA[1]; Paul M. Friedman, MD[1,2]; Adarsh Konda, PharmD[3]; Catherine Parker, NP, MSN[4]; Roy G. Geronemus, MD[1]

[1]Laser & Skin Surgery Center of New York, New York, NY; [2]Dermatology and Laser Surgery Center, Houston, TX; [3]Bausch Health US, LLC, Bridgewater, NJ; [4]Former employee of Solta Medical, Bothell, WA

Correspondence requests to:
Jordan V. Wang, MD, MBE, MBA
Laser & Skin Surgery Center of New York
317 E 34th St, 6th Fl Research Dept, New York, NY 10016
Phone: (212) 840-0499
Email: drjordanwang@gmail.com

Author Contact Information:
Jordan V. Wang, MD, MBE, MBA jwang@laserskinsurgery.com
Adarsh Konda, PharmD adarsh.konda@bauschhealth.com
Paul M. Friedman, MD drpaul@dermlasersurgery.com
Roy Geronemus, MD rgeronemus@laserskinsurgery.com
Catherine Parker, NP, MSN cparker222@yahoo.com

BACKGROUND: Although topical medications directly target the site of dermatologic conditions, limited uptake across the stratum corneum may impede their clinical efficacy. Non-ablative fractional laser pretreatment is a promising approach to enhancing topical uptake. Compared to ablative lasers, non-ablative fractional lasers have less effect on the stratum corneum, can minimize thermal side effects, and can shorten postprocedural downtime. However, the relationship between uptake and device settings must be quantified to optimize topical treatments. In this ex vivo analysis, we quantified uptake of topical 2% salicylic acid, a common component of antiaging topicals, after pretreatment with a 1440-nm non-ablative fractional diode laser with varying treatment densities.

OBJECTIVES: To quantify non-ablative laser-enhanced topical uptake.

METHODS: Excised human abdominal skin tissue samples of 500-µm thickness were pretreated with a low-power 1440-nm laser using either 80 or 320 microscopic treatment zones (MTZ)/cm2 or received no laser pretreatment. Following laser pretreatment, 2% salicylic acid was applied, and uptake was determined at various time points up to 24 hours after application. Samples were filtered and analyzed using high-performance liquid chromatography to obtain permeation and retention for laser-treated samples and untreated controls. Total uptake was calculated as the sum of the normalized cumulative permeation and retention in each sample. Average total uptake was compared between laser-treated samples and untreated controls to determine the uptake enhancement ratio.

RESULTS: Both 1440-nm pretreatments (80 MTZ/cm2 [1.2 W] and 320 MTZ/cm2 [3 W]) were associated with similar enhancement of cumulative permeation of 2% salicylic acid at 24 hours posttreatment (both 0.01 mg/cm2); however, cumulative permeation was similar to untreated control at 24 hours (0.009 mg/cm2). Retention of 2% salicylic acid was ~9 times greater with 320-MTZ/cm2 pretreatment compared to both 80-MTZ/cm2 pretreatment and untreated control.

CONCLUSIONS: In this ex vivo analysis of transdermal 2% salicylic acid uptake, low-power 1440-nm non-ablative fractional diode laser pretreatment with 320 MTZ/cm2 resulted in enhanced uptake compared to untreated control and the 80-MTZ/cm2 setting, as demonstrated by greater retention within skin tissue samples. Retention enhancement following treatment with greater MTZ density did not appear to have an additive effect on overall uptake at 24 hours, supporting the argument that salicylic acid uptake may be predominantly transfollicular. These results may guide the development of treatment protocols for clinical use of non-ablative fractional laser pretreatment to enhance uptake of salicylic acid–containing topicals.

DISCLOSURES: This study was supported by Solta Medical (a division of Bausch Health, LLC). Data included in this abstract were presented in full at The Fall Clinical Dermatology Conference; October 21-24, 2021; Las Vegas, Nevada; Poster.

FUNDING: Ortho Dermatologics is a division of Bausch Health US, LLC.

ABSTRACT 07

Efficacy of a Firming and Toning Aesthetic Body Lotion for Upper Arms in a Double-Blind, Randomized, Vehicle-Controlled Clinical Study

Elizabeth T. Makino, BS, CCRA, MBA[1]; Lily Jiang, PhD[2]; Summer F. Acevedo, PhD[2]; Rahul C. Mehta, PhD[1]

[1]Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA; [2]SGS Stephens Inc., Richardson, TX, USA

Corresponding author:
Elizabeth Makino, BS, CCRA, MBA
Director, Clinical Development, Skincare
Allergan Aesthetics, an AbbVie Company
2525 DuPont Drive
Irvine, CA 92612
Phone: 714-246-2598
E-mail: elizabeth.makino@abbvie.com

Co-author Contact Information:
L Jiang: Li.Jiang@sgs.com
S Acevedo: Summer.Acevedo@sgs.com
R Mehta: rahul.mehta@abbvie.com

BACKGROUND: Upper arm sagging is caused by excessive skin laxity associated with aging and sun exposure; in addition, increased skin laxity and loss of skin firmness occurs with age, weight changes, and loss of connective tissue.

OBJECTIVE: To assess the efficacy of a firming and toning aesthetic body lotion (FTB) when used over the course of 12 weeks by women with lack of firmness on the upper arms.

METHODS: A double-blinded, randomized, 12-week study comparing FTB and a vehicle control was conducted. Patients assigned to either treatment applied designated product twice daily (morning and evening) on the upper arms. Included patients were females 30–65 years of age with a Fitzpatrick skin type I–V, mild to moderate visual lack of firmness and sagging on the upper arms, and body mass index (BMI) 19–30 kg/m^2 with a willingness to maintain BMI ±2 kg/m^2 within baseline. Investigator assessments, instrumentation evaluations, and patient questionnaires were performed. Characteristics and outcomes were summarized descriptively. Changes from baseline were evaluated with a paired t test or Wilcoxon signed-rank test, as appropriate. Comparisons between treatments were evaluated with a 2-sample *t* test or Wilcoxon rank-sum test, as appropriate.

RESULTS: Forty-four patients completed treatment (FTB, 30; vehicle control, 14). Patients randomized to FTB showed significant improvements in the upper arms (all $P<0.05$) at week 12 compared with baseline for investigator assessments of crepiness (21.7%), skin smoothness (24.3%), skin tone evenness (8.9%), body skin texture (14.8%), body skin firmness (8.2%), and sagging (5.4%). Significant improvements in the upper arms (all $P<0.05$) at week 12 compared with baseline in patients randomized to FTB were observed for instrumentation analyses of skin firmness (extensibility, 16.4%) and epidermal and dermal tissue density (19.4%), and for skin hydration (15.5%). The improvements in investigator and instrument assessments of skin efficacy parameters at week 12 were accompanied by significant improvements in self-perceived efficacy ($P<0.02$) and overall satisfaction with the appearance of their skin following FTB treatment versus vehicle control.

CONCLUSIONS: FTB provided significant improvements in the upper arms compared with baseline and vehicle control across multiple investigator assessment and instrumentation evaluation parameters while improving self-reported efficacy and satisfaction in the majority of patients.

DISCLOSURES: ET Makino and RC Mehta are employees of AbbVie. L Jiang and SF Acevedo are investigators for Allergan Aesthetics, an AbbVie Company. Allergan Aesthetics, an AbbVie Company, was the study sponsor. Medical writing assistance was provided to the authors by Drayton Hammond, PhD (Peloton Advantage LLC, an OPEN Health company).

ABSTRACT 08

Efficacy of a Firming and Toning Aesthetic Body Lotion for Thighs in a Double-Blind, Randomized, Vehicle-Controlled Clinical Study

Elizabeth T. Makino, BS, CCRA, MBA[1]; Lily Jiang, PhD[2]; Summer F. Acevedo, PhD[2]; Rahul C. Mehta, PhD[1]

[1]Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA; [2]SGS Stephens Inc., Richardson, TX, USA

Corresponding author:
Elizabeth Makino, BS, CCRA, MBA
Director, Clinical Development, Skincare
Allergan Aesthetics, an AbbVie Company
2525 DuPont Drive
Irvine, CA 92612
Phone: 714-246-2598
E-mail: elizabeth.makino@abbvie.com

Co-author Contact Information:
L Jiang: Li.Jiang@sgs.com
S Acevedo: Summer.Acevedo@sgs.com
R Mehta: rahul.mehta@abbvie.com

BACKGROUND: Cellulite, the uneven distribution of subcutaneous tissue appearing as an irregular, dimpled skin surface, occurs in 80% to 90% of post-adolescent women.
OBJECTIVE: To assess the efficacy of a firming and toning aesthetic body lotion (FTB) when used over the course of 12 weeks by women with mild to moderate cellulite on the thighs.
METHODS: A double-blind, randomized, 12-week study comparing FTB and a vehicle control was conducted. Patients assigned to either treatment applied designated product twice daily (morning and evening) on the front and back of thighs. Included patients were females 30–65 years of age with a Fitzpatrick skin type I–V, mild to moderate cellulite on the backs of the thighs, and body mass index (BMI) 19–30 kg/m^2 with a willingness to maintain BMI ±2 kg/m^2 within baseline. Investigator assessments, instrumentation evaluations, and patient questionnaires were performed. Characteristics and outcomes were summarized descriptively. Changes from baseline were evaluated with a paired t test or Wilcoxon signed-rank test, as appropriate. Comparisons between treatments were evaluated with a 2-sample t test or Wilcoxon rank-sum test, as appropriate.
RESULTS: Forty-four patients completed treatment (FTB, 30; vehicle control, 14). Patients randomized to FTB showed significant improvements in the thighs (all $P<0.05$) at week 12 compared with baseline for investigator assessments of crepiness (20.2%), skin smoothness (19.3%), skin tone evenness (9.2%), body skin texture (14.1%), body skin firmness (12.1%), and cellulite (14.1%). Significant improvements (all $P<0.05$) were also achieved by FTB at week 12 compared with vehicle control for thigh crepiness (20.2% vs 10.7%), body skin texture (14.1% vs 7.0%), and skin tone evenness (9.2% vs 3.0%). Significant improvements in the thighs (all $P<0.05$) at week 12 compared with baseline in patients randomized to FTB were observed for instrumentation analyses of skin firmness (extensibility, 15.0%) and epidermal and dermal tissue density (29.5%), and for attenuation coefficient, which reflects tissue density (31.6%). The improvements in investigator and instrument assessments of skin efficacy parameters at week 12 were accompanied by significant improvements in self-perceived efficacy ($P<0.02$) and overall satisfaction with the appearance of their skin following FTB treatment versus vehicle control.
CONCLUSIONS: FTB provided significant improvements in the thighs compared with baseline and vehicle control across multiple investigator assessment and instrumentation evaluation parameters while improving self-reported efficacy and satisfaction in the majority of patients.
DISCLOSURES: ET Makino and RC Mehta are employees of AbbVie. L Jiang and SF Acevedo are investigators for Allergan Aesthetics, an AbbVie Company. Allergan Aesthetics, an AbbVie Company, was the study sponsor. Medical writing assistance was provided to the authors by Drayton Hammond, PhD (Peloton Advantage LLC, an OPEN Health company).

ABSTRACT 09

An Open-Label, Single-Center Pilot Study Evaluating the Efficacy and Tolerability of a Firming and Toning Aesthetic Body Lotion With Pre-Elected Body Contouring Procedures

Craig Teller, MD[a]; Harmony Saqr, MAa; Elizabeth T. Makino, BS, CCRA, MBAb; Priscilla Tan, BAb; Rahul C. Mehta, PhD[b]

[a]Bellaire Dermatology Associates, Bellaire, TX, USA; [b]Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA

Corresponding author:
Rahul C. Mehta, PhD
2525 Dupont Drive
Irvine CA 92612
Office: +1 714 246 2202
Mobile: +1 760 707 2412
Email: Rahul.Mehta@AbbVie.com

Co-author contact information:
C Teller: cteller@bellairedermatology.com
H Saqr: hsaqr@bellairedermatology.com
E Makino: elizabeth.makino@abbvie.com
P Tan: priscilla.tan@abbvie.com
R Mehta: rahul.mehta@abbvie.com

BACKGROUND: Changes in body skin quality are understudied compared with the well-described facial skin alterations that occur with age. Surface texture and loss of firmness may be of particular concern. Adipose remodeling that accompanies body contouring procedures may also alter skin texture and firmness.

OBJECTIVE: To conduct an open-label, single-center pilot study to explore the efficacy and tolerability of a firming and toning aesthetic body lotion (FTB) to improve skin quality when used after body contouring procedures on the inner thigh, posterior axillary, or submental areas.

METHODS: The study enrolled 16 women and 1 man 25–63 years of age with a Fitzpatrick skin type II–IV who had pre-elected to receive 1 or more cryolipolysis treatments on the inner thigh, posterior axillary, or submental areas. Patients applied FTB twice daily for 12 weeks on the treated area. Skin texture and firmness were graded visually by the investigator using a 9-point scale, and patients graded satisfaction with questionnaires.

RESULTS: After 12 weeks of FTB application, significant improvements in skin firmness were observed in all areas, while skin texture showed improvements on the inner thigh and posterior axillary ($P \leq 0.009$; paired t test). With continued use, 79% of patients agreed that FTB helped "enhance the effects of the body contouring procedure" and "improved the overall appearance of my skin." At week 12, 86% of patients reported "good" or "excellent" satisfaction with FTB. One patient withdrew due to mild pruritus on the inner thighs, but no other adverse events were reported.

CONCLUSIONS: This pilot study suggests that FTB may enhance the overall patient experience with body contouring procedures.

DISCLOSURES: C Teller serves as a speaker and advisor to Allergan Aesthetics, an AbbVie company. H Saqr is an investigator for Allergan Aesthetics, an AbbVie Company. ET Makino, P Tan, and RC Mehta are employees of AbbVie. Allergan Aesthetics, an AbbVie Company, was the study sponsor. Medical writing assistance was provided to the authors by Elizabeth Selwan-Lewis, PhD of AbbVie.

ABSTRACT 10

Efficacy and Tolerability of a Novel Cosmetic Growth Factor Serum When Used as Part of Biweekly Diamond Tip Microdermabrasion Treatments on Facial Skin

Rahul C. Mehta, PhD[1]; Tanja Emmerich, PhD[2]; Lily Jiang, PhD[2]; Priscilla Tan, BA[1]; Elizabeth T. Makino, BS, CCRA, MBA[1]

[1]Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA; [2]SGS Stephens Inc., Richardson, TX, USA

Corresponding author:
Rahul C. Mehta, PhD
2525 Dupont Drive
Irvine CA 92612
Office: +1 714 246 2202
Mobile: +1 760 707 2412
Email: Rahul.Mehta@AbbVie.com

Co-author contact Information:
T Emmerich: Tanja.Emmerich@sgs.com
L Jiang: Li.Jiang@sgs.com
P Tan: priscilla.tan@abbvie.com
E Makino: elizabeth.makino@abbvie.com

BACKGROUND: Our proprietary diamond tip microdermabrasion skin resurfacing device (DG) gently removes superficial skin layers and delivers topical cosmetic serums. Our proprietary growth factor blend serum (GFS) leverages growth factor technology to target key signs of aging.

OBJECTIVE: To conduct a prospective single-center clinical study to assess the efficacy and tolerability of a novel cosmetic growth factor serum (DG-GFS) when used as part of biweekly superficial facial skin resurfacing treatments in combination with a take-home topical GFS over 12 weeks in women with mild to severe photodamage of the face.

METHODS: Females 25–65 years of age with mild to severe facial photodamage received 6 biweekly DG-GFS in-office treatments with at-home twice-daily GFS for 12 weeks. Clinical grading (modified Griffiths scale, 0–9) of fine lines/wrinkles, coarse lines/wrinkles, skin smoothness, skin tone evenness, hyperpigmentation, photodamage, radiance, and firmness; subject self-assessments; instrumentation measurements; and clinical grading of irritation parameters (0–3, none to severe) were performed at baseline, immediately post-treatment (15 minutes), on day 3, and biweekly from weeks 2 to 12.

RESULTS: Twenty-nine women (Fitzpatrick skin type II–VI; 52% Caucasian; 41% African American) were enrolled. Immediate improvements after 1 treatment were observed for fine lines/wrinkles (10.4%), skin smoothness (visual, 3.5%; tactile, 11.7%), and radiance (7.1%; all $P \leq 0.004$, Wilcoxon signed rank test), as well as skin hydration measured by corneometer (33.3%; $P < 0.001$, paired t test). From week 6 onward, all investigator-assessed parameters showed significant improvements vs baseline (13% to 30% at week 12; all $P \leq 0.002$, Wilcoxon signed rank test). Treatment was well tolerated, with mean tolerability scores <1 across parameters. All subjects (100%) were satisfied with results from week 2 onward.

CONCLUSIONS: A single in-office DG-GFS treatment provided immediate skin improvements. Sustained facial rejuvenating effects were observed over 12 weeks with biweekly treatments and daily home GFS regimen.

DISCLOSURES: RC Mehta, P Tan, and ET Makino are employees of AbbVie. T Emmerich and L Jiang are investigators for Allergan Aesthetics, an AbbVie Company. Allergan Aesthetics, an AbbVie Company, was the study sponsor. Editorial assistance was provided to the authors by Marci Mikesell, PhD (Peloton Advantage LLC, an OPEN Health company).

ABSTRACT 11

Quantifying Uptake of Eye Serum After 1440-nm or 1927-nm Non-Ablative Fractional Diode Laser Treatment

Jordan V. Wang, MD, MBE, MBA[1]; Paul M. Friedman, MD[1,2]; Adarsh Konda, PharmD[3]; Catherine Parker, NP, MSN[4]; Roy G. Geronemus, MD[1]

[1]Laser & Skin Surgery Center of New York, New York, NY; 2Dermatology and Laser Surgery Center, Houston, TX; 3Bausch Health US, LLC, Bridgewater, NJ; 4Former employee of Solta Medical, Bothell, WA

Correspondence requests to:
Jordan V. Wang, MD, MBE, MBA
Laser & Skin Surgery Center of New York
317 E 34th St, 6th Fl Research Dept, New York, NY 10016
Phone: (212) 840-0499
Email: drjordanwang@gmail.com

Author Contact Information:
Jordan V. Wang, MD, MBE, MBA jwang@laserskinsurgery.com
Adarsh Konda, PharmD adarsh.konda@bauschhealth.com
Paul M. Friedman, MD drpaul@dermlasersurgery.com
Roy Geronemus, MD rgeronemus@laserskinsurgery.com
Catherine Parker, NP, MSN cparker222@yahoo.com

BACKGROUND: The stratum corneum limits transdermal uptake of topical therapies, potentially reducing their clinical efficacy. Non-ablative fractional laser pretreatment enhances topical delivery and absorption, reduces thermal side effects, and creates microscopic treatment zones (MTZ) that spare the stratum corneum. To better understand how to optimize topical therapy, the relationship between uptake and device settings must be identified. In this ex vivo analysis, we quantified uptake of an eye serum using donor skin tissue pretreated with a 1440-nm or 1927-nm non-ablative fractional diode laser.
OBJECTIVES: To quantify topical uptake with two wavelengths of non-ablative laser pretreatment.
METHODS: Human donor skin tissue samples of 500-µm thickness were pretreated with a low-power 1440-nm diode laser (9-mJ pulse energy, 3-W peak power, 130-µm spot size, 320-MTZ/cm^2 spot density), 1927-nm diode laser (4.5- or 7.5-mJ pulse energy, 0.6- or 1-W peak power, 130-µm spot size, 320-MTZ/cm^2 spot density), or received no pretreatment prior to application of eye serum. Laser-treated skin and untreated controls were analyzed using high-performance liquid chromatography at various time points up to 24 hours after application to measure cumulative permeation and retention and to calculate uptake of eye serum.
RESULTS: Skin samples pretreated with a 1440-nm non-ablative fractional laser had almost double the uptake of eye serum at 24 hours posttreatment compared to untreated controls (cumulative permeation, 39.7 vs 19.4 mg/cm^2, respectively). Pretreatment with the 1927-nm laser with lower power and energy settings (0.6 W, 4.5 mJ) enhanced uptake of eye serum by 1.6 times, while higher power and energy settings (1 W, 7.5 mJ) enhanced uptake by 2.7 times compared to untreated controls. Enhanced uptake of eye serum with laser pretreatment was evident as early as 15 minutes after application, whereas untreated controls did not begin to demonstrate eye serum permeation until 2 hours after application.
CONCLUSIONS: In this ex vivo analysis, pretreatment with low-power 1440-nm or 1927-nm non-ablative fractional diode lasers not only increased overall uptake of eye serum but also achieved more rapid absorption after application compared to untreated controls. Pretreatment with the 1927-nm wavelength at low power (0.6 W) showed similar uptake to 1440-nm laser pretreatment. Further, 1927-nm pretreatment at 1 W enhanced uptake of eye serum over untreated controls. Non-ablative laser therapy at this wavelength can be a useful option for enhancing topical uptake.
DISCLOSURES: This study was supported by Solta Medical (a division of Bausch Health, LLC). Data included in this abstract were presented in full at The Fall Clinical Dermatology Conference; October 21-24, 2021; Las Vegas, Nevada; Poster.

ABSTRACT 12

Enhanced Uptake of 10% Ascorbic Acid After 1440-nm or 1927-nm Non-Ablative Fractional Diode Laser Treatment

Jordan V. Wang, MD, MBE, MBA[1]; Paul M. Friedman, MD[1,2]; Adarsh Konda, PharmD[3]; Catherine Parker, NP, MSN[4]; Roy G. Geronemus, MD[1]

[1]Laser & Skin Surgery Center of New York, New York, NY; [2]Dermatology and Laser Surgery Center, Houston, TX; [3]Bausch Health US, LLC, Bridgewater, NJ; 4Former employee of Solta Medical, Bothell, WA

Correspondence requests to:
Jordan V. Wang, MD, MBE, MBA
Laser & Skin Surgery Center of New York
317 E 34th St, 6th Fl Research Dept, New York, NY 10016
Phone: (212) 840-0499
Email: drjordanwang@gmail.com

Author Contact Information:
Jordan V. Wang, MD, MBE, MBA jwang@laserskinsurgery.com
Adarsh Konda, PharmD adarsh.konda@bauschhealth.com
Paul M. Friedman, MD drpaul@dermlasersurgery.com
Roy Geronemus, MD rgeronemus@laserskinsurgery.com
Catherine Parker, NP, MSN cparker222@yahoo.com

BACKGROUND: The stratum corneum forms a protective barrier in the skin, but prevents optimal uptake of topical formulations. Non-ablative fractional laser pretreatment is a promising approach to enhancing topical uptake. Unlike ablative devices, non-ablative lasers

generally target dermal tissue, minimizing thermal side effects and postprocedural recovery time. However, the relationship between topical uptake and device settings must be quantified to optimize treatment benefits. In this ex vivo analysis, we quantified uptake of 10% ascorbic acid following pretreatment with low-power 1440-nm or 1927-nm non-ablative fractional diode lasers with varying treatment densities.

OBJECTIVES: To quantify topical uptake with two wavelengths of non-ablative laser pretreatment.

METHODS: Excised human abdominal skin samples of 500-µm thickness were pretreated with a 1440-nm diode laser with 80 MTZ/cm^2 (1.2 W), 1440-nm laser with 320 MTZ/cm^2 (3 W), 1927-nm diode laser with 320 MTZ/cm^2 (1 W), or received no pretreatment. Then, 10% ascorbic acid was applied, and permeation was measured up to 24 hours after application. Samples were filtered and analyzed using high-performance liquid chromatography to measure topical permeation and retention in laser-treated samples and untreated controls. Total uptake was calculated as the sum of the normalized cumulative permeation and retention in each sample. Average total uptake was compared between laser-treated samples and untreated controls to determine the uptake enhancement ratio.

RESULTS: Pretreatment with the 1927-nm laser with 320 MTZ/cm^2 enhanced uptake of 10% ascorbic acid by >4 times compared to the 1440-nm laser with 320 MTZ/cm^2 (7.8 vs 1.8 mg/cm^2), >15 times compared to the 1440-nm laser with 80 MTZ/cm2 (0.5 mg/cm^2), and >33 times compared to untreated control (0.2 mg/cm^2) at 24 hours posttreatment. Pretreatment with the 1440-nm laser with 320 MTZ/cm^2 was associated with >3-times greater uptake of 10% ascorbic acid compared to the 1440-nm laser with 80 MTZ/cm^2 (1.8 vs 0.5 mg/cm^2) and >7-times greater uptake compared to untreated control (1.8 vs 0.2 mg/cm^2). Pretreatment with the 1440-nm laser with 80 MTZ/cm^2 enhanced uptake by >2 times compared to untreated control (0.5 vs 0.2 mg/cm^2).

CONCLUSIONS: The greatest enhancement of 10% ascorbic acid uptake occurred with 1927-nm wavelength pretreatment at 320 MTZ/cm^2 and 1.0 W, compared to 1440-nm wavelengths at varying wattage and treatment densities. This provides a foundation for future clinical studies and can help clinicians better understand the relationship between quantifiable uptake enhancement and patient-centered outcomes.

DISCLOSURES: This study was supported by Solta Medical (a division of Bausch Health, LLC). Data included in this abstract were presented in full at The Fall Clinical Dermatology Conference; October 21-24, 2021; Las Vegas, Nevada; Poster.

ABSTRACT 13

Quantifying Uptake of Topical 4% Hydroquinone After 1440-nm and 1927-nm Non-Ablative Fractional Diode Laser Treatment

Jordan V. Wang, MD, MBE, MBA[1]; Paul M. Friedman, MD[1,2]; Adarsh Konda, PharmD[3]; Catherine Parker, NP, MSN[4]; Roy G. Geronemus, MD[1]

[1]Laser & Skin Surgery Center of New York, New York, NY; [2]Dermatology and Laser Surgery Center, Houston, TX; [3]Bausch Health US, LLC, Bridgewater, NJ; [4]Solta Medical, Bothell, WA

Correspondence requests to:
Jordan V. Wang, MD, MBE, MBA
Laser & Skin Surgery Center of New York
317 E 34th St, 6th Fl Research Dept, New York, NY 10016
Phone: (212) 840-0499
Email: drjordanwang@gmail.com

Author Contact Information:
Jordan V. Wang, MD, MBE, MBA jwang@laserskinsurgery.com
Adarsh Konda, PharmD adarsh.konda@bauschhealth.com
Paul M. Friedman, MD drpaul@dermlasersurgery.com
Roy Geronemus, MD rgeronemus@laserskinsurgery.com
Catherine Parker, NP, MSN cparker222@yahoo.com

BACKGROUND: Non-ablative fractional laser pretreatment can enhance transdermal delivery and uptake of topicals and minimize thermal side effects that are more typical of ablative laser therapy. Fractionation can create microscopic treatment zones that spare surrounding tissue and further minimize postprocedural downtime. Clinical practice may be improved by understanding the relationship between topical uptake and energy-device settings. In this ex vivo analysis, we quantified uptake of 4% hydroquinone serum using skin tissue pretreated with either a 1440-nm or 1927-nm non-ablative fractional diode laser.

OBJECTIVES: To quantify topical uptake following two wavelengths of non-ablative laser pretreatment.

METHODS: Ex vivo human donor skin tissue was pretreated with either 1440-nm (1.2 W [9 mJ]) or 1927-nm (0.6 W [4.5 mJ] or 1.0 W [7.5 mJ]) wavelengths or received no pretreatment prior to application of an in-house 4% hydroquinone serum (hydrophilic formulation). Laser-treated skin and untreated controls were analyzed using high-performance liquid chromatography at various time points up to 24 hours after application to measure cumulative permeation and retention and to calculate uptake of 4% hydroquinone serum.

RESULTS: Pretreatment with the 1927-nm wavelength resulted in greater cumulative uptake of 4% hydroquinone serum compared to the 1440-nm wavelength. Compared to untreated controls, topical uptake was 1.8-times greater with 1440-nm (1.2-W) pretreatment, 2.7 times greater with 1927-nm (0.6-W) pretreatment, and 4.6 times greater with 1927-nm (1.0-W)pretreatment.

The 1927-nm power settings (0.6 and 1.0 W) were associated with approximately 1.5- and 2.6-times greater uptake, respectively, compared to 1440-nm (1.2-W) pretreatment.

CONCLUSIONS: Diode laser pretreatment with the 1927-nm wavelength resulted in greater uptake of 4% hydroquinone serum compared to the 1440-nm wavelength, despite lower peak power settings. Various low-power wavelengths can affect topical uptake differently. Higher peak irradiance at higher power settings may cause greater superficial disruption to the stratum corneum and epidermis, which can affect uptake of topical therapies.

DISCLOSURES: This study was supported by Solta Medical (a division of Bausch Health, LLC). Data included in this abstract were presented in full at The Fall Clinical Dermatology Conference; October 21-24, 2021; Las Vegas, Nevada; Poster.

ABSTRACT 14

Improvement in Skin Quality With a Cosmetic Hydrating Serum Delivered Via Diamond Tip Microdermabrasion Combined With a Daily Topical Serum

Rahul C. Mehta, PhD[1]; Tanja Emmerich, PhD[2]; Lily Jiang, PhD[2]; Priscilla Tan, BA[1]; Elizabeth T. Makino, BS, CCRA, MBA[1]

[1]Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA; [2]SGS Stephens Inc., Richardson, TX, USA

Corresponding author:
Rahul C. Mehta, PhD
2525 Dupont Drive
Irvine CA 92612
Office: +1 714 246 2202
Mobile: +1 760 707 2412
Email: Rahul.Mehta@AbbVie.com

Co-author Contact Information:
T Emmerich: Tanja.Emmerich@sgs.com
L Jiang: Li.Jiang@sgs.com
P Tan: priscilla.tan@abbvie.com
E Makino: elizabeth.makino@abbvie.com

BACKGROUND: Our proprietary diamond tip microdermabrasion device (DG) exfoliates the skin, extracts impurities, and infuses nourishing serums customized to patients' skin needs. HAB serum is a novel cosmetic hydrating topical serum enriched with a blend of 5 different forms of hyaluronic acid.

OBJECTIVE: To conduct an open-label, single-center clinical study to assess the effectiveness and tolerability of HAB serum used in combination with biweekly microdermabrasion treatment plus a take-home HAB topical serum over 12 weeks in women with facial skin dryness, roughness, lack of radiance, and fine lines or wrinkles of mild or greater severity.

METHODS: Participants 25–65 years of age with a Fitzpatrick skin type I–VI received 6 in-office DG treatments every 2 weeks on the face and neck. The take-home HAB serum was applied twice daily on the face in addition to supplementary materials (facial cleanser, ultra-sheer moisturizer, and mineral sunscreen). Treatment efficacy was evaluated using investigator-graded facial skin condition parameters, instrumentation data, and self-assessment questionnaires.

RESULTS: The combined treatment demonstrated significant immediate and long-term improvements in skin conditions. Immediately after DG treatment, substantial changes from baseline were observed in fine lines/wrinkles, dryness, skin smoothness, radiance, firmness, and skin hydration (all $P \leq 0.013$). Effects continued 3 days after the first DG treatment for fine lines/wrinkles, dryness, skin smoothness, and radiance (all $P \leq 0.004$). At week 12, significant improvements were found in all the above parameters, as well as in skin tone evenness, hyperpigmentation, photodamage, coarse lines/wrinkles, and trans epidermal water loss (all $P \leq 0.05$). Further, there was high subject satisfaction and patients tolerated the treatment well.

CONCLUSIONS: These findings support the benefits of combining DG with HAB serum for skin rejuvenation.

DISCLOSURES: ET Makino, P Tan, and RC Mehta are employees of AbbVie. T Emmerich and L Jiang are investigators for Allergan Aesthetics, an AbbVie Company. Allergan Aesthetics, an AbbVie Company, was the study sponsor. Medical writing support was provided by Ana Vicente-Sanchez, PhD of AbbVie.

ABSTRACT 15

Safety and Efficacy of Collagenase Clostridium Histolyticum-aaes for Buttock Cellulite in Women With Skin of Color: A Pooled Analysis of Randomized, Placebo-Controlled Trials

Valerie D. Callender, MD[1]; Jeanine B. Downie, MD[2]; Jill Edgecombe, BS3; Qinfang Xiang, PhD[4]; Tara Margarella, DO[3]; Sabrina Guillen Fabi, MD[5]

[1]Callender Dermatology and Cosmetic Center, Glenn Dale, MD; [2]Image Dermatology P.C., Montclair, NJ; [3]Endo Aesthetics LLC, Malvern, PA; [4]Endo Pharmaceuticals Inc., Malvern, PA; [5]Cosmetic Laser Dermatology, San Diego, CA

Presenting and corresponding author:
Valerie D. Callender, MD
Callender Dermatology and Cosmetic Center
12200 Annapolis Rd #315, Glenn Dale, MD 20769
Phone: (301) 249-0970
E-mail: drcallender@callenderskin.com

Co-author Contact Information:
Valerie D. Callender, MD: drcallender@callenderskin.com
Jeanine B. Downie, MD: Jeaninedownie@imagedermatology.com
Jill Edgecombe, BS: Edgecombe.Jill@endo.com
Qinfang Xiang, PhD: xiang.qinfang@endo.com
Tara Margarella, DO: Margarella.Tara@endo.com
Sabrina Guillen Fabi, MD: sfabi@clderm.com

BACKGROUND: Collagenase clostridium histolyticum-aaes (CCH-aaes) is approved for the treatment of moderate to severe cellulite in the buttocks of adult women.

OBJECTIVES: To evaluate the efficacy and safety of CCH-aaes in the treatment of buttock cellulite in women with skin of color.

METHODS: Data were pooled from 2 identically designed, phase 3, randomized, double-blind, placebo-controlled trials of adult women with moderate/severe cellulite (rating, 3 or 4 on the Clinician Reported Photonumeric Cellulite Severity Scale [CR-PCSS] and the Patient Reported Photonumeric Cellulite Severity Scale [PR-PCSS]) on both buttocks. Skin of color was defined as Fitzpatrick skin type (FST) categories IV (light brown), V (brown), and VI (dark brown/black). Patients received up to 3 treatment sessions (CCH-aaes 0.84 mg or placebo subcutaneous in each buttock) administered on Days 1 (baseline), 22, and 43. Efficacy endpoints included composite and individual component response (≥2- or ≥1-level improvement from baseline in PR-PCSS and/or CR-PCSS scores in ≥1 buttock) at Day 71.

RESULTS: In the overall population (N=843), skin type was classified as skin of color (FST IV-VI) in 336 women (39.9%). Among women with skin of color, 170 received CCH-aaes and 166 received placebo treatment. A significantly larger percentage of women with skin of color had a ≥2-level and ≥1-level composite (PR-PCSS and CR-PCSS) response at Day 71 in CCH-aaes group vs placebo group (Figure). For the individual components, a significantly higher percentage of women with skin of color in CCH-aaes group vs placebo group had ≥1-level improvement from baseline in PR-PCSS or CR-PCSS ratings at Day 71 (Figure). In the overall population, the most common adverse events (AEs) in CCH-aaes group (n=424) were injection-site bruising (77.8%), injection-site pain (47.9%), injection-site nodule (25.5%), and injection-site pruritus (14.9%). In the subgroup of women with skin of color treated with CCH-aaes (n=170), the most common AEs were injection-site bruising (74.7%), injection-site pain (41.2%), injection-site nodule (30.6%), and injection-site pruritus (14.7%). The percentages of women treated with CCH-aaes with an AE of injection-site discoloration (which included post-inflammatory hyperpigmentation) were 7.8% in the overall population (n=424), 6.5% in women with FST IV-VI (n=170), and 8.7% in women with FST I-III (n=254).

CONCLUSIONS: In women with skin of color, treatment with CCH-aaes for moderate to severe cellulite in the buttock was efficacious and generally well tolerated. For any injectable, the risk of post-inflammatory hyperpigmentation occurring after injection-site bruising, which can last several months, is an important consideration in skin of color. The safety profile, including rates of discoloration/hyperpigmentation, with CCH-aaes treatment in women with skin of color, was similar to that observed in the overall population.

DISCLOSURES: Valerie D. Callender reports serving as a consultant for Endo Pharmaceuticals Inc. Jeanine B. Downie reports serving as a clinical investigator for Endo Pharmaceuticals Inc. Jill Edgecombe and Tara Margarella are employees of Endo Aesthetics LLC. Qinfang Xiang is an employee of Endo Pharmaceuticals Inc. Sabrina Guillen Fabi reports serving as a clinical investigator for Endo Pharmaceuticals Inc.

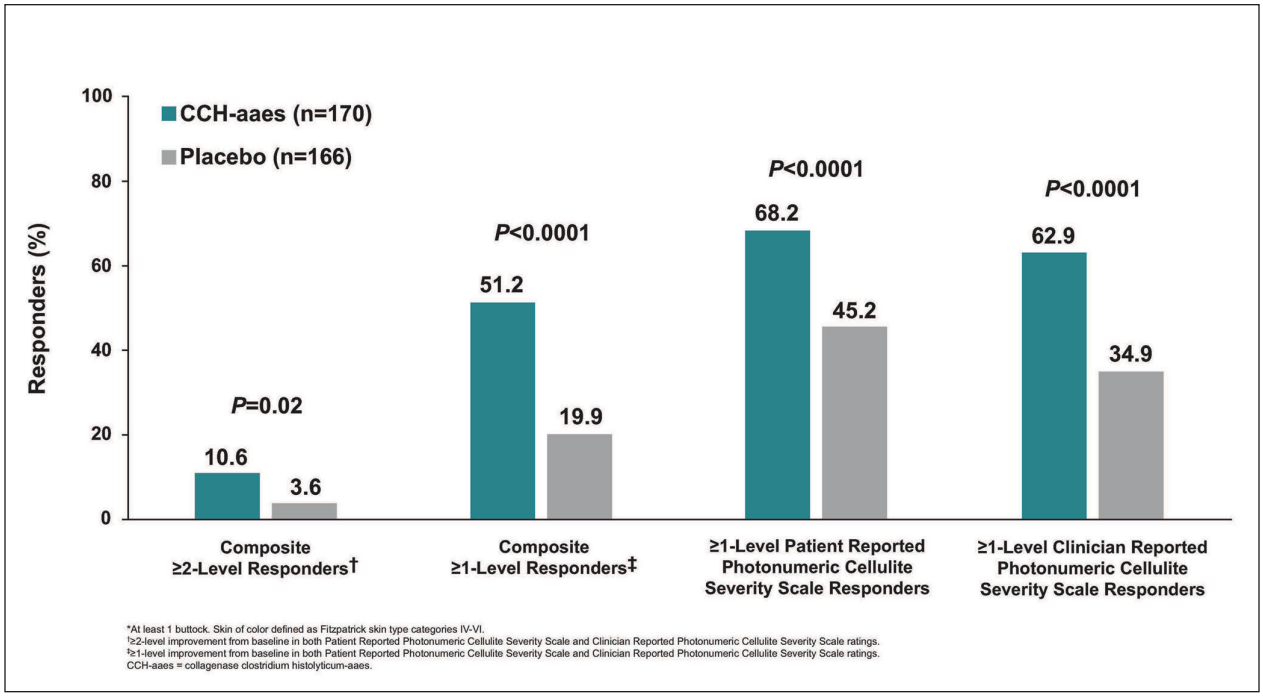


FIGURE. Responders at Day 71 (Women With Skin of Color)*

ATOPIC DERMATITIS

ABSTRACT 16

Efficacy and Safety of Tralokinumab in Adolescents With Moderate-to-Severe Atopic Dermatitis: Results of The Phase 3 ECZTRA 6 Trial

Amy Paller,[1] Andrew Blauvelt,[2] Weily Soong,[3] Shinichi Imafuku,[4] Chih-ho Hong,[5] Marie L.A. Schuttelaar,[6] Petra Amoudruz,[7] Azra Kurbasic,[7] Lise Soldbro,[7] Katja Lophaven,[7] Shannon Schneider,[8] Michael Cork,[9] Anthony Bewley,[10] Eric L. Simpson[11]

[1]Feinberg School of Medicine, Northwestern University, Chicago, IL, USA; [2]Oregon Medical Research Center, Portland, OR, USA; [3]Allervie Health-Alabama Allergy & Asthma Center, Birmingham, AL, USA; [4]Fukuoka University, Fukuoka, Japan; [5]University of British Columbia, Vancouver, BC, Canada; [6]University Medical Centre Groningen, University of Groningen, The Netherlands; [7]LEO Pharma A/S, Ballerup, Denmark; [8]LEO Pharma Inc., Madison, NJ, USA; [9]University of Sheffield, Sheffield, UK; [10]Barts Health NHS Trust, London, UK; [11]Oregon Health & Science University, Portland, OR, USA

BACKGROUND: In adult phase 3 trials, tralokinumab demonstrated efficacy and safety for AD treatment [Wollenberg A, et al. *Br J Dermatol.* 2021;184:437-449; Silverberg JI, et al. *Br J Dermatol.* 2021;184:450-463]. We evaluated tralokinumab efficacy and safety in adolescents with moderate-to-severe AD in the phase 3 ECZTRA 6 trial (NCT03526861).

METHODS: Adolescents (aged 12-17 years) were randomized to receive subcutaneous tralokinumab 150 mg (n=100) or 300 mg (n=101), or placebo (n=100) every 2 weeks. Primary endpoints were Investigator's Global Assessment (IGA) score 0/1 and ≥75% improvement in Eczema Area and Severity Index (EASI-75) at Week 16. Patients achieving primary endpoints without rescue treatment were re-randomized for 36 weeks of maintenance treatment. EASI-75, IGA 0/1, and ≥4-point improvement in adolescent pruritus Numerical Rating Scale (NRS) were analyzed using Cochran-Mantel-Haenszel test stratified by geographic region and baseline disease severity. Patients receiving rescue therapy or with missing data were considered non-responders. SCORing AD (SCORAD) and Children's Dermatology Life Quality Index (CDLQI) were analyzed using a linear mixed model for repeated measurements.

RESULTS: At Week 16, significantly greater proportions of patients receiving tralokinumab (150 mg/300 mg vs placebo) achieved IGA 0/1 (21.4%/17.5% vs 4.3%; $P<0.001/P=0.002$), EASI-75 (28.6%/27.8% vs 6.4%; $P<0.001/P<0.001$), and ≥4-point improvement in adolescent pruritus NRS (23.2%/25.0% vs 3.3%; $P<0.001/P<0.001$). Tralokinumab treatment was associated with greater improvement than placebo in SCORAD (adjusted mean change ± SE: –27.5 ± 2.4/–29.1 ± 2.4 vs –9.5 ± 3.0; $P<0.001/P<0.001$) and CDLQI (–6.1 ± 0.6/–6.7 ± 0.6 vs –4.1 ± 0.7; $P=0.040/P=0.007$) from baseline to Week 16. Through Week 16, percentages of adverse events (AEs; 67.3/64.9 vs 61.7), serious AEs (3.1/1.0 vs 5.3), AEs leading to discontinuation (1.0/0 vs 0), and conjunctivitis events (4.1/3.1 vs 2.1) were similar between the tralokinumab and placebo groups.

CONCLUSIONS: At Week 16, tralokinumab 150 mg and 300 mg every 2 weeks demonstrated efficacy compared with placebo across primary and secondary endpoints in adolescents with AD. Tralokinumab was well tolerated; efficacy and safety profiles were comparable to those in phase 3 adult tralokinumab trials.

FUNDING SOURCE: The ECZTRA 6 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark.

ABSTRACT 17

Tralokinumab Treatment Substantially Improves Patient-reported Outcomes in Adolescents With Moderate-to-Severe Atopic Dermatitis at 16 Weeks

Weily Soong,[1] Andrew Blauvelt,[2] Andreas Wollenberg,[3] H. Chih-ho Hong,[4] Jeffrey Leflein,[5] Anthony Bewley,[6] Petra Amoudruz,[7] Marie Holst Moerch,[7] Lise Soldbro,[7] Shannon Schneider,[8] Eric L. Simpson,[9] Amy Paller[10]

[1]Allervie Health-Alabama Allergy & Asthma Center, Birmingham, AL, USA; [2]Oregon Medical Research Center, Portland, OR, USA; [3]Department of Dermatology and Allergy, University Hospital, Ludwig Maximilian University of Munich, Munich, Germany; [4]Department of Dermatology and Skin Science, University of British Columbia, Vancouver, BC, Canada; [5]St Joseph Mercy Hospital, Ann Arbor, MI, USA; [6]Barts Health NHS Trust, London, UK; [7]LEO Pharma A/S, Ballerup, Denmark; [8]LEO Pharma Inc., Madison, NJ, USA; [9]Oregon Health & Science University, Portland, OR, USA; [10]Feinberg School of Medicine, Northwestern University, Chicago, IL, USA

BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory skin disease that negatively impacts quality of life (QoL) at any age. Tralokinumab, a high-affinity, monoclonal antibody, specifically neutralizes interleukin (IL)-13 activity. In the phase 3 ECZTRA 6 trial (NCT03526861), tralokinumab demonstrated substantial efficacy and was well-tolerated in adolescents with moderate-to-severe AD. We evaluated the impact of tralokinumab on patient-reported outcomes (PROs) through Week 16 in ECZTRA 6.

METHODS: Adolescents (12-17 years) were randomized to subcutaneous tralokinumab 150 mg (n=100) or 300 mg (n=101), or placebo (n=100), every 2 weeks. Patients recorded itch (adolescent worst pruritus Numeric Rating Scale (NRS)) and sleep interference (eczema-related sleep NRS) daily via eDiary. Assessments for Children's Dermatology Life Quality Index (CDLQI), Patient Oriented Eczema Measure (POEM), and Hospital Anxiety and Depression Scale (HADS) were recorded during scheduled visits. Patients receiving rescue therapy or with missing data were considered non-responders.

RESULTS: At Week 16, significantly greater proportions of patients receiving tralokinumab (150 mg/300 mg vs. placebo) achieved ≥4-point improvement in adolescent

worst pruritus NRS (23.2%/25.0% vs. 3.3%; *P*<0.001/*P*<0.001), ≥6-point improvement in CDLQI (31.0%/39.5% vs. 15.9%; *P*=0.029/P<0.001), and ≥6-point improvement in POEM (38.7%/46.8% vs. 10.5%; *P*<0.001/*P*<0.001). Tralokinumab was associated with greater improvement than placebo in eczema-related sleep NRS (adjusted mean change±SE –2.9±0.3/–3.1±0.3 vs. –1.8±0.4; *P*=0.015/*P*=0.005). Tralokinumab vs. placebo adjusted mean change±SE for HADS was –1.8±0.7/–4.4±0.6 vs. –2.1±0.8 (*P*=0.81/*P*=0.023).

CONCLUSIONS: Tralokinumab significantly improved symptomatic and psychosocial impacts of moderate-to-severe AD in adolescents utilizing clinically relevant PROs at Week 16, including itch, sleep interference, anxiety/depression, and overall QoL.

FUNDING SOURCE: The ECZTRA 6 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark.

ABSTRACT 18

Efficacy and Safety of Tralokinumab Plus Topical Corticosteroids in Patients With Severe Atopic Dermatitis and Prior History of Dupilumab Treatment: A Post Hoc Subgroup Analysis from ECZTRA 7 Trial

Jan Gutermuth,[1] Andrew Pink,[2] Margritta Worm,[3] Lise Soldbro,[4] Thomas Mark,[4] Joshua Corriveau,[5] Christian Bjerregård Øland,[4] Shannon Schneider,[5] Stephan Weidinger[6]

[1]Universitair Ziekenhuis Brussel and Vrije Universiteit Brussel, Brussels, Belgium; [2]St John's Institute of Dermatology, Guy's and St Thomas' NHS Foundation Trust, London, UK; [3]Charité – Universitätsmedizin Berlin, Berlin, Germany; [4]LEO Pharma A/S, Ballerup, Denmark; [5]LEO Pharma, Madison, NJ; [6]University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany

INTRODUCTION: Despite currently available treatment options, patients with moderate-to-severe AD continue to experience high disease burden. We performed a post hoc analysis to describe the efficacy and safety of tralokinumab in a subgroup of ECZTRA 7 patients with prior history of dupilumab treatment.

METHODS: In the Phase 3 ECZTRA 7 trial, adult patients with moderate-to-severe AD were randomized 1:1 to subcutaneous tralokinumab 300 mg q2w + TCS as needed or placebo + TCS as needed for 26 weeks. For this analysis, prior history of dupilumab treatment was collected retrospectively via queries.

RESULTS: The dupilumab-experienced (n=14) and dupilumab-naive (n=263) cohorts had comparable baseline characteristics, except the dupilumab-experienced group was older (median age, 51.5 vs 33.0 years). Median (IQR) EASI and percent of patients with an IGA of 4 were 35.5 and 57.1% among dupilumab-experienced patients and 28.7 and 49.0% among dupilumab-naive patients, respectively. Among dupilumab-experienced patients at Week 16, 6 of 6 patients (100%) receiving tralokinumab + TCS achieved EASI-75, compared with 4 of 8 of those (50%) receiving placebo + TCS. Numerically greater proportions of dupilumab-experienced patients receiving tralokinumab + TCS achieved IGA 0/1 (66.7% vs 37.5%) and improvement in worst daily pruritus NRS (weekly average) ≥4 points (50% vs 37.5%) at week 16 than those who received placebo + TCS. At Week 26, numerically greater proportions of dupilumab-experienced patients receiving tralokinumab + TCS achieved EASI-75 (100% vs 37.5%), IGA 0/1 (66.7% vs 25%), and improvement in worst daily pruritus NRS (weekly average) ≥4 points (50% vs 37.5%), compared with those who received placebo + TCS. Through the 26 weeks, 66.7% of dupilumab-experienced patients receiving tralokinumab + TCS reported any adverse event, compared with 87.5% of those receiving placebo + TCS.

CONCLUSIONS: This post hoc subgroup analysis indicates that dupilumab-experienced patients, including those who discontinued dupilumab due lack of efficacy or because of adverse events, can benefit from tralokinumab + TCS as needed. Overall frequencies of adverse events in dupilumab-experienced patients treated with tralokinumab + TCS as needed were consistent with results in the pooled analysis of tralokinumab Phase 2 and 3 trials (Simpson E, et al. Presented at: 29th EADV Congress, October 29-31, 2020; Abstract 1464).

FUNDING SOURCE: The ECZTRA 7 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark.

ABSTRACT 19

Lebrikizumab Improves Atopic Dermatitis Signs in Head-and-Neck Area

Jacob P. Thyssen[1], MD, PhD, DmSci, jacob.pontoppidan.thyssen@regionh.dk

Marjolein Bruin-Weller[2], MD, PhD, m.s.debruin-weller@umcutrecht.nl

Thomas Bieber[3], PhD, Thomas.Bieber@ukbonn.de

Eric Simpson[4], M.D., M.C.R., simpsone@ohsu.edu

Vivian Y. Shi[5], MD, vshi@email.arizona.edu

Leo Kircik[6], MD, wedoderm@yahoo.com

Meritxell Falqués[7], MS, Meritxell.Falques@almirall.com

Helena Agell[7], BS, helena.agell@almirall.com

Sebastien Barbarot[8], M.D., Ph.D, sebastien.barbarot@chu-nantes.fr

[1]Department of Dermatology, Bispebjerg Hospital and University of Copenhagen, Denmark; [2]Department of Dermatology and Allergology, National Expertise Center for Atopic Dermatitis, University Medical Center Utrecht, Utrecht, the Netherlands; [3]Department of Dermatology and Allergy, Christine Kühne-Center for Allergy Research and Education (CK-CARE), University Medical Center, Bonn, Germany; [4]Department of Dermatology, Oregon Health and Science University, OR, USA; [5]Department of Dermatology, University of Arkansas for Medical Sciences, AR, USA; [6]Icahn School of Medicine at Mount Sinai, NY, USA; [7]Almirall S.A., Barcelona, Spain; [8]Nantes Université, Department of Dermatology, CHU Nantes, UMR 1280 PhAN, INRA, F-44000 Nantes, France

INTRODUCTION: Lebrikizumab (LEB) is a high-affinity monoclonal antibody targeting interleukin (IL)-13, a central mediator in atopic dermatitis (AD). A recent post-hoc analysis of a double-blind, placebo-controlled dose-ranging study (NCT03443024) showed that LEB was equally efficacious in treating AD in different body regions.
OBJECTIVE: This post-hoc analysis evaluates the efficacy of LEB in treating AD on the head-and-neck (H&N) area.
METHODS: Adults with moderate-to-severe AD (Eczema Area Severity Index [EASI] ≥16, Investigator's Global Assessment (IGA) ≥3, ≥10% Body Surface Area affected, AD for ≥1 year) were randomised (3:3:3:2) to LEB 125 mg every 4 weeks (Q4W; 250 mg loading dose [LD]; N=73), 250 mg Q4W (500 mg LD; N=80), 250 mg Q2W (500 mg LD at Baseline and week (W)2; N=75), or placebo Q2W (N=52) for 16W. TCS were allowed as rescue medication for as short period as possible. This post-hoc analysis focuses on 250 mg LEB Q2W (dose which has progressed to phase 3) and placebo. EASI H&N was calculated as the product of Severity x Area x 0.1 (weight of the H&N region). Mean percent change from baseline (%CFB) by week was calculated for each EASI H&N sign and area affected score. Last observation carried forward (LOCF) was used for imputing missing data. An ANCOVA model was performed and $p<0.05$ was considered statistically significant.

RESULTS: 85.7% of the overall patients had H&N involvement, 88% in 250 mg LEB Q2W and 88% in placebo. Mean (SD) H&N EASI %CFB at Week 16 was -65.6(40.4) in 250 mg Q2W vs -35.2(42.7) in placebo. Mean (SD) score at baseline and at W16 (LOCF) and %CFB at Week 16 for each EASI sign and area affected in H&N are shown in the table. Significant improvement was observed for 250 mg Q2W vs. placebo at W16 for all signs and area affected score. All EASI signs decreased rapidly across weeks, being excoriation the sign improving sooner, and showing larger decreases from baseline at each timepoint.
CONCLUSION: LEB showed significant improvement in all EASI signs in H&N, a burdensome and difficult to treat area. Excoriation was the EASI sign improving sooner, which is consistent with the early pruritus response reported in the phase 2b study (Guttman-Yassky E, et. al., *JAMA Dermatol* 2020).

REFERENCE:
Guttman-Yassky E, et. al., JAMA Dermatol 2020;156(4):411-20

DISCLOSURE: This study was funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. This study was previously presented at the European Academy of Dermatology and Venereology- 30th Congress.

TABLE: Mean (SD) H&N EASI %CFB from baseline to W16

	250 mg Q2W (N=75)			Placebo (N=52)			
	BL	W16	Mean (SD) % change	BL	W16	Mean (SD) % change	P value
Erythema, n mean (SD)	66	66	**-51.4 (43.8)**	45	45	**-18.2 (31.8)**	p=0.0001
	2.2 (0.7)	**1.1 (1.0)**		**2.3 (0.6)**	**1.9 (0.9)**		
Edema, n mean (SD)	66	66	**-55.8 (43.0)**	44	44	**-17.1 (44.7)**	p<0.0001
	2.0 (0.7)	**0.9 (1.0)**		**2.0 (0.6)**	**1.6 (0.9)**		
Excoriation, n mean (SD)	56	56	**-68.8 (45.4)**	36	36	**-13.0 (52.3)**	p<0.0001
	1.8 (0.7)	**0.6 (1.0)**		**1.7 (0.7)**	**1.5 (1.0)**		
Lichenification, n mean (SD)	58	58	**-49.0 (53.9)**	42	42	**-15.8 (45.9)**	0.0016
	2.0 (0.7)	**1.0 (1.0)**		**2.0 (0.7)**	**1.7 (1.0)**		
Area affected Score, n mean (SD))	66	66	**-42.6 (48.3)**	46	46	**-13.9 (34.3)**	0.0022
	3.2 (1.5)	**1.8 (1.7)**		**3.4 (1.5)**	**2.9 (1.6)**		

BL, baseline; W, week; n, number of patients; SD, standard deviation.

Each sign was assessed using the following scores: 0 [None], 1[mild], 2[Moderate], 3[severe]

Area affected was assessed using the following scores: 0 [No active eczema in this region], 1[1–9%], 2[10–29%], 3[30–49%], 4[50–69%], 5[70–89%], 6[90–100%: the entire region is affected by eczema].

ABSTRACT 20

Efficacy and Safety of Dupilumab in Children Aged ≥6 Months to <6 Years With Moderate-to-Severe Atopic Dermatitis

Amy S. Paller, MD[1,2], Elaine C. Siegfried, MD[3,4], Eric L. Simpson, MD[5], Andreas Wollenberg, MD[6], Mercedes E. Gonzalez, MD[7], Robert Sidbury, MD[8], Benjamin Lockshin, MD[9], Yiping Sun, PhD[10], John T. O'Malley, MD[11], Ashish Bansal, MD[10]

[1]Northwestern University Feinberg School of Medicine, Chicago, IL; [2]Ann and Robert H. Lurie Children's Hospital, Chicago, IL; [3]Saint Louis University, St. Louis, MO; [4]Cardinal Glennon Children's Hospital, St. Louis, MO; [5]Oregon Health and Science University, Portland, OR; [6]Ludwig-Maximilian University, Munich, Germany; [7]University of Miami Miller School of Medicine, Miami, FL; [8]Seattle Children's Hospital, Seattle, WA, USA; [9]Georgetown University, Rockville, MD; [10]Regeneron Pharmaceuticals, Inc., Tarrytown, NY; 11Sanofi, Cambridge, MA

BACKGROUND: There is a high unmet medical need in pediatric patients aged 6 months to <6 years with moderate-to-severe atopic dermatitis (AD). We present pivotal phase 3 efficacy and safety data of dupilumab in children aged 6 months to <6 years with moderate-to-severe AD.

METHODS: In LIBERTY AD INFANTS/PRE-SCHOOL (NCT03346434 part B), a double-blind, placebo-controlled trial, children aged 6 months to <6 years with moderate-to-severe AD inadequately controlled with topical therapies were randomized 1:1 to subcutaneous dupilumab every 4 weeks (q4w) (baseline weight ≥5–<15kg: 200mg; ≥15–<30kg: 300mg) or placebo for 16 weeks. From Day –14, all patients initiated standardized treatment with low-potency topical corticosteroids (TCS).

RESULTS: 162 patients were randomized (dupilumab/placebo groups, n=83/79); 157 (96.9%; dupilumab/placebo n=82/75) completed 16 weeks of treatment. At Week 16, 27.7%/3.9% (P<0.0001) of patients receiving dupilumab/placebo achieved an IGA score of 0–1 (clear/almost clear), and 53.0%/10.7% (P<0.0001) achieved ≥75% improvement in Eczema Area and Severity Index (EASI). Least squares (standard error) mean percent change from baseline at Week 16 in EASI and weekly averaged worst scratch/itch score in dupilumab/placebo was –70.0%(4.9)/–19.6%(5.1) (P<0.0001) and –49.4%(5.0)/–2.2%(5.2) (P<0.0001), respectively. Improvements were statistically significant by Week 4. In dupilumab/placebo groups, treatment-emergent adverse events (TEAE), serious TEAE and TEAE-related treatment discontinuation were reported in 63.9%/74.4%, 0%/5.1% and 1.2%/1.3% of patients, respectively. Incidence of conjunctivitis (narrow cluster) and skin infection was 4.8%/0% and 12.0%/24.4%, respectively. Most common TEAEs were dermatitis atopic (13.3%/32.1%), nasopharyngitis (8.4%/9.0%), upper respiratory tract infection (6.0%/7.7%), impetigo (3.6%/7.7%), and lymphadenopathy (3.6%/7.7%).

CONCLUSIONS: In children (6 months to <6 years) with moderate-to-severe AD, dupilumab q4w+TCS vs placebo+TCS rapidly and significantly improved AD signs and symptoms. Dupilumab was well tolerated with a favorable safety profile.

ACKNOWLEDGEMENTS: Data first presented at the 3rd Annual Revolutionizing Atopic Dermatitis Virtual Conference (RAD); Dec 11-13, 2021. Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifier: NCT03346434. Medical writing/editorial assistance was provided by Anne Slomp, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

DISCLOSURES: Paller AS: AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, KrystalBio, Regeneron Pharmaceuticals, Inc., UCB – investigator; AbbVie, Abeona Therapeutics, Alcimed, Almirall, Amagma, AnaptysBio, Arena, Azitra, BiomX, Boehringer Ingelheim, Castle Biosciences, Catawba, Dermira, Eli Lilly, Exicure, Forte, Kamari, LEO Pharma, LifeMax, NAOS, Novartis, Pfizer, Phoenix, Pierre Fabre Dermo-Cosmetics, Regeneron Pharmaceuticals, Inc., Sanofi, Seanergy, Trifecta, UCB – consultant with honorarium; AbbVie, Bausch, Galderma, Novan – Data Safety Monitoring Board. Siegfried EC: Dermavant, Eli Lilly, Pfizer, Regeneron Pharmaceuticals, Inc., Verrica Pharmaceuticals – consultant; GSK, LEO Pharma, Novan – data and safety monitoring board; Eli Lilly, Janssen, Regeneron Pharmaceuticals, Inc., Stiefel, Verrica Pharmaceuticals – Principal Investigator in clinical trials. Simpson EL: AbbVie, Eli Lilly, Galderma, Kyowa Hakko Kirin, LEO Pharma, Merck, Pfizer, Regeneron Pharmaceuticals, Inc. – investigator; AbbVie, Boehringer Ingelheim, Dermavant, Eli Lilly, Forté, Incyte, LEO Pharma, Menlo Therapeutics, Pfizer, Pierre Fabre Dermo-Cosmetics, Regeneron Pharmaceuticals, Inc., Sanofi, Valeant – consultant fees. Wollenberg A: Beiersdorf, Eli Lilly, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi– investigator; AbbVie, Almirall, Anacor Pharmaceuticals, Eli Lilly, Galapagos, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi– consultant; Beiersdorf, LEO Pharma, Pierre Fabre – research grants. Gonzalez ME: AbbVie, Arcutis Biotherapeutics, Eli Lilly, Dermira, Incyte, Krystal Biotech, Regeneron Pharmaceuticals, Inc., SUN Pharma, Verrica Pharmaceuticals – Investigator; Galderma, Pfizer, Primus Pharmaceuticals, Regeneron Pharmaceuticals, Inc., Sanofi–Speaker; Verrica Pharmaceuticals, Unilever – consultant. Sidbury R: Brickell Biotech, Galderma, Regeneron Pharmaceuticals, Inc. – investigator; Pfizer – advisory board member; Micreos – consultant. Lockshin B: Eli Lilly, Regeneron Pharmaceuticals, Inc. – investigator, speaker; Anacor Pharmaceuticals, Dermira, Franklin Bioscience, LEO Pharma – investigator; AbbVie – investigator, speaker, consultant. Sun Y, Bansal A: Regeneron Pharmaceuticals, Inc. – employees and shareholders. O'Malley JT: Sanofi – employees, may hold stock and/or stock options in the company.

ABSTRACT 21

Infections in Dupilumab Pediatric Clinical Trials in Atopic Dermatitis—A Pooled Analysis

Lisa A. Beck MD[1], Andrew Blauvelt MD[2], Michael J. Cork PhD[3], Andreas Wollenberg MD[4], Zhen Chen PhD[5], Faisal A. Khokhar MD[5], Lauren Bates PharmD[5], Annie Zhang MD[6]

[1]University of Rochester Medical Center, Rochester, NY, USA; [2]Oregon Medical Research Center, Portland, OR, USA; [3]Sheffield Dermatology Research, University of Sheffield, Sheffield, UK; [4]Ludwig-Maximilian University, Munich, Germany; [5]Regeneron Pharmaceuticals, Inc., Tarrytown, NY; USA; 6Sanofi, Cambridge, MA, USA

INTRODUCTION: Patients with moderate-to-severe atopic dermatitis (AD) are at increased risk of infections, including skin and systemic infections. The efficacy and safety of dupilumab have been established in clinical trials in adults, adolescents aged 12–17 years, and children aged 6–11 years. We assessed infection rates for dupilumab vs placebo in children aged 6–11 years with severe AD and adolescents aged 12–17 years with moderate-to-severe AD.

METHODS: This was a comprehensive, pooled analysis of infections in two 16-week, randomized, placebo-controlled, phase 3 clinical trials. LIBERTY AD ADOL (NCT03054428) tested dupilumab monotherapy in adolescents aged 12–17 years with moderate-to-severe AD; LIBERTY AD PEDS (NCT03345914) tested dupilumab with concomitant use of topical corticosteroids (TCS) in children aged 6–11 years with severe AD. Data were pooled according to treatment: placebo; approved dupilumab doses (in children: 300 mg every 4 weeks [q4w] if baseline weight < 30 kg, 300 mg q4w or 200 mg every 2 weeks [q2w] if ≥ 30 kg; in adolescents: 200 mg q2w if < 60 kg, 300 mg q2w if ≥ 60 kg); other studied dupilumab doses (100 mg q2w in children < 30 kg and 300 mg q4w in adolescents < 60 kg); and all dupilumab doses. Exposure-adjusted rates (patients with ≥ 1 event per 100 patient-years [nP/100 PY]) were used to compare treatment groups.

RESULTS: Overall, 612 patients were included: 205 received placebo (with TCS in children aged 6–11 years); 261 received approved dupilumab doses; 146 received other dupilumab doses studied. 407 patients were included in the pooled dupilumab doses group. Overall infection rates were numerically lower for dupilumab vs placebo (nP/100 PY: placebo, 227; approved dupilumab doses, 173; other dupilumab doses, 206; and all dupilumab doses, 184). Total skin infections (non-herpetic and herpetic) were less frequent in all dupilumab-treated groups vs placebo (nP/100 PY: placebo, 67; approved dupilumab doses, 30 [$P < 0.05$]; other dupilumab doses, 46; all dupilumab doses, 36 [$P < 0.01$]). Non-herpetic skin infections were significantly less frequent in the dupilumab groups than in the placebo group (nP/100 PY: placebo, 57; approved dupilumab doses, 26; other dupilumab doses, 31; and all dupilumab doses, 28; all $P < 0.05$ vs placebo). Systemic anti-infective medication use was numerically lower in all dupilumab-treated groups vs placebo (nP/100 PY: placebo, 149; approved dupilumab doses, 109; other dupilumab doses, 131; and all dupilumab doses, 116).

DISCUSSION: Dupilumab was associated with lower overall infections and significantly lower non-herpetic skin infections vs placebo in children and adolescent patients with AD, contributing important data to the safety profile of dupilumab in pediatric patients.

ACKNOWLEDGMENTS: Data first presented at the 30th Congress of the European Academy of Dermatology and Venereology (EADV); Sep 29–Oct 2, 2021. Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifiers: NCT03345914 (LIBERTY AD PEDS); NCT03054428 (LIBERTY AD ADOL). Medical writing/editorial assistance was provided by Alexandre Houzelle, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

DISCLOSURES: Beck LA: AbbVie, Allakos, AstraZeneca, BenevolentAI, DermTech, Eli Lilly, Incyte, Janssen, LEO Pharma, NAOS/Bioderma, Novartis, Pfizer, Principia Biopharma, RAPT Therapeutics, Regeneron Pharmaceuticals Inc., Ribon Therapeutics, Sanofi, UCB, Vimalan – consultant. AbbVie, AstraZeneca, Kiniksa Pharmaceuticals, LEO Pharma, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi – Investigator. 3M, Gilead, Medtronic, Moderna – shareholder. Blauvelt A: AbbVie, Abcentra, Aligos Therapeutics, Almirall, Amgen, Arcutis Antiobix, Arena Pharmaceuticals, Athenex, Boehringer Ingelheim, BMS, Dermavant, Eli Lilly, Evommune, Forté, Galderma, Incyte, Janssen, Landos Biopharma, LEO Pharma, Novartis, Pfizer, RAPT Therapeutics, Regeneron Pharmaceuticals, Inc., Sanofi, Sun Pharma, UCB – scientific adviser, clinical study investigator. Cork MJ: AbbVie, Astellas, Boots, Dermavant, Galapagos, Galderma, Hyphens Pharma, Johnson & Johnson, LEO Pharma, L'Oréal, Menlo Therapeutics, Novartis, Oxagen, Pfizer, Procter & Gamble, Reckitt Benckiser, Regeneron Pharmaceuticals, Inc., Sanofi– investigator and/or consultant. Wollenberg A: Beiersdorf, Eli Lilly, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi–investigator; AbbVie, Almirall, Anacor Pharmaceuticals, Eli Lilly, Galapagos, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi– consultant; Beiersdorf, LEO Pharma, Pierre Fabre – research grants. Chen Z, Khokhar FA, Bates L: Regeneron Pharmaceuticals, Inc. – employees and shareholders. Zhang A: Sanofi – employees, may hold stock and/or stock options in the company.

ABSTRACT 22

Dupilumab Provides Long-Term Efficacy for Up to 4 Years in an Open-Label Extension Study of Adults with Moderate-to-Severe Atopic Dermatitis

Andrew Blauvelt, MD[1], Jacob P. Thyssen, PhD[2], Benjamin Lockshin, PhD[3], Ryszard Galus, PhD[4], Charles Lynde, PhD[5,6], Jing Xiao, PhD7, Noah A. Levit, PhD[7], Ainara Rodríguez Marco, MD[8], Arsalan Shabbir,MD[7]

[1]Oregon Medical Research Center, Portland, OR, USA; [2]Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark; [3]Georgetown University, Washington, D.C., USA; [4]Medical University of Warsaw, Warsaw, Poland; [5]University of Toronto, Markham, ON, Canada; [6]Lynderm Research, Markham, ON, Canada; [7]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [8]Sanofi, Madrid, Spain

BACKGROUND: Patients with chronic moderate-to-severe atopic dermatitis (AD) often have an inadequate response to topical therapies. Here, we present the long-term efficacy of dupilumab up to 4 years in adult patients with moderate-to-severe AD from an open-label extension (OLE) study (LIBERTY AD OLE, NCT01949311).

METHODS: Adults (≥ 18 years) with moderate-to-severe AD who had participated in any dupilumab parent study (phase 1 to 3) were enrolled into the long-term, multicenter, OLE with an initial duration of 3 years and up to 5 years in certain countries. Initially, patients enrolled in the OLE were treated with 300 mg dupilumab weekly. In 2019, patients remaining in the study transitioned to dupilumab 300 mg every 2 weeks in alignment with the approved dupilumab dose regimen. Concomitant treatments for AD, including topical corticosteroid (TCSs) and topical calcineurin inhibitors (TCIs), were permitted. Data shown are for the overall study population.

RESULTS: Of the 2677 patients who enrolled in the OLE, 2207 completed treatment up to Week 52, 1065 up to Week 100, 557 up to Week 148, 362 up to Week 172, and 352 up to Week 204. 240 patients had treatment duration > 204 weeks. Most withdrawals (810 [59.5%]) during the OLE study period were due to dupilumab approval and commercialization in the country in which the patient had enrolled, 114 (8.4%) patients withdrew due to adverse events and 58 (4.3%) withdrew due to lack of efficacy. At Week 204, 91% of patients achieved a 75% reduction in Eczema Area and Severity Index (EASI) from parent study baseline (PSBL), 76% of patients achieved a 90% reduction in EASI from PSBL, and 70.8% of patients achieved a ≥4-point reduction in the Peak Pruritus Numerical Rating Scale score from PSBL. A total of 2273 (84.9%) patients reported treatment-emergent adverse events, and 99 (3.7%) patients discontinued treatment permanently due to reported adverse events. Dupilumab had an acceptable safety profile.

CONCLUSIONS: Long-term dupilumab treatment showed sustained efficacy with durable and progressive improvements in AD signs and symptoms in adults with moderate-to-severe AD up to 204 weeks. Dupilumab was generally well tolerated with an acceptable safety profile.

ACKNOWLEDGEMENTS: Data first presented at the 3rd Annual Revolutionizing Atopic Dermatitis Virtual Conference (RAD); Dec 11-13, 2021. Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifier: NCT01949311. Medical writing/editorial assistance was provided by Nigel De Melo, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

DISCLOSURES: Thyssen JP: AbbVie, Almirall, Arena Pharmaceuticals, OM Pharma, Aslan Pharmaceuticals, Union Therapeutics, Eli Lilly & Co, LEO Pharma, Pfizer, Regeneron, and Sanofi– advisor, AbbVie, Almirall, Eli Lilly & Co, LEO Pharma, Pfizer, Regeneron, and Sanofi– speaker, Pfizer, Regeneron, and Sanofi-– research grants. Blauvelt A: AbbVie, Abcentra, Aligos Therapeutics, Almirall, Amgen, Arcutis Pharmaceuticals, Arena Pharmaceuticals, Aslan Pharmaceuticals, Athenex, BMS, Boehringer Ingelheim, Dermavant, EcoR1, Eli Lilly, Evommune, Landos Biopharma, LEO Pharma, Galderma, Incyte, Janssen, Landos Biopharma, LEO Pharma, Novartis, Pfizer, RAPT Therapeutics, Regeneron Pharmaceuticals, Inc., Sanofi, Sun Pharma, UCB Pharma, Vibliome – scientific adviser and/or clinical study investigator. Lockshin B: Eli Lilly, Regeneron Pharmaceuticals, Inc. – investigator, speaker; Anacor Pharmaceuticals, Dermira, Franklin Bioscience, LEO Pharma – investigator; AbbVie – investigator, speaker, consultant. Galus R: Amgen, Boehringer Ingelheim, Chugai, Dermira, Galderma, Incyte, Janssen, Pfizer, Regeneron Pharmaceuticals Inc. Lynde C: Abbott, AbbVie, Allergan, Amgen, Aralez Bio, Arcutis Antiobix, Astellas Pharma, Basilea, Bausch Health, Bayer, Boehringer Ingelheim, BMS, Cipher, Eli Lilly, EMD Serono, Fresenius Kabi, Galderma, GSK, H3 Biomedicine, Innovaderm, Janssen, Johnson & Johnson, Kyowa Kirin, La Roche-Posay, L'Oreal, LEO Pharma, Merck, Medexus, Novartis, Ortho Biotech, Pediapharm, Pfizer, Roche, Sanofi, Stiefel, Teva, Tribute Pharmaceuticals, Valeant, Westwood Squibb Pharmaceuticals, Wyeth – Principal Investigator and/or consultant. Xiao J, Levit NA, Shabbir A: Regeneron Pharmaceuticals, Inc. – employees and shareholders. Rodríguez Marco A: Sanofi– employee, may hold stock and/or stock options in the company.

ABSTRACT 23

Dupilumab Monotherapy Provides Long-Term Control and Prevents Flares in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16

Andreas Wollenberg, MD[1], Diamant Thaçi, MD[2], Eric L. Simpson, MD[3], Robert Bissonnette, MD[4], Amy Praestgaard, MD[5], Gerald Wilson, PharmD[6], Ana B. Rossi, MD[5]

[1]Ludwig-Maximilian University, Munich, Germany; [2]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [3]Oregon Health and Science University, Portland, OR, USA; [4]Innovaderm Research, Montreal, QC, Canada; [5]Sanofi, Cambridge, MA, USA; [6]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

OBJECTIVES: Atopic dermatitis (AD) is a chronic inflammatory systemic disease with recurrent exacerbations (flares), requiring long-term management. The long-term efficacy and safety of dupilumab have been reported in combination with topical corticosteroids (TCS) (LIBERTY AD CHRONOS: NCT02260986). In CHRONOS, dupilumab every 2 weeks (q2w) + TCS prevented flares in over 80% of patients. We now report the incidence of flares in AD patients over 36 weeks of maintenance treatment with dupilumab monotherapy compared with placebo.

MATERIALS & METHODS: Adult patients with moderate-to-severe AD who had previously participated in LIBERTY AD SOLO 1 or 2 (NCT02277743, NCT02277769) and had achieved a 75% reduction from baseline in Eczema Area and Severity Index (EASI-75) and/or an Investigator's Global Assessment (IGA) score of 0/1 at week 16 were enrolled in LIBERTY AD SOLO-CONTINUE (NCT02395133), a randomized, 36 week, double-blind, placebo-controlled phase 3 study. Herein we report incidence of flares for patients treated in SOLO-CONTINUE with 300 mg dupilumab monotherapy q2w or placebo for an additional 36 weeks. Flares were defined as worsening of disease requiring rescue treatment.

RESULTS: At SOLO-CONTINUE baseline (week 16 of parent study), patients treated with dupilumab in SOLO who met response criteria were re-randomized to either continuing dupilumab q2w (n=80) or switched to placebo (n=82). The proportion of patients with a flare event up to week 52 was significantly lower for dupilumab-treated patients compared with placebo (20% vs 48%; *P*=0.0004). Dupilumab was generally well tolerated, with an acceptable safety profile.

CONCLUSIONS. Most (80%) patients who had achieved IGA 0/1 or EASI-75 response after 16 weeks of treatment and continued dupilumab 300 mg q2w monotherapy remained flare-free during an additional 36 weeks. Compared to placebo, long-term treatment with dupilumab monotherapy significantly prevents flares over 1 year in most adults with moderate-to-severe AD who have optimally responded at week 16 of treatment.

ACKNOWLEDGMENTS. Data first presented at the 30th Congress of the European Academy of Dermatology and Venereology (EADV); Sep 29–Oct 2, 2021. Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifier: NCT02395133. Medical writing/editorial assistance was provided by Nigel De Melo, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

DISCLOSURES: Wollenberg A: Beiersdorf, Eli Lilly, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi – investigator; AbbVie, Almirall, Anacor, Eli Lilly, Galapagos, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi– consultant; Beiersdorf, LEO Pharma, Pierre Fabre – research grants. Thaçi D: AbbVie, Almirall, Amgen, Beiersdorf, Bristol-Meiers-Squibb, Boehringer Ingelheim, Eli Lilly, Galapagos, Janssen-Cilag, LEO Pharma, MorphoSys, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Samsung, Sandoz, Sanofi, Sun Pharma, UCB – consultant, advisory board member, and/or investigator. Simpson EL: Amgen, Celgene, Chugai, Galderma, Genentech, Lilly, MedImmune, Regeneron Pharmaceuticals, Inc., Sanofi, Tioga Pharmaceuticals, Vanda Pharmaceuticals – grants/research support; Anacor Pharmaceuticals, Celgene, Galderma, Genentech, Medicis Pharmaceutical, Merck, Regeneron Pharmaceuticals, Inc., Sanofi – consultant. Bissonnette R: AbbVie, Arcutis Antiobix, Arena Pharmaceuticals, Asana BioSciences, Bellus Health, Boehringer Ingelheim, Dermavant, Eli Lilly, EMD Serono, Galderma, Incyte, Kiniksa Pharmaceuticals, Kyowa Kirin, LEO Pharma, Novan, Pfizer, Ralexar Therapeutics, RAPT Therapeutics, Regeneron Pharmaceuticals, Inc., Sanofi, Siena Biopharmaceuticals – consultant, speaker, and/or grants/research support; Innovaderm Research – employee and shareholder. Praestgaard A, Rossi AB: Sanofi – employees, may hold stock and/or stock options in the company. Wilson G: Regeneron Pharmaceuticals, Inc. – employee and shareholder.

CUTANEOUS MALIGNANCIES

ABSTRACT 24

Phase 2 Study of Cemiplimab in Patients (Pts) With Advanced Cutaneous Squamous Cell Carcinoma (CSCC): Follow-Up at 43 Months

Danny Rischin,[1] Nikhil I. Khushalani,[2] Chrysalyne D. Schmults,[3] Alexander Guminski,[4] Anne Lynn S. Chang,[5] Karl D. Lewis,[6] Annette M. Lim,[1] Leonel Hernandez-Aya,[7] Brett G.M. Hughes,8 Dirk Schadendorf,[9] Axel Hauschild,[10] Elizabeth Stankevich,[11] Jocelyn Booth,[11] Suk-Young Yoo,[11] Emmanuel Okoye,[11] Israel Lowy,[11] Matthew G. Fury,[11] Michael R. Migden[12]

[1]Department of Medical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia; [2]Department of Cutaneous Oncology, Moffitt Cancer Center, Tampa, FL, USA; [3]Department of Dermatology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [4]Department of Medical Oncology, Royal North Shore Hospital, St Leonards, NSW, Australia; [5]Department of Dermatology, Stanford University School of Medicine, Redwood City, CA, USA; [6]University of Colorado Denver Cancer Center, Aurora, CO, USA; [7]Division of Medical Oncology, Department of Medicine, Washington University School of Medicine, St Louis, MO, USA; [8]Royal Brisbane & Women's Hospital and University of Queensland, Brisbane, Australia; [9]University Hospital Essen, Essen and German Cancer Consortium, Essen, Germany; [10]Schleswig-Holstein University Hospital, Kiel, Germany; [11]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [12]Departments of Dermatology and Head and Neck Surgery, University of Texas MD Anderson Cancer Center, Houston, TX, USA.

Presenting author:
Danny Rischin
Department of Medical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia
305 Grattan Street
Melbourne, VIC 3000, Australia
Phone number: +61-03-8559-5000
Email: Danny.Rischin@petermac.org

BACKGROUND: Primary analysis data from this pivotal study supported the approval of cemiplimab for patients with metastatic CSCC (mCSCC) or locally advanced CSCC (laCSCC) that is not suitable for curative

surgery or curative radiation, collectively referred to as advanced CSCC. The 36-month update of this data set demonstrated durable responses and the emergence of new objective responses, including complete responses (NCT02760498). The safety profile was comparable to that of other anti–programmed cell death–1 (PD–1) agents.

OBJECTIVES: We present follow-up data at approximately 43 months after the primary analysis of the first group in this study.

METHODS: Patients received cemiplimab 3 mg/kg every 2 weeks (Group [Gp] 1; mCSCC; Gp 2, laCSCC) or cemiplimab 350 mg every 3 weeks [Q3W] (Gp 3, mCSCC). The primary endpoint was objective response rate (ORR; complete response + partial response) per independent central review (ICR). Data cut was October 11, 2020, for the current follow-up analysis.

RESULTS: A total of 193 patients were enrolled (Gp 1, n=59; Gp 2, n=78; Gp 3, n=56). As of the data cut-off, the median duration of follow-up (range) was 15.7 months (0.6–43.2) for all patients; 18.5 months (1.1–41.0) in Gp 1; 15.5 months (0.8–43.2) in Gp 2; and 17.3 months (0.6–38.5) in Gp 3. Overall, there was a slight improvement in the ORR by ICR for all patients to 47.2% [95% confidence interval (CI) 39.9–54.4], which has remained the same for Gps 1 and 2 but increased in Gp 3 to 46.4% (95% CI: 33.0–60.3; vs 42.9% [95% CI: 29.7–56.8] in our last update; this includes two new complete responses; 19.6%). Median duration of response (DOR) had not been reached (observed DOR range: 1.9–39.4 months). In responding patients, the estimated proportion of ongoing response at 24 months improved overall to 72.8% (95% CI: 61.2–81.4), compared to 69.4% (95% CI: 55.6–79.6) in our last update. The median Kaplan–Meier (KM) estimation of progression-free survival for all patients was 18.5 months (95% CI 10.3–31.3), 18.4 months (95% CI 6.8–32.8) in Gp 1, 18.5 months (95% CI 11.1–not evaluable [NE]) in Gp 2, and 21.7 months (95% CI 3.6–NE) in Gp 3. Median overall survival by ICR was not reached. Incidence of immune-related adverse events (AEs) and treatment-emergent AEs (TEAEs) were consistent with our previous update. The most common TEAEs of any grade were fatigue (34.7%), diarrhea (27.5%), and nausea (23.8%).

CONCLUSIONS: The 43-month follow-up from this study shows incremental improvements in DOR with cemiplimab treatment across all advanced CSCC study groups, as well as improvements in ORR and complete response rate on the cemiplimab 350 mg Q3W regimen. There were no new safety signals.

FUNDING: Regeneron Pharmaceuticals, Inc., and Sanofi

ACKNOWLEDGEMENT: The authors would like to thank the patients, their families, all other investigators, and all investigational site members involved in this study. The study was funded by Regeneron Pharmaceuticals, Inc. and Sanofi. Medical writing support and typesetting was provided by Daniel Himmel, PhD, of Prime, Knutsford, UK, funded by Regeneron Pharmaceuticals, Inc. and Sanofi.

DISCLOSURES: Danny Rischin: institutional research grant and funding from Regeneron Pharmaceuticals, Inc., Roche, Merck Sharp & Dohme, Bristol-Myers Squibb, and GlaxoSmithKline; uncompensated scientific committee and advisory board from Merck Sharp & Dohme, Regeneron Pharmaceuticals, Inc., Sanofi, GlaxoSmithKline, and Bristol-Myers Squibb; travel and accommodation from Merck Sharp & Dohme and GlaxoSmithKline. Nikhil I. Khushalani: grants from Regeneron Pharmaceuticals, Inc.; grants and advisory board fees from Bristol-Myers Squibb and HUYA Bioscience International; advisory board fees from EMD Serono, Regeneron Pharmaceuticals, Inc., Genentech, AstraZeneca (data safety monitoring committee), Merck, ARRAY Biopharma, Jounce Therapeutics, and Immunocore; grants from Merck, Novartis, GlaxoSmithKline, Cellgene, and Amgen; honorarium from Sanofi; and common stock ownership of Bellicum Pharmaceuticals, Mazor Robotics, Amarin, and Transenetrix. Chrysalyne D. Schmults: steering committee member for Castle Biosciences; a steering committee member and consultant for Regeneron Pharmaceuticals, Inc.; a consultant for Sanofi; has received research funding from Castle Biosciences, Regeneron Pharmaceuticals, Inc., Novartis, Genentech, and Merck, and is a chair for the National Comprehensive Cancer Network. Alexander Guminski: personal fees and non-financial support (advisory board and travel support) from Bristol-Myers Squibb and Sun Pharma; personal fees (advisory board) from Merck KGaA, Eisai, and Pfizer; non-financial (travel) support from Astellas; and clinical trial unit support from PPD Australia. Anne Lynn S. Chang: consulting and advisory roles at Regeneron Pharmaceuticals, Inc., Merck; research funding from Regeneron Pharmaceuticals, Inc., Novartis, Galderma, and Merck. Karl D. Lewis: grants and personal fees from Regeneron Pharmaceuticals, Inc. during the conduct of the study. Annette M. Lim: uncompensated advisory board from Merck Sharp & Dohme and Bristol-Myers Squibb with travel and accommodation expenses; uncompensated consultancy for Eisai. Leonel Hernandez-Aya: performed consulting and advisory roles at Massive Bio; speakers' bureau roles at Sanofi and Regeneron Pharmaceuticals, Inc., and received travel, accommodations, and expenses from Regeneron Pharmaceuticals, Inc., Sanofi, and Bristol-Myers Squibb and research funding from Bristol-Myers Squibb, Regeneron Pharmaceuticals, Inc., Immunocore, Merck Sharp & Dohme, Polynoma, Corvus Pharmaceuticals, Roche, Merck Serono, Amgen, MedImmune, and Takeda. Brett G.M. Hughes: consulting or advisory roles at Merck Sharp & Dohme, BristolMyers Squibb, AstraZeneca, Pfizer, Roche, Eisai, Merck and institutional research funding from Amgen. Dirk Schadendorf: institutional patients' fees from Regeneron Pharmaceuticals, Inc.; advisory board honorarium fees from Amgen and Leo Pharma; speaker fee from Boehringer Ingelheim; advisory board, speaker honorarium and patients' fees from Roche, Novartis, Bristol-Myers Squibb, and Merck-EMD; advisory board and speaker honorarium fees from Incyte and Pierre Fabre; advisory board honorarium and patients' fees from MSD, steering committee honorarium fees from 4SC, advisory board fees from AstraZeneca, Pfizer, and Array; and advisory board and patients' fees from Philiogen. Axel Hauschild: institutional grants, speaker's honoraria, and consultancy fees from Amgen, Bristol-Myers Squibb, Merck Sharp & Dohme / Merck, Pierre Fabre, Provectus, Roche, and Novartis; institutional grants and consultancy fees from Merck Serono, Philogen, and Regeneron Pharmaceuticals, Inc.; and consultancy fees from

OncoSec. Elizabeth Stankevich: employee and shareholder of Regeneron Pharmaceuticals, Inc. Jocelyn Booth: employee and shareholder of Regeneron Pharmaceuticals, Inc. Suk-Young Yoo: employment, stock, and other ownership interests at Regeneron Pharmaceuticals, Inc. Emmanuel Okoye: employee and shareholder of Regeneron Pharmaceuticals, Inc. Israel Lowy: employee and shareholder of Regeneron Pharmaceuticals, Inc. Matthew G. Fury: employee and shareholder of Regeneron Pharmaceuticals, Inc. Michael R. Migden: honoraria and travel expenses from Regeneron Pharmaceuticals, Inc., Sanofi, Novartis, Genentech, Eli Lilly, and Sun Pharma; and institutional research funding from Regeneron Pharmaceuticals, Inc., Novartis, Genentech, and Eli Lilly.

ABSTRACT 25

Health-related Quality of Life (Hrqol) in Patients With Locally Advanced Basal Cell Carcinoma (Labcc) Treated With Cemiplimab: Analysis of A Phase 2, Open-Label Clinical Trial

Alexander J. Stratigos,[1] Chieh-I Chen,[2] Cristina Ivanescu,[3] Karl D. Lewis,[4] Ketty Peris,[5] Oliver Bechter,[6] James Harnett,[2] Vera Mastey,[2] Matthew Reaney,[3] Christina Daskalopoulou,[3] Patrick R LaFontaine,[7] Gerasimos Konidaris,[7] Denise Bury,[7] Suk-Young Yoo,[2] Kosalai Mohan,[2] Ebony Coates,[2] Timothy Bowler,[2] Matthew G. Fury,[2] Aleksandar Sekulic[8]

[1]University of Athens, A. Sygros Hospital, Athens, Greece; [2]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [3]IQVIA, Durham, NC, USA; [4]University of Colorado Cancer Center, Aurora, CO, USA; [5]Catholic University Fondazione Policlinico Universitario, Rome, Italy; [6]UZ Leuven, Leuven, Belgium; [7]Sanofi, Cambridge, MA, USA; [8]Mayo Clinic, Scottsdale, AZ, USA.

Presenting author:
Alexander J. Stratigos, MD
University of Athens, A. Sygros Hospital, Athens, Greece
Athens 157 72, Greece
Email: alstrat2@gmail.com

BACKGROUND: Cemiplimab-rwlc is the first immunotherapy approved in the US, fully for patients with laBCC and accelerated for metastatic BCC, post hedgehog inhibitors (HHIs) or for whom HHIs are not appropriate. Cemiplimab resulted in clinically meaningful anti-tumor activity in patients with laBCC who progressed on or were intolerant to HHI therapy (NCT03132636).

OBJECTIVES: This analysis evaluated HRQoL among these patients.

METHODS: Adults with laBCC and ECOG performance status ≤1 (n=84) received intravenous cemiplimab 350 mg Q3W for up to 9 cycles. At baseline (BL) and day 1 of each cycle (C), patients completed EORTC QLQ-C30 and SKINDEX-16 questionnaires that assess Global Health Status (GHS)/QoL, functioning, and BCC-related symptoms. Mixed-effects repeated measures (MMRM) models were used to estimate least squares (LS) mean (standard error [SE]) change from BL during treatment (i.e., across C2 to C9); changes ≥|10| points were considered clinically meaningful. Responder analyses were conducted in patients with non-missing data from BL to determine the proportions with clinically meaningful improvement (CMI) or deterioration, or stability on QLQ-C30 and SKINDEX-16 at C2 and C9; a 10-point threshold was considered meaningful for both instruments.

RESULTS: BL scores showed moderate to high levels of functioning and low symptom burden. In MMRM models, overall changes from BL on QLQ-C30 indicated stability for GHS/QoL and all scales except for clinically meaningful worsening of fatigue (LS mean [SE] change 12.5 [3.9]; $P<.05$). In responder analysis, a majority of patients reported clinically meaningful improvement or stability at C2 and C9 on all QLQ-C30 functioning scales and the key symptom of pain (C2 74.7%, C9 77.8%) but not fatigue (C2 61.3%, C9 44.4%). On SKINDEX-16, MMRM models showed clinically meaningful improvement on the emotional subscale (LS mean [SE] change –13.2 [3.9]; $P<0.05$) and stability on the symptom and functional subscales. Responder analysis showed clinically meaningful improvements or stability across the SKINDEX-16 subscales in approximately 80% of patients at C2, and 70–80% of patients at C9.

CONCLUSIONS: Among patients with laBCC treated with cemiplimab, the majority reported CMI or stability in GHS/QoL and functional status while maintaining low symptom burden except for fatigue.

FUNDING: Regeneron Pharmaceuticals, Inc. and Sanofi

ACKNOWLEDGEMENT: The authors would like to thank the patients, their families, all other investigators, and all investigational site members involved in this study. The study was funded by Regeneron Pharmaceuticals, Inc. and Sanofi. Medical writing support was provided by E. Jay Bienen, PhD, and typesetting was provided by Prime, Knutsford, UK, funded by Regeneron Pharmaceuticals, Inc. and Sanofi.

DISCLOSURES: Alexander J. Stratigos reports consulting or advisory role at Regeneron Pharmaceuticals, Inc.; research funding from Sanofi, Abbvie, Janssen, Genesis Pharma, Novartis, Leo Pharma, Lilly, Bristol-Myers Squibb, Genesis Pharma, and Merck-Sharp Dohme; and patents, royalties, other intellectual property from Color Atlas of Pediatric Dermatology and MacGraw Hill editions. Chieh-I Chen, Vera Mastey, Suk-Young Yoo, Ebony Coates, and Timothy Bowler reports employment and stock interests at Regeneron Pharmaceuticals, Inc.
Cristina Ivanescu reports employment at IQVIA and institutional research funding from Regeneron Pharmaceuticals, Inc. Karl D. Lewis reports consulting or advisory roles from Array BioPharma, Merck, Roche, Regeneron Pharmaceuticals, Inc., Sanofi, and Iovance Biotherapeutics; travel, accommodations, expenses from Merck, Roche/Genentech, Regeneron Pharmaceuticals, Inc, Neon Therapeutics, and Alkermes; honoraria from Array BioPharma and Iovance Biotherapeutics; institutional research funding from Roche/Genentech, Merck, Array BioPharma, Incyte, Nektar, Iovance Biotherapeutics, Bristol-Myers Squibb, Kartos Therapeutics,

OncoSec, Regeneron Pharmaceuticals, Inc., Alkermes, Neon Therapeutics, Ultimovacs, Senhwa Biosciences, Replimune, and Amgen; and uncompensated relationships at Roche/Genentech and Regeneron Pharmaceuticals, Inc. Ketty Peris Ketty Peris reports consulting or advisory role for Almirall, LEO Pharma, Novartis, Lilly, Sanofi, and Sun Pharma, and speaker's bureau fees from Sanofi. Oliver Bechter reports consulting or advisory roles at Novartis, Bristol-Myers Squibb, Merck Sharp & Dohme, Pierre Fabre, Sanofi, Almirall, and Ultimovacs. James Harnett reports employment and stock interests at Regeneron Pharmaceuticals, Inc. and Pfizer. Matthew Reaney reports employment at IQVIA. Christina Daskalopoulou reports consulting or advisory role at IQVIA. Patrick R. LaFontaine reports employment at Sanofi and stock interests at Sanofi, Neos Therapeutics, and Applied Genetic Technologies. Gerasimos Konidaris reports employment at Sanofi. Denise Bury reports employment and stock interests at Sanofi. Kosalai Kal Mohan reports employment and travel, accommodations, expenses from Regeneron Pharmaceuticals, Inc.; and stock interests from Merck, Gilead Sciences, Sarepta Therapeutics, Agenus, Bellicum Pharmaceuticals, Amicus Therapeutics, CelSci, Progenics, Soligenix, Sorrento Therapeutics, Veracyte, Navidea, Newlink Genetics, and Celldex. Matthew G. Fury reports employment, stock interests, research funding, and patents, royalties, other intellectual property from Regeneron Pharmaceuticals, Inc.; and an immediate family member's employment, stock interests, and patents, royalties, other intellectual property from Regeneron Pharmaceuticals, Inc. Aleksandar Sekulic reports institutional research funding from Genentech and Regeneron Pharmaceuticals, Inc.

ABSTRACT 26

Checkpoint inhibition in immunosuppressed or immunocompromised (IS/IC) patients with advanced cutaneous squamous cell carcinoma (CSCC): Data from prospective CemiplimAb-rwlc Survivorship and Epidemiology (C.A.S.E.) study

Guilherme Rabinowits,[1] Soo Park,[2] David M Ellison,[3] Francis P Worden,[4] Rhonda Gentry,[5] John Strasswimmer,[6] Suraj Venna,[7] Michael R. Migden,[8] Sunandana Chandra,9 Emily Ruiz,[10] Nikita Mehta,[11] Haixin R. Zhang,[12] Jennifer McGinniss[12]

1Department of Hematology and Oncology, Miami Cancer Institute/Baptist Health South Florida, Miami, FL, USA; 2Division of Hematology and Oncology, University of California San Diego; CA, USA; 3Charleston Oncology, Charleston, SC, USA; 4Michigan Medicine Rogel Cancer Center, Ann Arbor, MI, USA; 5CARTI Cancer Center, Little Rock, AR, USA; 6College of Medicine (Dermatology) and College of Sciences (Biochemistry), Florida Atlantic University, FL, USA; 7Inova Schar Cancer Institute Melanoma Center, Fairfax, VA, USA; 8Departments of Dermatology and Head and Neck Surgery, University of Texas MD Anderson Cancer Center, Houston, TX, USA; 9Division of Hematology Oncology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; 10Brigham and Women's Hospital, Boston, MA, USA; 11Sanofi, Cambridge, MA, USA, 12Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA.

BACKGROUND: Immunosuppressed and/or immunocompromised patients are at increased risk for solid tumors and cutaneous malignancies. Limited data exist on the safety and effectiveness of immune checkpoint inhibitors (ICIs) in these patients because they are frequently excluded from clinical trials.

OBJECTIVES: In this study, we describe the safety and effectiveness results from the initial cohort of immunosuppressed and/or immunocompromised patients with advanced CSCC enrolled in the C.A.S.E. study (NCT03836105).

METHODS: C.A.S.E. is a prospective, real-world, multicenter, longitudinal study evaluating the effectiveness, safety, quality of life, and survivorship in patients with advanced CSCC treated with cemiplimab. Patients received cemiplimab 350 mg intravenously every 3 weeks per routine standard of care. Patient demographics, disease characteristics, immunosuppression status, and relevant medical history were collected. Immunosuppressive regimens varied amongst patients. Investigator assessment of objective response rate (ORR), safety, and tolerability was conducted. Data from 26 immunosuppressed and/or immunocompromised patients with advanced CSCC treated with cemiplimab are presented. Recruitment is ongoing.

Character count: 2654 (maximum of 3000 characters including spaces, not including the title, authors, or affiliations).

Abstract submission deadline: Friday, March 11, 2022

Presenting author

Guilherme Rabinowits, MD

Head and Neck and Cutaneous Medical Oncology, Miami Cancer Institute

8900 N. Kendall Dr.

Miami, FL 33176

Email: GuilhermeR@baptisthealth.net

FUNDING: Regeneron Pharmaceuticals, Inc., and Sanofi Acknowledgement: The authors would like to thank the patients, their families, all other investigators, and all investigational site members involved in this study. The study was funded by Regeneron Pharmaceuticals, Inc. and Sanofi. Medical writing support and typesetting was provided by Jenna Lee of Prime, Knutsford, UK, funded by Regeneron Pharmaceuticals, Inc. and Sanofi.

MEDICAL DERMATOLOGY

ABSTRACT 27

Efficacy and Safety of Low-Dose Oral Minoxidil in Alopecia: A Retrospective Analysis of 18 Patients

Imhof, Reese, MD[1]; Villalpando, Beija, BS[2]; and Torgerson, Rochelle, MD, PhD[3]

[1]Mayo Clinic Department of Internal Medicine, Rochester, MN
[2]Mayo Clinic Alix School of Medicine, Rochester, MN
[3]Mayo Clinic Department of Dermatology, Rochester, MN

CORRESPONDING AUTHOR: Reese L. Imhof, MD, Mayo Clinic, 200 First St. SW, Rochester, MN, 55905; Email: imhof.reese@mayo.edu

BACKGROUND: Alopecia remains a therapeutic challenge. While topical minoxidil is an effective alopecia treatment, many patients have adherence difficulty due to twice daily application, undesirable hair texture changes, scalp irritation, and long-term use as benefits regress if treatment is discontinued (Randolph M, et al. JAAD 2021). Recently, low dose oral minoxidil (LDOM) was reported as an alternative treatment for healthy patients with poor response to topical minoxidil formulation (Randolph and Tosti, JAAD 2021). While androgenetic alopecia has been the most reported condition to utilize LDOM, other hair loss conditions have also demonstrated treatment benefit (Randolph M, et al. *JAAD* 2021).

LDOM doses range from 0.25-5 mg/d with increasing doses associated with higher rates of hypertrichosis, while mild hypotension, lightheadedness, fluid retention, and ECG changes were less commonly reported (Randolph M, et al. *JAAD* 2021). Prior studies have evaluated LDOM efficacy in patients receiving multiple hair loss treatments at once. Our study aims to evaluate LDOM efficacy as a standalone treatment for a variety of hair loss conditions.

METHODS: Retrospective chart review of patients who were seen in the Dermatology Department at Mayo Clinic in Rochester, MN between 08/15/2016-08/15/2021 and prescribed LDOM (2.5 mg or less) for treatment of hair loss/alopecia. Patients were excluded if they did not consent to research, were under 18 years of age, or were receiving other treatment(s) for alopecia.

RESULTS: A total of 18 patients met inclusion criteria with a mean age of 50.4 years (range, 22-78). The sample included 12 females (66.7%) and 6 males (33.3%). Hair loss diagnoses included androgenetic alopecia (14, 77.8%), chronic telogen effluvium (2, 11.1%), and alopecia areata (2, 11.1%). Most patients (13, 72.2%) had previously tried topical minoxidil however discontinued due to side effects or adherence difficulty. The most common LDOM strength prescribed was 2.5 mg daily (12, 66.7%), followed by 1.25 mg daily (3, 16.7%) and 0.625 mg daily (3, 16.7%). Mean duration of treatment was 18.9 months (range, 3-53). Increased scalp hair growth was noted in 12 (66.7%) patients. Three patients (16.7%) reported adverse effects which included facial/body hypertrichosis (2, 11.1%) and lightheadedness/dizziness (1, 5.6%). No severe cardiopulmonary adverse events were noted. One patient who was prescribed 2.5 mg permanently discontinued due to unwanted facial/body hypertrichosis. The other patient who experienced unwanted hair growth did not discontinue as she reported this was mild and manageable. The patient who experienced lightheadedness/dizziness decreased from 1.25 mg to 0.625 mg and her symptoms resolved, so she continued the 0.625 mg strength. There were no reports of fluid retention, weight gain, or pedal edema.

CONCLUSION: LDOM was an effective, well-tolerated treatment, particularly for patients who had difficulty with topical formulations.

DISCLOSURES: None

ABSTRACT 28

Assessment of Measurement Properties of the Facial and Total Vitiligo Area Scoring Index Instruments in the Topical Ruxolitinib Evaluation in Vitiligo (TRuEV) Phase 3 Studies

Kristen Bibeau, PhD, MSPH,[1] Kathleen Butler, MD,[1] Kang Sun, PhD,1 Konstantina Skaltsa, PhD,[2] Iltefat H. Hamzavi, MD[3]

[1]Incyte Corporation, Wilmington, DE, USA; [2]IQVIA Consulting Services, Barcelona, Spain; [3]Henry Ford Medical Center, Detroit, MI, USA

Corresponding author information:
Kristen Bibeau, PhD, MSPH Incyte Corporation 1801 Augustine Cut-Off Wilmington, DE 19803 Phone: 302-274-4685 Email: KBibeau@incyte.com

BACKGROUND: Vitiligo is a chronic autoimmune disease resulting in skin depigmentation.

OBJECTIVES: This analysis evaluated the psychometric properties of the facial and total Vitiligo Area Scoring Index (FVASI and T-VASI, respectively) using data from two phase 3, double-blind, randomized, vehicle-controlled studies of ruxolitinib cream (TRuE-V1 [NCT04052425]; TRuE-V2 [NCT04057573]).

METHODS: Patients ≥12 years old with nonsegmental vitiligo with depigmented areas ≤10% total body surface area (BSA) including ≥0.5% BSA on the face, ≥3% BSA on nonfacial areas, ≥0.5 on F-VASI, and ≥3 on T-VASI were enrolled in TRuE-V1 and TRuE-V2. Data collected in these studies using the facial and total Patient Global Impression of Change–Vitiligo (PaGIC-V) and Physician's Global Vitiligo Assessment (PhGVA) instruments were used to assess F-VASI (range, 0–3) and T-VASI (range, 0–100) for reliability, validity, sensitivity to change, and clinically meaningful change. Transcripts of exit interviews performed at Week 24 were examined, and patients were classified as reporting clinically meaningful improvement

or not to further support anchor-based determination of clinically meaningful change.

RESULTS: The analysis included 652 patients; 36 completed an exit interview. Median F-VASI and T-VASI scores were 0.70 and 6.76, respectively, at baseline and decreased to 0.48 and 4.80 at Week 24, indicating reduced vitiligo lesions with ruxolitinib cream application. Among stable patients (ie, no change from baseline to Week 24) per PaGIC-V, reliability was moderate to good for F-VASI (intraclass correlation coefficient [ICC], 0.891) and TVASI (ICC, 0.768). Among stable patients per PhGVA, reliability was also moderate to good for F-VASI (ICC, 0.739) and T-VASI (ICC, 0.686). F-VASI and T-VASI differentiated well among most PhGVA categories (ie, mild, moderate, severe) at baseline, thus demonstrating known-group validity. As more patients achieved clear/almost clear per PhGVA with ruxolitinib cream treatment at Week 24, F-VASI and T-VASI differentiated well between clear/almost clear and mild disease. Changes in both VASI instruments correlated with PaGIC-V scores at Week 24 (Spearman correlation: F-VASI, r=0.610; T-VASI, r=0.512) and changes in PhGVA scores from baseline to Week 24 (F-VASI, r=0.501; T-VASI, r=0.344). Using PaGIC-V and PhGVA as anchors to determine clinically meaningful change indicated improvement threshold ranges of 0.38–0.60 for FVASI and 1.69–3.88 for TVASI; these thresholds were similar to those from patient exit interviews (0.51 and 2.40, respectively).

CONCLUSIONS: These results indicate that F-VASI and T-VASI instruments are reliable, valid, and responsive to change, with defined clinically meaningful change from baseline in adolescents and adults with nonsegmental vitiligo with depigmented areas ≤10% total BSA (facial and nonfacial) including ≥0.5% facial BSA and ≥3% nonfacial BSA. Thus, these scales are fit-for-purpose to evaluate facial and total vitiligo.

DISCLOSURES: Kristen Bibeau, Kathleen Butler, and Kang Sun are employees and shareholders of Incyte Corporation. Konstantina Skaltsa is an employee of IQVIA contracted by Incyte Corporation to perform the psychometric analysis reported in this abstract. Iltefat H. Hamzavi has served as an advisory board member for AbbVie; a consultant for Boehringer Ingelheim, Galderma Laboratories LP, Incyte Corporation, Pfizer, and UCB; a principal investigator for Avita, Bayer, Estée Lauder, Ferndale Laboratories, Incyte Corporation, Lenicura, L'Oréal, Pfizer, and Unigen; a subinvestigator for Arcutis; president of the HS Foundation; and board member of the Global Vitiligo Foundation.

ABSTRACT 29

Lebrikizumab Allows (Interleukin) IL-13 Membrane Binding and Subsequent Internalization Through IL-13 Receptor Alpha 2 (Ra2) [IL-13 Decoy Receptor]

Isabella Wulur[1], MS, wulur_isabella_h@lilly.com
Robert D. Van Horn[2], B.S., benschop_robert@lilly.com
Aya Ryuzoji[3], MS, ryuzoji_aya_felicia@lilly.com
Montanea Daniels[1], BA, daniels_montanea_rashawn@lilly.com
Angela Okragly[1], MS, okragly_angela@lilly.com
Chetan Patel[3], PhD, patel_chetan_cp@lilly.com
Robert Benschop[1], PhD, benschop_robert@lilly.com

[1]Immunology Research, Eli Lilly and Company, Indianapolis IN, USA; [2]Flow Cytometry-Imaging Core Lab, Research and Development Technology Hub, Eli Lilly and Company, Indianapolis, IN, USA; [3]BioTechnology Discovery Research, Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

BACKGROUND: Lebrikizumab is a novel, monoclonal antibody that selectively targets interleukin (IL)13 and prevents formation of the IL13 receptor alpha 1 (Rα1)/IL4 receptor alpha (Rα) heterodimer receptor signaling complex. A previous crystal structure report showed that lebrikizumab does not interfere with IL13/IL13 receptor alpha 2 (Ra2) binding. In contrast, other IL13 antibodies tralokinumab and cendakimab had been reported to inhibit IL13 binding to both IL13Ra1 and IL13Ra2.

OBJECTIVE: To investigate whether lebrikizumab binding to IL13 interfered with IL13 binding to IL13Ra2 and the subsequent internalization.

METHODS: Competitive binding of anti-IL-13 mAbs to recombinant glycosylated human IL-13 were performed. Cendakimab and tralokinumab were immobilized on separate flow cells of a CM4 chip. Sequential injections of human IL-13 (100 nM) and either cendakimab, lebrikizumab, tralokinumab, or control IgG (5 µg/mL) were made to assess binding. STAT6 reporter assay was performed in human HEK293 cells (transfected with STAT6 reporter construct, Invivogen, San Diego, CA) incubated with a titration of human IL-13, human IL-13-AF568, human IL-4, and human IL-4-AF568 at 37°C at 5% CO2. STAT6 reporter activation measured after overnight incubation using QUANTI-Blue reagent (Invivogen). Confocal microscopy live cell imaging was performed in human A375 skin melanoma cells cultured on CellCarrier-96 Ultra microplates (Perkin Elmer, Waltham, USA) or chambered coverglass (ThermoFisher Scientific, Waltham, USA).

RESULTS: Through competitive binding experiments using surface plasmon resonance, we confirmed that lebrikizumab can bind to the tralokinumab/IL13 and cendakimab/IL13 complexes. These data showed that lebrikizumab binds to IL13 at a different epitope. Next, we confirmed that A375 cells only express IL13Ra2, but not IL13Ra1, making these cells an appropriate model system to examine the IL13/IL13Ra2 interaction in the presence

of lebrikizumab. Using live-cell confocal imaging, we observed that IL13 can bind IL13Ra2 and is internalized into the cells. Importantly, we also observed binding and internalization of the IL13/lebrikizumab complex, while IL13/tralokinumab and IL13/cendakimab complexes do not bind to the receptor and get into the cells. The internalized IL13/lebrikizumab complex colocalized with a lysosome marker, therefore indicating that it is likely to be degraded in lysosome.

CONCLUSIONS: Lebrikizumab allows IL13 to bind and internalize through the IL13Ra2. This mode of action differentiates it from tralokinumab and cendakimab, since lebrikizumab allows natural endogenous regulation of IL13 levels through IL13Ra2 (IL-13 decoy receptor).

DISCLOSURE: Study was sponsored by Dermira, a wholly-owned subsidiary of Eli Lilly and Company. Abstract previously presented at Inflammatory Skin Disease Summit (ISDS), 2021

ABSTRACT 30

Comparison of the Affinity and In Vitro Activity of Lebrikizumab, Tralokinumab, and Cendakimab

Angela Okragly[1], MS, okragly_angela@lilly.com
Aya Ryuzoji[2], MS, ryuzoji_aya_felicia@lilly.com
Montanea Daniels[1], BA, daniels_montanea_rashawn@lilly.com
Chetan Patel[2], PhD, patel_chetan_cp@lilly.com
Robert Benschop[1], PhD, benschop_robert@lilly.com

[1]Immunology Research and [2]BioTechnology Discovery Research, Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN 46285

BACKGROUND: Interleukin 13 (IL-13) is the primary upregulated cytokine in atopic dermatitis skin biopsy samples and is a central pathogenic mediator driving multiple features of atopic dermatitis pathophysiology. Lebrikizumab is a novel, monoclonal antibody that selectively targets IL-13 and prevents formation of the IL-13 receptor alpha 1 (IL-13Rα1)/IL-4 receptor alpha (IL-4Rα) heterodimer receptor-signaling complex. Tralokinumab and cendakimab are other antibodies to IL-13 that inhibit signaling by preventing IL-13 from binding to both IL-13Rα1 and IL-13Rα2.

OBJECTIVE: We undertook studies to compare the in vitro binding affinities and functional activities of lebrikizumab, tralokinumab, and cendakimab.

Methods: The binding kinetics and affinity were studied using surface plasmon resonance. Antibodies were captured on the surface of a CM4 chip with immobilized Protein A followed by the injection of different concentrations of IL-13 to assess the binding kinetics on a Biacore T200 (Cytiva, Marlborough, MA) at 37°C. IL-13 reagents were expressed in HEK293 and purified by standard methods. STAT6 reporter assay was performed in human HEK293 cells (transfected with STAT6 reporter construct, Invivogen, San Diego, CA) were incubated with compounds and 3 ng/mL glycosylated human IL-13 at 37°C at 5% CO2. STAT6-reporter activation was measured after overnight incubation using QuantiBlue reagent (Invivogen). Primary cell assays were performed in primary human dermal and lung fibroblasts incubated with compounds and 200 ng/mL glycosylated human IL-13 at 37°C with 5% CO2. After 48-hour incubation, cell culture supernatants were collected and periostin secretion was measured by ELISA (R&D Systems Inc., Minneapolis, MN).

RESULTS: The binding affinity of lebrikizumab to aglycosylated human IL-13 was <5.9 pM (n=1) at 37°C, which is similar to previously published values. Lebrikizumab binds the more physiological relevant glycosylated form of human IL-13 with a binding affinity of 187±7.9 pM (n=3, SD) at 37°C. In comparison, the binding affinity to glycosylated IL-13 was 1804±154 pM for tralokinumab and 1132±67 pM for cendakimab. The IC50 of lebrikizumab was 13.3±1.0 pM (n=3, SD) while the IC50 was 97±19.8 pM for tralokinumab and 37±19.5 pM for cendakimab, demonstrating that lebrikizumab was significantly more potent in preventing IL13Rα1/IL-4Rα signaling. Similar potency differences were observed in primary fibroblast assays. Our data show that, across these monoclonal antibodies, lebrikizumab has the highest affinity and in vitro potency, followed by cendakimab, and then tralokinumab.

CONCLUSION: Overall, lebrikizumab binds human IL-13 with high affinity and neutralizes its functional activity with high potency, providing insight to the clinical efficacy seen by lebrikizumab in Phases 2b and 3 atopic dermatitis studies.

DISCLOSURES: This study was funded by Dermira, a wholly-owned subsidiary of Eli Lilly and Company. The study was previously presented at Inflammatory Skin Disease Summit - 4th, 2021.

ABSTRACT 31

Dermatophytoma Treatment: A Systematic Review of the Literature

Shari R. Lipner, MD, PhD[1]; Tracey C. Vlahovic, DPM[2]; Boni Elewski, MD[3]; Mahmoud Ghannoum, PhD[4]; Warren S. Joseph, DPM[5]; Nicole Rawnsley, PharmD[6]

[1]Department of Dermatology, Weill Cornell Medicine, New York, NY; [2]Temple University School of Podiatric Medicine, Philadelphia, PA; [3]University of Alabama at Birmingham School of Medicine, Birmingham, AL; [4]Case Western Reserve University and University Hospitals Cleveland Medical Center, Cleveland, OH; [5]Arizona College of Podiatric Medicine, Midwestern University, Glendale, AZ; [6]Ortho Dermatologics, Bridgewater, NJ*

*Ortho Dermatologics is a division of Bausch Health US, LLC

BACKGROUND: Dermatophytomas are a form of onychomycosis presenting as dense yellow/white streaks/patches in the subungual space with fungal masses encased in biofilm (Roberts & Evans. Br J Dermatol 1998;

Burkhart et al. *J Am Acad Dermatol* 2002). Historically, dermatophytomas have been considered hard-to-treat, and treatment response data are limited as these patients are frequently excluded from onychomycosis clinical trials (Roberts & Evans. Br J Dermatol 1998; Burkhart et al. JAAD 2002; Sigurgeirsson. J Eur Acad Dermatol Venereol 2010; Wang et al. 2019 Skin Appendage Disord). The objective of this systematic review was to assess efficacy of oral/topical drugs for dermatophytoma treatment.

METHODS: Pubmed and Embase were searched for keywords "dermatophytoma" or "longitudinal spike" in December 2021. Included studies comprised English-language publications, with ≥5 participants with dermatophytoma, and use of an oral or topical drug (US-approved for onychomycosis) without surgical removal.

RESULTS: Of 44 unique publications, 6 were included (4 post hoc/retrospective, 2 open label): 3 topical efinaconazole 10% (N=106 with dermatophytoma; 2 studies: 48-72 weeks treatment; 1 study: 59 weeks mean treatment; Wang et al. 2019 Skin Appendage Disord; Watanabe et al. 2021 *J Dermatol*; Shimoyama et al. 2019 Med Mycol J), 1 topical tavaborole 5% (N=39; 24-52 weeks; Aly et al. 2018 *J Drug Dermatol*), and 2 oral terbinafine 150mg/250mg (N=25; 12 weeks treatment, follow-up at weeks 24 or 48; Sommer et al. 2003 *Clin Exp Dermatol*; Escalante et al. 2013 Dermatologia Kliniczna). Efficacy outcome definitions, when provided, varied across studies. With efinaconazole, complete cure rates (three definitions: 0% target nail clinical involvement with negative potassium hydroxide test [KOH]; completely normal nail or <10% target nail involvement with negative KOH/microscopy; not defined) ranged from 41.5%-65%; negative KOH was 72.0% at 72 weeks (1 study). With tavaborole, resolution (no dermatophytoma clinical features) was 28.2% at 52 weeks. With terbinafine, clinical cure rates (various definitions) were 42% at 24 weeks and 45% at 48 weeks; mycologic cure (negative culture and KOH) was 67% at 24 weeks.

CONCLUSION: In this systematic review of dermatophytoma treatments, topical efinaconazole exhibited clinical cure rates of up to 65%, higher than topical tavaborole (28.2%) or oral terbinafine (up to 45%), though endpoints differed across studies and there were no head-to-head comparisons. While dermatophytoma are associated with severe onychomycosis, results demonstrate successful treatment is possible.

FUNDING: Ortho Dermatologics

ABSTRACT 32

Assessing Participants' Experiences With Vitiligo From Qualitative Interviews

Pandya, MD,[1,2] Theresa Amoloja, MPH,[3] Kristen Bibeau, PhD, MSPH,[3] Dana DiBenedetti, PhD,[4] Katherine Kosa, MS,[4] Kathleen Butler, MD,[3] Deanna Kornacki, PhD,[3] Khaled Ezzedine, MD, PhD[5]

[1]Palo Alto Foundation Medical Group, Sunnyvale, CA, USA; [2]Department of Dermatology, University of Texas Southwestern Medical Center, Dallas, TX, USA; [3]Incyte Corporation, Wilmington, DE, USA; [4]RTI Health Solutions, Patient-Centered Outcomes Assessment Group, Research Triangle Park, NC, USA; [5]Henri Mondor University Hospital and Université Paris-Est Créteil Val de Marne, Paris, France

Corresponding author information: Kristen Bibeau, PhD, MSPH,
Incyte Corporation
1801 Augustine Cut-Off Wilmington, DE 19803
Phone: 302-274-4685
Email: KBibeau@incyte.com

BACKGROUND: Vitiligo is a chronic autoimmune disease leading to skin depigmentation.

OBJECTIVES: This analysis aimed to evaluate facial and total body vitiligo burden and establish treatment goals using data from (1) semi-structured qualitative exit interviews (conducted by IQVIA) of adolescents and adults with vitiligo from two phase 3, double-blind, randomized, vehicle-controlled studies of twice-daily 1.5% ruxolitinib cream (TRuE-V1 [NCT04052425] and TRuE-V2 [NCT04057573]; Study 1) and (2) semi-structured qualitative interviews with adolescents and adults with facial vitiligo identified by a recruiting firm via their proprietary database, support groups, and social media advertising (Study 2).

METHODS: In Study 1, meaningful change was assessed as a function of the facial and total Vitiligo Area Scoring Index (F-VASI and TVASI, respectively) and Vitiligo Noticeability Scale (VNS) at baseline to Week 24. Study 2 participants were interviewed to explore their experiences with facial vitiligo and the smallest amount of repigmentation considered meaningful. Transcripts were analyzed using text-based and standard qualitative approaches.

RESULTS: In Study 1, 36 of 652 participants completed exit interviews (mean [range] age, 38.2 [12–80] years); in Study 2, 23 participants were interviewed (mean [range] age, 42.4 [15–66] years). Study 1 participants described vitiligo (facial/total body) as having emotional, social, and physical impacts, with highest burden in social inhibition (66%/61%) and reduced selfesteem/confidence (63%/56%). Most (83%) indicated that facial improvement was equally (36%) or more (47%) important than total body improvement. Meaningful change at Week 24 in Study 1 was ≥50% F-VASI reduction or ≥25% T-VASI reduction; 83% of participants reported 50%–74% F-VASI or 25%–49% T-VASI reductions as meaningful. Facial VNS score ≥3 (slightly less noticeable to no longer noticeable) at Week 24 was the threshold of facial and total body

improvement participants considered clinically meaningful. Most Study 2 participants (83%) reported that the noticeability of their facial vitiligo affected their behavior. Nearly half (44%) reported that vitiligo affects them emotionally and mentally. Some participants (39%) reported effects on social life, and 22% reported they wear skin protection on affected areas. Prescription topicals (52%) and light therapy (48%) were the most commonly used treatments. At the time of the interview, 74% of participants were not receiving treatment. Overall, 57% reported ≥50% facial repigmentation to be the smallest meaningful improvement to them.

CONCLUSIONS: Results from these qualitative interviews indicate that facial and total body vitiligo affects participants emotionally, socially, and physically, causing them to alter their behavior in several ways. Participants reported that improvements in both face and total body were important, with ≥50% facial and ≥25% total body repigmentation considered to be clinically meaningful.

DISCLOSURES: Amit G. Pandya has served as an investigator for Aclaris Therapeutics, Immune Tolerance Network, Incyte Corporation, and Pfizer; a consultant for AbbVie, Arcutis, Avita Medical, Chromaderm, Immune Tolerance Network, Incyte Corporation, Pfizer, TWi, Viela Bio, and Villaris; and holds stock options for Tara Medical and Zerigo Health. Theresa Amoloja, Kristen Bibeau, Kathleen Butler, and Deanna Kornacki are employees and shareholders of Incyte Corporation. Dana DiBenedetti and Katherine Kosa are employees of RTI Health Solutions, which was contracted by Incyte Corporation to conduct Study 2. Khaled Ezzedine is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio.

ABSTRACT 33

Exploring the Natural and Treatment History of Vitiligo: Findings From the Global VALIANT Study

Kristen Bibeau, PhD, MSPH,[1] Davinder Parsad, MD,[2] John E. Harris, MD, PhD,[3] Yan Valle, MSc, MBA,[4] Mukta Tulpule, MBBS,[5] Gaone Tlhong Matewa, BBA,[6] Christine LaFiura, BA,[7] Anouk Lindley, MBA,[1] Khaled Ezzedine, MD, PhD[8]

[1]Incyte Corporation, Wilmington, DE, USA; [2]Post Graduate Institute of Medical Education and Research, Chandigarh, India; [3]University of Massachusetts Medical School, Worcester, MA, USA; [4]Vitiligo Research Foundation, New York, NY, USA; [5]Shweta Association, Pune, India; [6]Beyond Vitiligo, Johannesburg, South Africa; [7]Envision Health Partners LLC, Riverside, CT, USA; [8]Henri Mondor University Hospital and Université Paris-Est Créteil Val de Marne, Paris, France

Corresponding author information:
Kristen Bibeau, PhD, MSPH
Incyte Corporation
1801 Augustine Cut-Off
Wilmington, DE 19803
Phone: 302-274-4685
Email: KBibeau@incyte.com

BACKGROUND: Vitiligo is a chronic autoimmune disease of the skin, for which there is a need to better understand patient experiences based on disease characteristics.

OBJECTIVES: The population-based Vitiligo and Life Impact Among International Communities (VALIANT) study explored the natural history and patient journey with vitiligo from the patient perspective.

METHODS: Patients (≥18 years) self-reporting a vitiligo diagnosis were recruited online in 17 countries and completed questions regarding their clinical characteristics and vitiligo management history.

RESULTS: Among 3541 patients, 54.6% were male; mean (SD) disease duration was 11.7 (12.6) years. Nearly half (45.2%) of patients had >5% affected body surface area (BSA), as measured by the Self Assessment Vitiligo Extent Score. These patients were significantly ($P<0.05$) younger at first appearance of lesions (mean [SD], 27.3 [12.9] years) than those with 1%–5% (29.3 [12.6] years) or <1% (31.8 [14.4] years) affected BSA. Family history of vitiligo (57.1%) was more common among patients with >5% affected BSA (71.2%), darker skin types (69.0%), and facial involvement (64.3%). Patients had used a mean (SD) of 5.9 (4.9) treatments to manage their vitiligo, with significantly more treatments used by patients with >5% affected BSA (7.2 [5.3]), facial involvement (6.7 [5.1]), and darker skin types (6.5 [5.1]).

CONCLUSIONS: Overall, these findings provide a new perspective on the diagnosis and treatment journey for patients with vitiligo globally. Patients with higher affected BSA often had earlier disease onset, family history of vitiligo, and used a greater number of treatments than other patients.

DISCLOSURES: KB and AL are employees and shareholders of Incyte Corporation.

DP has served as an expert or primary investigator for Incyte Corporation, Pfizer, and Sun Pharmaceuticals. JEH has served as a consultant for AbbVie, Aclaris Therapeutics, BiologicsMD, EMD Serono, Genzyme/Sanofi, Janssen, Pfizer, Rheos Medicines, Sun Pharmaceuticals, TeVido BioDevices, The Expert Institute, 3rd Rock Ventures, and Villaris Therapeutics; has served as an investigator for Aclaris Therapeutics, Celgene, Dermira, EMD Serono, Genzyme/Sanofi, Incyte Corporation, LEO Pharma, Pfizer, Rheos Medicines, Stiefel/GlaxoSmithKline, Sun Pharmaceuticals, TeVido BioDevices, and Villaris Therapeutics; holds equity in Aldena Therapeutics, NIRA Biosciences, Rheos Medicines, TeVido BioDevices, and Villaris Therapeutics; is a scientific founder of Aldena Therapeutics, NIRA Biosciences, and Villaris Therapeutics; and has patents pending for IL-15 blockade for treatment of vitiligo, JAK inhibition with light therapy for vitiligo, and CXCR3 antibody depletion for treatment of vitiligo.

YV is CEO of the Vitiligo Research Foundation, has served as a scientific advisor at Temprian Therapeutics and as an invited professor at Guglielmo Marconi University. MT has no conflicts of interest to disclose. GTM is founder of Beyond Vitiligo South Africa and cofounder of Beyond Vitiligo Botswana. CL is a co-owner of Envision Health Partners, who received funding for conducting this project from Incyte Corporation. KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio.

ABSTRACT 34

Mental Health and Psychosocial Burden Among Patients Living With Vitiligo: Findings From the Global VALIANT Study

Kristen Bibeau, PhD, MSPH,[1] Iltefat H. Hamzavi, MD,[2] Khaled Ezzedine, MD, PhD,[3] Nanja van Geel, MD, PhD,[4] Pearl Grimes, MD,[5] Jackie Gardner, BA,[6] Christine LaFiura, BA,[7] Anouk Lindley, MBA[1]

[1]Incyte Corporation, Wilmington, DE, USA; [2]Henry Ford Medical Center, Detroit, MI, USA; [3]Henri Mondor University Hospital and Université Paris-Est Créteil Val de Marne, Paris, France; [4]Ghent University Hospital, Ghent, Belgium; [5]Vitiligo & Pigmentation Institute of Southern California, Los Angeles, CA, USA; [6]Vitiligo Support International, Lynchburg, VA, USA; [7]Envision Health Partners LLC, Riverside, CT, USA

Corresponding author information:
Kristen Bibeau, PhD, MSPH
Incyte Corporation
1801 Augustine Cut-Off
Wilmington, DE 19803
Phone: 302-274-4685
Email: KBibeau@incyte.com

BACKGROUND: Vitiligo is a chronic autoimmune disease of the skin that is associated with high quality-of-life (QoL) burden.
OBJECTIVES: The population-based Vitiligo and Life Impact Among International Communities (VALIANT) study explored the impact and burden of vitiligo on QoL from the patient perspective.
METHODS: Adults (≥18 years) who self-reported a vitiligo diagnosis were recruited online in 17 countries to answer questions regarding their mental health, psychosocial burden, and behavior in professional/social situations.
RESULTS: Of 3541 patients, 54.6% were male and 59.2% had Fitzpatrick skin phototypes I–III (ie, fairer skin). Median (range) age was 38 (18–95) years. Mean (SD) global Vitiligo Impact Patient scale score was 27.3 (15.6), with the highest scores (ie, more burden) in India (40.2 [14.1]) and South Africa (32.7 [18.8]). Most (59.4%) patients reported often hiding their vitiligo. Clothing choices (55.2%), attending social activities (beach/pool [51.1%], parties/events [48.0%], work/school [47.4%]), shaking hands (47.0%), and being intimate (46.8%) were the most stressful daily activities for patients. More than half (58.7%) reported diagnosed mental health conditions, including anxiety and depression (28.8% and 24.5%, respectively). Scores on the Patient Health Questionnaire-9 showed that 55.0% of patients had moderate to severe depressive symptoms. Rates of such symptoms were significantly (P<0.05) higher among patients with >5% affected body surface area (72.0%), darker skin types (68.3%), and facial involvement (64.4%).
CONCLUSIONS: In summary, patients with vitiligo alter their behavior, experience high burden, and have symptoms consistent with depression, which may be undiagnosed.

DISCLOSURES: KB and AL are employees and shareholders of Incyte Corporation. IHH has served as an advisory board member for AbbVie; a consultant for Boehringer Ingelheim, Galderma Laboratories LP, Incyte Corporation, Pfizer, and UCB; a principal investigator for Avita, Bayer, Estée Lauder, Ferndale Laboratories, Incyte Corporation, Lenicura, L'Oréal, Pfizer, and Unigen; a subinvestigator for Arcutis; president of the HS Foundation; and a board member of the Global Vitiligo Foundation. KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. NvG is a consultant and/or investigator for AbbVie, Incyte Corporation, Pfizer, and Sun Pharma; and is chair of the Vitiligo Task Force for the European Academy of Dermatology and Venereology (EADV). PG has served as a consultant for Aclaris Therapeutics, Clarify Medical, DermaForce, Incyte Corporation, Proctor & Gamble, and Versicolor Technologies; and a principal investigator for Aclaris Therapeutics, Allergan/SkinMedica, Clinuvel Pharmaceuticals, Incyte Corporation, Johnson & Johnson, L'Oréal, Merz Pharma, Pfizer, Thync Global Inc., and VT Cosmetics. JG has served as a consultant for AbbVie, Avita Medical, Concert Pharmaceuticals, Incyte Corporation, Mitsubishi Tanabe Pharma Corporation, and Pfizer. CL is a coowner of Envision Health Partners, who received funding for conducting this project from Incyte Corporation.

ABSTRACT 35

Diagnosis and Management of Vitiligo From the Perspectives of Patients and Healthcare Professionals: Findings From the Global VALIANT Study

Kristen Bibeau, PhD, MSPH,[1] John E. Harris, MD, PhD,[2] Christine LaFiura, BA,[3] Khaled Ezzedine, MD, PhD,[4] Iltefat H. Hamzavi, MD[5]

[1]Incyte Corporation, Wilmington, DE, USA; [2]University of Massachusetts Medical School, Worcester, MA, USA; [3]Envision Health Partners LLC, Riverside, CT, USA; [4]Henri Mondor University Hospital and Université Paris-Est Créteil Val de Marne, Paris, France; [5]Henry Ford Medical Center, Detroit, MI, USA

Corresponding author information:
Kristen Bibeau, PhD, MSPH
Incyte Corporation
1801 Augustine Cut-Off
Wilmington, DE 19803
Phone: 302-274-4685
Email: KBibeau@incyte.com

BACKGROUND: Vitiligo is a chronic autoimmune disease of the skin, for which there is no approved repigmentation therapy.
OBJECTIVES: The population-based Vitiligo and Life Impact Among International Communities (VALIANT) study explored the diagnosis and management of vitiligo from patient and physician perspectives.
METHODS: Patients (≥18 years) who self-reported a vitiligo diagnosis and healthcare professionals (HCPs)

who treat patients with vitiligo were recruited online in 17 countries. Patients and HCPs completed questions regarding their clinical characteristics and vitiligo treatment, or diagnosis and management of patients with vitiligo, respectively.

RESULTS: Globally, 3541 patients and 1203 HCPs (1099 dermatologists, 104 primary care providers) were included. Most patients (62.3%) were diagnosed in a dermatology-focused practice; almost half of patients reported being previously misdiagnosed (44.9%). Among HCPs, 16.4% had encountered patients who were previously misdiagnosed. Top treatment goals among patients and HCPs, respectively, included reduction/cessation of spread (24.7% and 18.5%) and repigmentation of affected skin (22.5% and 37.2%). HCPs most commonly recommended prescription topical medications (91.4%); however, comparatively fewer patients reported ever using these (62.2%). Two-thirds (68.4%) of HCPs were frustrated by the lack of effective treatment options, which corresponded with 44.6% of patients having given up on finding an effective treatment. Many patients (56.7%) reported being told that their vitiligo could not be treated. Similarly, 53.9% of HCPs reported their belief that patients who never treated their vitiligo were told that there is no treatment for the disease.

CONCLUSIONS: Overall, these findings highlight the need for improved management strategies for vitiligo.

DISCLOSURES: KB is an employee and shareholder of Incyte Corporation. JEH has served as a consultant for AbbVie, Aclaris Therapeutics, BiologicsMD, EMD Serono, Genzyme/Sanofi, Janssen, Pfizer, Rheos Medicines, Sun Pharmaceuticals, TeVido BioDevices, The Expert Institute, 3rd Rock Ventures, and Villaris Therapeutics; has served as an investigator for Aclaris Therapeutics, Celgene, Dermira, EMD Serono, Genzyme/Sanofi, Incyte Corporation, LEO Pharma, Pfizer, Rheos Medicines, Stiefel/GlaxoSmithKline, Sun Pharmaceuticals, TeVido BioDevices, and Villaris Therapeutics; holds equity in Aldena Therapeutics, NIRA Biosciences, Rheos Medicines, TeVido BioDevices, and Villaris Therapeutics; is a scientific founder of Aldena Therapeutics, NIRA Biosciences, and Villaris Therapeutics; and has patents pending for IL-15 blockade for treatment of vitiligo, JAK inhibition with light therapy for vitiligo, and CXCR3 antibody depletion for treatment of vitiligo. CL is a co-owner of Envision Health Partners, who received funding for conducting this project from Incyte Corporation. KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. IHH has served as an advisory board member for AbbVie; a consultant for Boehringer Ingelheim, Galderma Laboratories LP, Incyte Corporation, Pfizer, and UCB; a principal investigator for Avita, Bayer, Estée Lauder, Ferndale Laboratories, Incyte Corporation, Lenicura, L'Oréal, Pfizer, and Unigen; a subinvestigator for Arcutis; president of the HS Foundation; and a board member of the Global Vitiligo Foundation.

ABSTRACT 36

The Efficacy and Safety of Roflumilast Foam 0.3% for the Treatment of Seborrheic Dermatitis Including Patient Quality of Life: Results From a Phase 2 Study

Zoe D. Draelos[1], Seth B. Forman[2], Lawrence J. Green[3], Terry M. Jones4, Steven E. Kempers[5], Charles W. Lynde[6], Matthew Zirwas[7], Robert C. Higham8, Amy Feng[8], Patrick Burnett[8], David R. Berk[8]

[1]Dermatology Consulting Services, High Point, NC, USA; [2]ForCare Clinical Research, Tampa, FL, USA; [3]George Washington University School of Medicine, Washington, DC, USA; [4]J&S Studies, Inc., College Station, TX, USA; [5]Minnesota Clinical Study Center, Fridley, MN USA; [6]Lynderm Research Inc., Markham, ON, Canada; [7]Dermatologists of the Central States, Probity Medical Research, and Ohio University, Bexley, OH, USA; [8]Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

BACKGROUND: Seborrheic dermatitis is a chronic inflammatory skin condition that may cause discomfort, itching, and reduced quality of life. No novel treatments have been developed in decades. A phase 2, 8-week trial investigated once-daily roflumilast foam 0.3%, a selective and highly potent phosphodiesterase-4 inhibitor, in patients with seborrheic dermatitis.

OBJECTIVES: Here we present the efficacy results from a Phase 2 trial of roflumilast foam 0.3% in patients with seborrheic dermatitis, with a focus on patient quality of life.

METHODS: Adult patients with seborrheic dermatitis of at least moderate Investigator Global Assessment (IGA) severity affecting ≤20% of body surface area were randomized to roflumilast foam 0.3% (n=154) or vehicle (n=72).

RESULTS: For the primary endpoint, significantly more roflumilast-treated patients (73.8%) than vehicle-treated patients (40.9%; P<0.0001) achieved an IGA score of Clear or Almost clear plus 2-grade improvement from Baseline at Week 8; significant differences occurred as early as the first post-baseline visit (Week 2, P=0.0033). Patients in the roflumilast foam 0.3% group had greater improvement in health-related quality of life (Scalpdex) scores compared to those in the vehicle group at all post-baseline assessments (P≤0.0019). At Weeks 4 and 8, roflumilast-treated patients had greater improvement in Dermatology Life Quality Index compared to vehicle-treated patients (P≤0.0380). Roflumilast also increased the percentage of patients achieving a 4-point response on the Worst Itch-Numeric Rating Scale at all post-baseline visits (evaluated in patients with baseline score ≥4; P≤0.0009). Rates of application site pain, treatment-related adverse events, and discontinuations due to adverse events were low and comparable to vehicle.

CONCLUSION: These data demonstrated improvement in quality of life in patients with seborrheic dermatitis, supporting the further investigation of once-daily roflumilast foam 0.3% as a topical therapy for patients with seborrheic dermatitis.

ABSTRACT 37

Virtual Wound Management as a New Tool for the Pandemic Era: A Case Report of Healing Complex Pressure Injuries

Li, Vincent, M.D., M.B.A.*
The Angiogenesis Foundation, Cambridge, Massachusetts, U.S.A.
Angiogenesis & Wound Healing Center, Department of Dermatology, Brigham & Women's Hospital, Boston, Massachusetts
Email Address: vli@angio.org

Mittiga, Sydney
The Angiogenesis Foundation, Cambridge, Massachusetts
Email Address: smittiga@angio.org

Schurr, Delaney King, M.S.
The Angiogenesis Foundation, Cambridge, Massachusetts
Email Address: dschurr@angio.org

Shah, Ravi
The Angiogenesis Foundation, Cambridge, Massachusetts
Email Address: rshah@angio.org

Li, William, M.D.
The Angiogenesis Foundation, Cambridge, Massachusetts
Email Address: wli@angio.org
Correspondence:

Dr Vincent Li
Angiogenesis Foundation, One Broadway, 14th Floor, Cambridge, Massachusetts, 02142
vli@angio.org
(617) 308-9693

BACKGROUND: Conventional wound management requires in-person clinical interactions, especially for complex wounds requiring advanced therapeutics. However, the COVID-19 pandemic posed a challenge to clinical care due to the postponement of non-urgent clinic appointments and public avoidance of healthcare settings. Chronic wounds and SARS-CoV-2 share co-morbid risk factors, such as diabetes, vascular disease, and obesity.

OBJECTIVE: We present the case of a 73-year-old male with a history of insulin-dependent diabetes, diabetic foot ulcers, diabetic enteropathy and neuropathy, dialysis-dependent nephropathy, and congestive heart failure. The patient presented with multiple Stage IV pressure injuries on the sacrum and buttocks, over 3-month duration, in the setting of extended ICU hospitalization for sepsis and cardiac arrest. This case reports how serious chronic wounds can be healed using advanced wound care techniques implemented by a caregiver via the virtual guidance of wound care specialists.

METHODS & RESULTS: The patient was discharged to home; however, his wounds did not respond to conventional wound care and he was also unable to find a wound care center during the pandemic surge. A multi-specialty advanced wound care protocol was created in cooperation with the family. Interventions that would normally be used at in-person clinic visits were established for the home setting and implemented by virtual monitoring and communication tools and with the assistance of a family caregiver. To promote offloading, bacterial bioburden control, perfusion, granulation, and epithelialization the following therapeutics were employed: dry flotation air cushion (ROHO), local antisepsis (hypochlorous solution, cadexomer iodine), topical growth factor therapy (rhPDGF-BB, becaplermin) (Li WW et al. *Wounds* 2003, Gilligan AM et al *Wounds* 2018), bioactive dressings (ORC-collagen) (Kloeters O, et al. *Int Wound J* 2016), topical collagenase, and oral L-arginine (Rizk M, et al. World J Surg 2004). Wound supplies were delivered by specialty pharmacies. Under remote guidance, the caregiver performed sharp debridement using a curette. Wound closure progress was tracked remotely

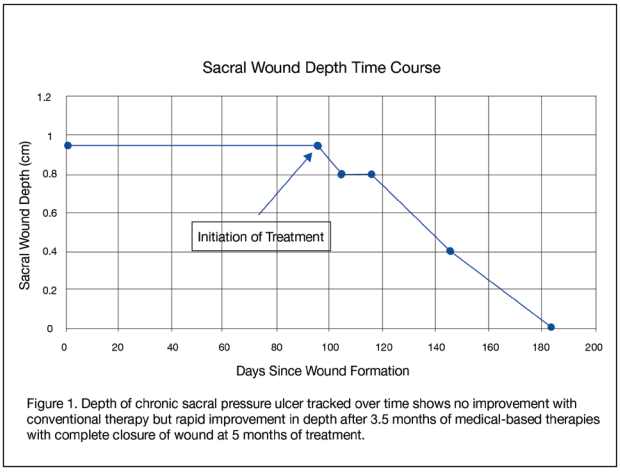


Figure 1. Depth of chronic sacral pressure ulcer tracked over time shows no improvement with conventional therapy but rapid improvement in depth after 3.5 months of medical-based therapies with complete closure of wound at 5 months of treatment.

FIGURE 1. Sacral Wound Depth Time Course

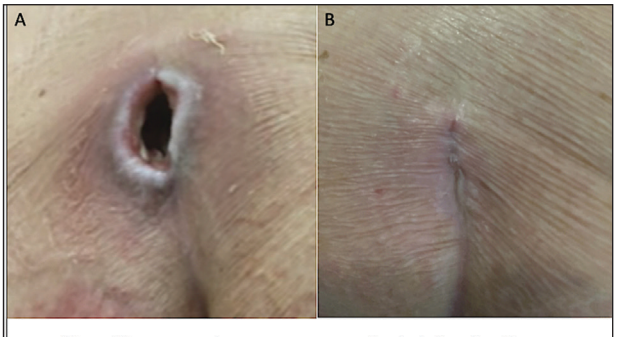


Figure 2A: Deep, chronic pressure ulcer on the sacrum, recalcitrant to conventional therapy. Figure 2B: Healed site, after 5 months of advanced medical therapies applied at home.

FIGURE 2. Complete Wound Closure All Sites Achieved Within 5 Months

through digital photography and planimetry for real-time assessment (Figure 1). Complete wound closure at all sites was achieved within 5 months (Figure 2).

CONCLUSION: This case demonstrates that successful at-home wound care can be achieved, even for complex wounds, under the guidance of a multispecialty team using telemedicine. When clinic visits are not feasible, wound specialists can provide virtual guidance to family caregivers using digital technologies. This practice innovation has application for pandemics and patients located in remote settings.

DISCLOSURE: No conflicts.

ABSTRACT 38

Diagnostic Challenges of Hypertrophic Lupus Erythematosus, A Case Report

Garcia, Natalie BS[1]; Hill, Callie MD2; Jiminez, Victoria BS[1]; Phillips, Carlton B. MD[2]

[1]HEERSINK University of Alabama at Birmingham School of Medicine; [2]University of Alabama at Birmingham, Department of Dermatology

CORRESPONDING AUTHOR: Natalie Garcia, nhvoss@uab.edu, 3347907839

BACKGROUND: Hypertrophic lupus erythematosus (HLE), a variant of cutaneous LE, often occurs in the absence of systemic symptoms and can be misdiagnosed as squamous cell carcinoma (SCC) as both appear clinically as erythematous scaling plaques in sun exposed areas and histologically show significant epithelial hyperplasia (Perniciaro C, et al. *Dermatologic* 1995). Distinguishing HLE from SCC can be difficult, thus a detailed clinical history and adjunct testing to rule out inflammatory conditions are necessary to direct treatment. CD123 immunostains are helpful in diagnosing HLE and should be considered for locally recurring presumed SCC (Ko C, et al. *Cutaneous* 2011).

CASE REPORT: A 76-year-old woman presented for evaluation of multiple well-differentiated SCCs (wdSCC) of the left lower leg. Previous treatments included curettage, multiple Mohs micrographic surgeries (MMS), and topical fluorouracil resulting in more inflammation and pain. Despite surgical clearance, she developed new biopsy-proven wdSCC near treated sites. She presented for a second opinion due to non-healing wounds and surgical fatigue. A trial of intralesional Kenalog (ILK) injections significantly decreased pain and size of plaques.

PAST MEDICAL HISTORY: Negative history of personal or familial autoimmune diseases, rash elsewhere, joint pain, and immunosuppression.

PHYSICAL EXAM: Examination showed erythematous, violaceous round plaques and smaller satellite papules with thin overlying scale coalescing on the left lower shin and erosions with yellow-brown crust on the lateral and medial aspect of the left lower leg.

LABS: Labs were negative for ANA, SSA, and SSB. Urinalysis was negative for blood and protein.

PATHOLOGY REPORT: Ten prior left lower leg outside biopsies reported wdSCC. A second-read revealed lichenoid dermatitis with pseudoepitheliomatous hyperplasia. Due to her clinical course and differential including HLE, immunostains were performed revealing CD123 positivity and increased peripheral epidermal plasmacytoid cells. These findings with improvement after ILK injections favored the diagnosis of HLE.

DISCUSSION: Given the excellent cure rate of wdSCC when treated appropriately, apparent recurrent local metastasis should prompt clinicians to rule out inflammatory processes, such as HLE or hypertrophic lichen planus. Diagnosing HLE is difficult due to a lack of systemic symptoms and clinical and microscopic similarity to other cutaneous diseases. No single criterion confidently differentiates HLE from SCC histologically, postulating the need for CD123 immunostaining in evaluating locally recurring, supposed SCCs (Perniciaro C, et al. Dermatologic 1995). CD123 is highly expressed on the surface of plasmacytoid dendrocytes, seen in HLE lesions densely at the epidermal-dermal junction, while SCC lacks this positive band staining. Recurrent lesions unresponsive to MMS and positive CD123 immunostaining are highly suggestive of HLE (Ko C, et al. Cutaneous 2011).

DISCLOSURES: The authors report no disclosures.

ABSTRACT 39

An Innovative Tool to Treat Post-Procedural Periocular Swelling

Fariha Khan MS, TOURO-COM, fkhan13@student.touro.edu,

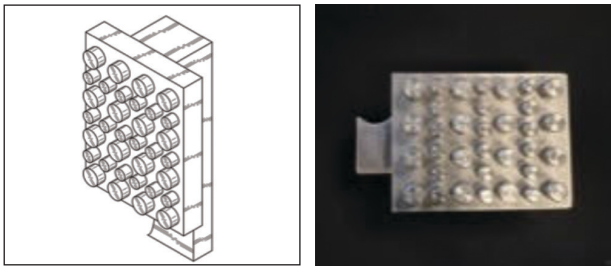
Chase Fishman, Mark Albert, MD

Fariha Kahn, TOURO-COM Middletown, NY; Chase Fishman is High School Student; Northern Highlands Regional High School; Mark Albert, MD, Manhattan Plastic Surgery

BACKGROUND: Swelling is a common complication of periocular procedures. This post-operative edema is, in part, caused by cytokine release in response to injury which increases the permeability of capillaries allowing redistribution of intravascular fluid into interstitial space (Vaughan-Shaw et al. Annals 2013). Cold compression can constrict blood vessels and disrupt inflammation causing cytokine release (Wang et al. Am J Mens Health 2022). Ice packs are commonly used to cool periorbital skin but this treatment poses a two-fold problem. Periocular skin contains the thinnest skin in the entire body (Pugliese et al., Optometric Management 2001). Commercial ice packs are often too cold for periocular use and can further damage skin in this area ("Cold Compresses" n.d.). The flat surface of an ice pack also applies pressure diffusely, diminishing potential for more focal treatment. Changing the material through which cryotherapy is applied as well as the surface shape of the applicator can assuage both of these shortcomings. An Enswell is a device made of chilled, surgical steel

$$P=\frac{F}{A}$$

P=pressure
F=force
A=area



FIGURES: Proposed Design of Modified Enswell.

used by cutmen in boxing. This device is used to treat athletes with facial hematomas via cold compression. We present a variation of the Enswell that was redesigned to avoid this blunt compression whilst preventing cold-induced injury to sensitive periorbital skin.

OBJECTIVES: To propose an innovative modification to traditional cold compression modalities that will allow more efficient treatment of postoperative periorbital swelling.

METHODS: The advance made on the traditional enswell design replaces the smooth, flat surface with one composed of a series of pegs. A prototype of the device was made with stainless steel and an undulating surface as described. The pressure distribution across each peg may be estimated using the equation:

RESULTS: Beauregard et al., conducted a study comparing the efficacy of different forms of rapid cryotherapy in changing the skin surface temperature in athletes who sustained facial hematomas through combat sports. Their study found that the Enswell did not reduce the temperature of facial skin as rapidly and to the extent of an ice pack. These very findings make the Enswell an ideal applicator for periocular cryotherapy due its predisposition to cutaneous injury. Subsequently, the addition of pegs decreases the blunt pressure applied to the anatomically loculated periorbital skin allowing for focal treatment. As the pressure applied is broken up into components, it is intermittent, and the risk of hematoma/clot disruption may be alleviated.

CONCLUSIONS: A useful medical application was discovered by reimagining a tool commonly used to treat facial hematomas and its resulting edema in combat sports. By changing the material used to reduce cutaneous temperature from frozen water to steel and the surface shape through which cryotherapy is applied, a more effective treatment of post-procedural periocular swelling has been described.

REFERENCES:

"Cold Compresses | Rand Eye Institute." n.d. Accessed March 5, 2022. https://www.randeye.com/cold-compresses/

"Optometric Management - Ophthalmic Management of the Periocular Skin Leads to Better Patient Care." n.d. Optometric Management. Accessed March 5, 2022. https://www.optometricmanagement.com/issues/2001/february-2001/ophthalmic-management-of-the-periocular-skin-leads

Vaughan-Shaw, PG, J Saunders, T Smith, AT King, and MA Stroud. 2013. "Oedema Is Associated with Clinical Outcome Following Emergency Abdominal Surgery." Annals of The Royal College of Surgeons of England 95 (6): 390–96. https://doi.org/10.1308/003588413X13629960046552

Wang, Zewen, Yongzhao Fan, Xiaoyang Kong, Patrick Viroux, Ivo J. H. Tiemessen, and Hao Wu. 2022. "The Physiological Profile Following Two Popular Cold Interventions After Activity in Hot and Humid Environment." American Journal of Men's Health 16 (1): 15579883221079150. https://doi.org/10.1177/15579883221079150

Psoriasis

ABSTRACT 40

Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 (TYK2) Inhibitor, in Moderate-to-Severe Plaque Psoriasis: 52-Week Efficacy Results From the Phase 3 POETYK PSO-1 and PSO-2 Trials

Richard B Warren, MD, PhD[1]; April W Armstrong, MD, MPH[2]; Melinda Gooderham, MD[3]; Bruce Strober, MD, PhD[4]; Diamant Thaçi, MD[5]; Shinichi Imafuku, MD[6]; Howard Sofen, MD[7]; Lynda Spelman, MD[8]; Neil J Korman, MD, PhD[9]; Min Zheng, MD[10]; Elizabeth Colston, MD, PhD[11]; John Throup, PhD[11]; Sudeep Kundu, PhD[11]; Renata M Kisa, MD[11]; Subhashis Banerjee, MD[11]; Andrew Blauvelt, MD, MBA[12]

[1]Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; [2]University of Southern California, Los Angeles, CA, USA; [3]SKiN Center for Dermatology, Queen's University and Probity Medical Research, Peterborough, ON, Canada; [4]Yale University, New Haven, and Central Connecticut Dermatology Research, Cromwell, CT, USA; [5]University of Lübeck, Lübeck, Germany; [6]Fukuoka University Hospital, Fukuoka, Japan; [7]UCLA School of Medicine, Los Angeles, CA, USA; [8]Veracity Clinical Research, Woolloongabba, QLD, Australia; [9]Case Western Reserve University and University Hospitals, Cleveland, OH, USA; [10]Second Affiliated Hospital, Zhejiang University School of Medicine, National Key Clinical Department of Dermatology, Hangzhou, China; [11]Bristol Myers Squibb, Princeton, NJ, USA; 12Oregon Medical Research Center, Portland, OR, USA

BACKGROUND: TYK2, an intracellular kinase, mediates signaling of cytokines (interleukin [IL]-23, IL-12, and type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral, allosteric inhibitor of TYK2, achieves high selectivity by uniquely binding to the regulatory rather than the active domain of the enzyme. The

16-week, placebo-controlled periods of 2 phase 3 trials (POETYK PSO-1 and PSO-2) demonstrated that deucravacitinib was significantly more efficacious vs placebo and apremilast based on the coprimary endpoints, PASI 75 and sPGA 0/1 (clear/almost clear) at week 16.

OBJECTIVE: We evaluated the efficacy of deucravacitinib over 52 weeks in both trials.

METHODS: POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) were double-blind trials that randomized patients with moderate-to-severe plaque psoriasis (body surface area [BSA] involvement ≥10%, PASI ≥12, sPGA ≥3) 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily. Placebo patients were switched to deucravacitinib at week 16 in both trials. PSO-2 included a randomized withdrawal phase in which patients originally randomized to deucravacitinib who achieved PASI 75 response at week 24 were rerandomized 1:1 to placebo or deucravacitinib, whereas those who did not achieve PASI 75 response at week 24 continued receiving deucravacitinib. Proportions of patients achieving PASI 75 and sPGA 0/1 responses were evaluated up to week 52. Secondary efficacy endpoints evaluated over this period included PASI 90, PASI 100, percentage change in PASI from baseline, sPGA 0, change from baseline in Psoriasis Symptoms and Signs Diary symptom score, and Dermatology Life Quality Index 0/1 (no impact on patient's life).

RESULTS: 666 and 1020 patients were randomized in PSO-1 and PSO-2, respectively. Patients enrolled in PSO-1 received continuous deucravacitinib treatment through week 52; PASI 75 and sPGA 0/1 responses were maintained from weeks 16 to 52 in these patients (Figure 1). Efficacy was also maintained for 52 weeks across multiple secondary efficacy endpoints in patients treated with deucravacitinib in PSO-1 (Figure 1). Patients who switched from placebo to deucravacitinib at week 16 in PSO-1 demonstrated PASI 75 and sPGA 0/1 responses at week 52 comparable to those observed in patients who received continuous deucravacitinib treatment from day 1 (Figure 2). In PSO-2, the majority of deucravacitinib-treated patients who achieved PASI 75 responses at

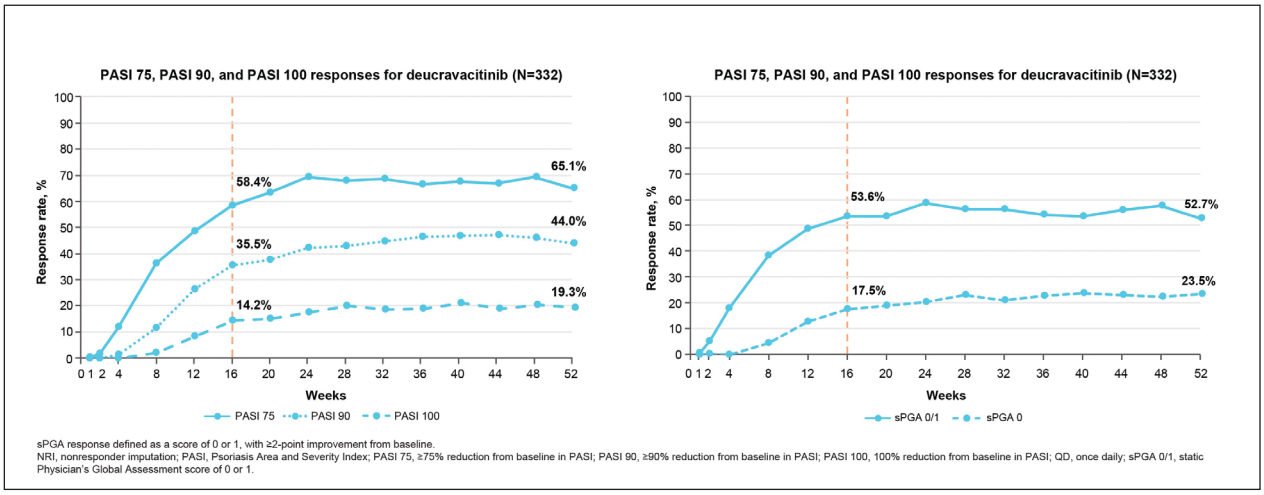


FIGURE 1. PASI and sPGA Responses with Deucravacitinib 6 mg QD Through Week 52 – POETYK PSO-1 (NRI)

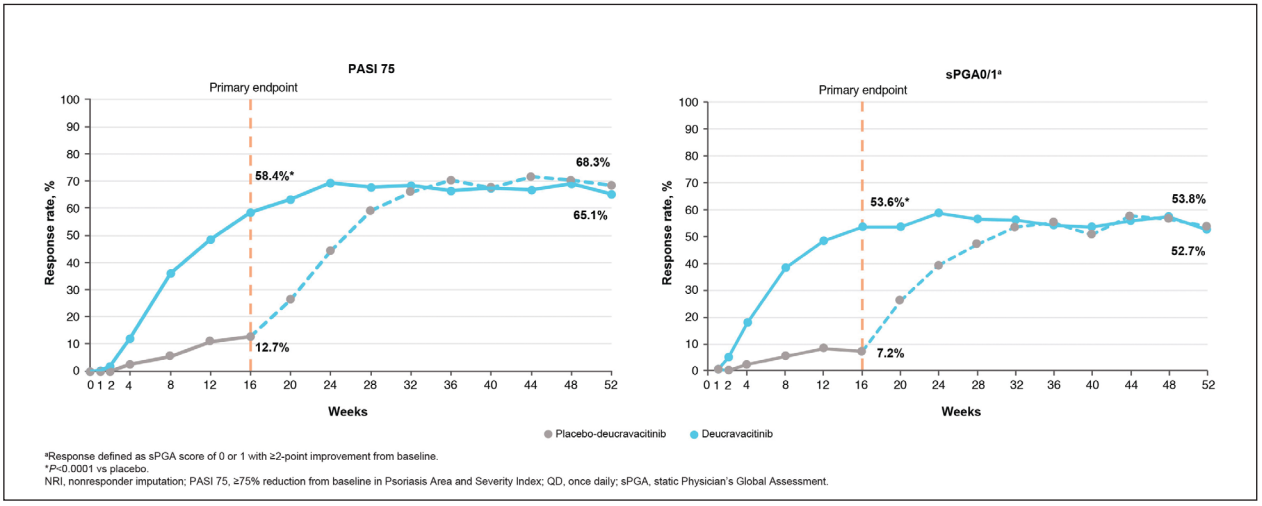


FIGURE 2. PASI 75 and sPGA 0/1 Responses Through Week 52 in Patients Randomized to Deucravacitinib and Placebo – POETYK PSO-1 (NRI)

week 24 and were rerandomized to continue treatment maintained their responses at week 52 (PASI 75, 80.4% [119/148]; sPGA 0/1, 70.3% [83/118]).

CONCLUSIONS: Results from the phase 3 POETYK PSO-1 and PSO-2 trials demonstrated that deucravacitinib was efficacious through 52 weeks in patients with moderate-to-severe plaque psoriasis. Clinical responses were maintained in patients who received continuous deucravacitinib treatment and were improved in patients who switched from placebo at week 16 to deucravacitinib treatment.

Funding: This clinical trial was sponsored by Bristol Myers Squibb

ACKNOWLEDGMENTS: Writing and editorial assistance were provided by Lisa Feder, PhD, of Peloton Advantage, LLC, an OPEN Health company, Parsippany, NJ, USA, funded by Bristol Myers Squibb

DISCLOSURES: RBW: Research grants: AbbVie, Almirall, Amgen, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, and UCB; Consulting fees: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, Sanofi, UCB, and Xenoport; Honorarium: Biogen. AWA: Grants and personal fees: AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Leo Pharma, and Novartis; Personal fees: Boehringer Ingelheim/Parexel, Celgene, Dermavant, Genentech, GlaxoSmithKline, Menlo Therapeutics, Merck, Modernizing Medicine, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Science 37, Sun Pharma, and Valeant; Grants: Dermira, Kyowa Hakko Kirin, and UCB, outside the submitted work. MG: Advisory board, principal investigator, and lecture fees: AbbVie, Arcutis, Galderma, Leo Pharma, Pfizer, and Regeneron; Advisory board and lecture fees: Actelion; Principal investigator and consulting fees: Akros Pharma and Kyowa Kirin; Advisory board, principal investigator, lecture fees, and consulting fees: Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Novartis, Sanofi Genzyme, and Valeant; Principal investigator: Arcutis, Bristol Myers Squibb, Dermavant, Dermira, GlaxoSmithKline, MedImmune, Merck, Roche Laboratories, and UCB; Principal investigator and lecture fees: Glenmark. BS: Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, Equillium, Janssen, Leo Pharma, Maruho, Meiji Seika Pharma, Mindera, Novartis, Pfizer, GlaxoSmithKline, Ortho Dermatologics, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, Ventyxbio, and vTv Therapeutics; Speaker: AbbVie, Eli Lilly, Janssen, and Sanofi Genzyme; Co-Scientific Director (consulting fee): CorEvitas' Psoriasis Registry; Investigator: AbbVie, Cara, CorEvitas' Psoriasis Registry, Dermavant, Dermira, and Novartis. DT: Advisory board, principal investigator, and lecture fees: AbbVie, Almirall, Amgen, Biogen Idec, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DS Pharma, Eli Lilly, Galapagos, Galderma, Janssen-Cilag, Leo Pharma, Novartis, Pfizer, Regeneron, Roche-Posay, Samsung, Sandoz-Hexal, Sanofi, and UCB. SI: Grants and personal fees: AbbVie, Eisai, Kyowa Kirin, Taiho, Maruho, Tanabe Mitsubishi, Leo Pharma, Janssen, Sun Pharma, Torii, and Yakuhin; Personal fees from Amgen, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly, Novartis, and UCB. HS: Clinical Investigator: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, Leo Pharma, Novartis, and Sun Pharma. LS: Consultant, paid investigator, and/or speaker: AbbVie, Amgen, Anacor, Ascend, Astellas, AstraZeneca, Blaze Bioscience, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Hexima, Janssen, Leo Pharma, Mayne, Medimmune, Merck, Merck-Serono, Novartis, Otsuka, Pfizer, Phosphagenics, Photon MD, Regeneron, Roche, Samumed, Sanofi Genzyme, SHR, Sun Pharma, Trius, UCB, and Zai Lab. NJK: Advisory board, consulting fees: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis, Principia, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB; Grant support/principal investigator: AbbVie, Amgen, Argenx, Bristol Myers Squibb, Celgene, Chemocentryx, Eli Lilly, Galderma, Kyowa Hakko Kirin, Leo Pharma, Menlo, Principia, Prothena, Rhizen, Syntimmune, Trevi, and Xbiotech; Speaker: AbbVie, Eli Lilly, Janssen, Novartis, Regeneron, and Sanofi Genzyme. MZ: Consultant (honoraria), clinical investigator, and lecture fees: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly China, Leo Pharma China, Novartis China, Pfizer, Sanofi China, and Xian-Janssen. EC, JT, SK, RMK, and SB: Employees and shareholders: Bristol Myers Squibb. AB: Scientific advisor and/or clinical study investigator: AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, Leo Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB

ABSTRACT 41

Deucravacitinib, a Selective Tyrosine Kinase 2 (TYK2) Inhibitor: Overview of Clinical Pharmacology Including ADME, Food and pH Effects, Pharmacokinetics in Special Populations, and Drug-Drug Interactions

Anjaneya Chimalakonda, PhD, Shalabh Singhal, MD, Randy Dockens, PhD, Miroslawa Nowak, MD, David Marchisin, BS, Ihab G Girgis, PhD, Subhashis Banerjee, MD, John Throup, PhD, Urvi Aras, PhD, Wenying Li, PhD, Bindu Murthy, PharmD

Bristol Myers Squibb, Princeton, NJ, USA

BACKGROUND: TYK2, an intracellular enzyme, mediates signaling of cytokines (IL-23, IL-12, and Type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral inhibitor of TYK2, achieves high selectivity by binding to the regulatory rather than the active domain of TYK2. Two pivotal phase 3 trials of deucravacitinib in plaque psoriasis (POETYK PSO-1 and PSO-2) demonstrated the superiority of deucravacitinib versus placebo and apremilast.

OBJECTIVES: To summarize key clinical pharmacologic properties of deucravacitinib, including absorption, distribution, metabolism, and excretion (ADME), food

effects, pH effects, pharmacokinetics (PK) in special populations, and drug-drug interactions (DDIs).
METHODS: The PK/ADME profile of deucravacitinib was generated by integrating in vitro and in vivo data. Exposure and ADME characteristics were analyzed in single-dose and multiple-ascending-dose studies and in a mass balance study. Dedicated studies evaluated food effects, pH effects, PK in renal- and hepatic-impaired patients, and DDIs (including medications commonly used in inflammatory diseases) on maximum plasma concentration (Cmax) and area under the curve (AUC) of deucravacitinib.
RESULTS: PK/ADME analyses demonstrated that oral deucravacitinib is rapidly absorbed and subsequently eliminated by multiple, well-balanced metabolic and elimination pathways, including renal elimination. Deucravacitinib does not meaningfully induce or inhibit common cytochrome P450 (CYP) or uridine 5′-diphosphoglucuronosyltransferase (UGT) enzymes or drug transporters. Gastric pH modulators (famotidine, rabeprazole) and food had minor effects on deucravacitinib Cmax (<30%) and AUC (<11%). Cmax (maximum change, ≤1.1-fold) and AUC (maximum change, ≤1.6-fold) values were only modestly affected in patients with mild, moderate, or severe renal impairment and in patients with mild or moderate hepatic impairment. Concomitant medications cyclosporine, fluvoxamine, ritonavir, pyrimethamine, and diflunisal had only minor effects on deucravacitinib Cmax (maximum change, <1.2-fold) and AUC (maximum change, <1.6-fold). Deucravacitinib had negligible effects on the Cmax and AUC of rosuvastatin (≤15%), oral contraceptives (≤10%), methotrexate (≤11%), and mycophenolate mofetil (≤8% based on major active species [mycophenolic acid]). Based on the extent of changes, these effects on drug exposures are not considered clinically meaningful.
CONCLUSIONS: Deucravacitinib exhibited favorable PK/ADME profiles and its exposures were not meaningfully influenced by multiple concomitant medications. Deucravacitinib did not meaningfully alter the exposure of relevant medications, including oral contraceptives and common medications used in psoriasis/psoriatic disease, suggesting that deucravacitinib can be administered regardless of food consumption, to patients with any level of renal or mild-moderate hepatic impairment, and along with relevant concomitant medications.
FUNDING: These clinical trials were sponsored by Bristol Myers Squibb.
ACKNOWLEDGMENTS: Writing and editorial assistance were provided by Lisa Feder, PhD, of Peloton Advantage, LLC, an OPEN Health company, Parsippany, NJ, USA, funded by Bristol Myers Squibb
DISCLOSURES: AC, SS, RD, MN, DM, IGG, SB, JT, UA, WL, and BM: Employees and shareholders of Bristol Myers Squibb.

ABSTRACT 42

Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 (TYK2) Inhibitor, Versus Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Efficacy Analysis by Prior Treatment in the Phase 3 POETYK PSO-1 and PSO-2 Trials

Richard B Warren, MD, PhD,[1] April W Armstrong, MD, MPH[2] Shinichi Imafuku, MD[3] Carle Paul, MD, PhD,[4] Leon Kircik, MD,[5] Subhashis Banerjee, MD,[6] Elizabeth Colston, MD, PhD,[6] Tao Wang, PhD,[6] John Throup, PhD,[6] Bruce Strober, MD, PhD[7]

[1]Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; [2]University of Southern California, Los Angeles, CA, USA; [3]Fukuoka University Hospital, Fukuoka, Japan; [4]Toulouse University and CHU, Toulouse, France; [5]Icahn School of Medicine at Mount Sinai, New York City, NY, USA; [6]Bristol Myers Squibb, Princeton, NJ, USA; [7]Yale University, New Haven, CT, and Central Connecticut Dermatology Research, Cromwell, CT, USA

BACKGROUND: Deucravacitinib, an oral, allosteric TYK2 inhibitor, achieves high selectivity by uniquely binding to the regulatory rather than the active domain of TYK2. In 2 pivotal phase 3 trials, POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751), deucravacitinib was associated with a significantly higher proportion of patients achieving ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and static Physician's Global Assessment (sPGA) score of 0/1 versus placebo and apremilast.
OBJECTIVES: To evaluate efficacy in each trial stratified by predefined subgroups of prior treatments received.
METHODS: Adults with moderate to severe plaque psoriasis were randomized 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily. Prior use of any biologic or oral systemic therapy, except apremilast, was permitted after an appropriate washout period before study day 1, and prior phototherapy was permitted up to 4 weeks before study day 1. Coprimary endpoints were PASI 75 and sPGA 0/1 at Week 16 among patients receiving deucravacitinib versus placebo. PASI 75 and sPGA 0/1 responses were assessed according to prior use of any systemic therapy (biologic or oral), biologics for psoriasis or other inflammatory diseases (including antibodies to IL-17, IL-23, and IL-12p40, and tumor necrosis factor inhibitors), and phototherapy (yes/no for all).
RESULTS: 666 and 1020 patients were randomized in PSO-1 and PSO-2, respectively. In PSO-1, 62.8% of patients received any prior systemic therapy (including biologic and oral) before enrollment, 38.9% of patients (259/666) received prior biologic therapy; 23.9% (159/666) of patients received prior oral systemic therapy and no biologic therapy, and 35.9% (239/666) received prior phototherapy. In PSO-2, 54.2% of patients received any prior systemic therapy, 32.1% (327/1020) received prior biologic therapy, 22.2% (226/1020) received prior oral systemic therapy and no biologic therapy, and 42.6%

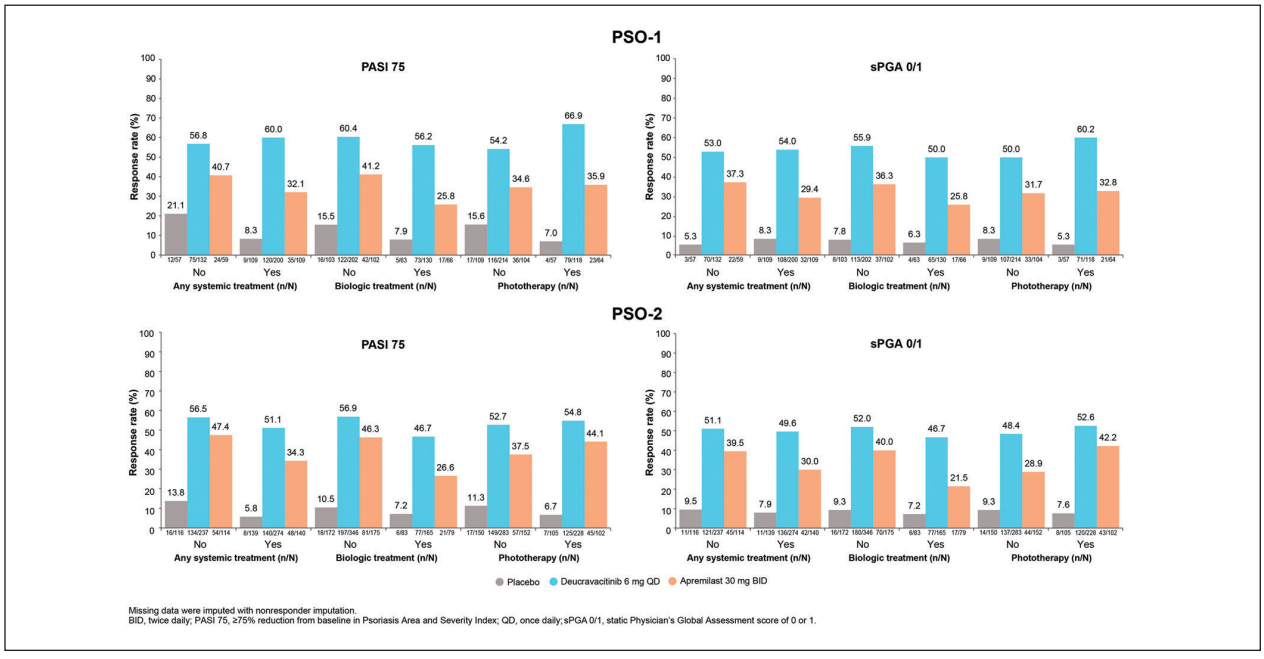


FIGURE. PSAI 75 and sPGA 0/1 by prior treatment in POETYK PSO-1 and PSO-2

(435/1020) received phototherapy. Overall in both trials, significantly more patients receiving deucravacitinib versus placebo and versus apremilast achieved PASI 75 (PSO-1: 58.7% vs 12.7% vs 35.1%, $P<0.0001$; PSO-2: 53.6% vs 9.4% vs 40.2%, $P\leq0.0003$) and sPGA 0/1 (PSO-1: 53.6% vs 7.2% vs 32.1%, $P<0.0001$; PSO-2: 50.3% vs 8.6% vs 34.3%, $P<0.0001$) responses at Week 16. Subgroup analyses of PASI 75 and sPGA 0/1 at Week 16 revealed that response rates in PSO-1 and PSO-2 were numerically higher with deucravacitinib versus placebo and apremilast regardless of prior treatment (Figure). The treatment effect for deucravacitinib versus placebo and apremilast was generally consistent with the overall treatment effect.

CONCLUSIONS: In POETYK PSO-1 and PSO-2, deucravacitinib showed superior PASI 75 and sPGA 0/1 responses versus both placebo and apremilast regardless of prior treatment with any systemic therapy (including biologic and oral), biologic treatment, or phototherapy.

FUNDING: These clinical trials were sponsored by Bristol Myers Squibb

ACKNOWLEDGMENTS: Writing and editorial assistance were provided by Lisa Feder, PhD, of Peloton Advantage, LLC, an OPEN Health company, Parsippany, NJ, USA, funded by Bristol Myers Squibb.

DISCLOSURES: RBW: Research grants: AbbVie, Almirall, Amgen, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, and UCB; consulting fees: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, Sanofi, UCB, and Xenoport; honorarium: Biogen. AWA: Grants and personal fees from AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Leo Pharma, and Novartis; personal fees from Boehringer Ingelheim/Parexel, Celgene, Dermavant, Genentech, GlaxoSmithKline, Menlo Therapeutics, Merck, Modernizing Medicine, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Science 37, Sun Pharma, and Valeant; and grants from Dermira, Kyowa Hakko Kirin, and UCB, outside the submitted work. SI: Grants and personal fees from AbbVie, Eisai, Kyowa Kirin, Taiho Yakuhin, Maruho, Tanabe Mitsubishi, Leo Pharma, Janssen, Sun Pharma, and Torii Yakuhin. Personal fees from Amgen (Celgene), Eli Lilly, Daiichi Sankyo, Novartis, Bristol Myers Squibb, and UCB. CP: Nothing to disclose. LK: Research grants: AbbVie, Allergan, Almirall, Amgen, Arcutis, Bristol Myers Squibb, Boehringer Ingelheim, Breckinridge Pharma, Celgene, Centocor, Cellceutix, Combinatrix, Connetics Corporation, Coria, Dermavant, Dermira, Dow Pharmaceutical Sciences, Dr. Reddy's Lab, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Idera, Johnson & Johnson, Leo Pharma, Maruho, Merck, Medicis Pharmaceutical Corp, Novartis AG, Promius, PharmaDerm, Pfizer, Stiefel Laboratories, Sun Pharma, UCB, Valeant Pharmaceuticals, and XenoPort; Honoraria: Abbott Laboratories, AbbVie, Allergan, Almirall, Amgen, Arcutis, Biogen Idec, Bristol Myers Squibb, Celgene, Cipher, Connetics Corporation, Dermavant, Dermira, Dr. Reddy's Lab, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Johnson & Johnson, Leo Pharma, Merck, Novartis AG, Promius, PharmaDerm, Serono (Merck Serono International SA), Stiefel Laboratories, Sun Pharma, Taro, UCB, and Valeant. SB, EC, TW, and JT: Employees and shareholders of Bristol Myers Squibb. BS: Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol Myers Squibb, Connect Biopharma, Dermavant, Equillium, Janssen, Leo Pharma, Eli Lilly, Maruho, Meiji Seika Pharma, Mindera, Novartis, Pfizer, GlaxoSmithKline, UCB Pharma, Sun Pharma, Ortho Dermatologics, Regeneron, Sanofi-Genzyme, Ventyxbio, and vTv Therapeutics; Speaker: AbbVie, Eli Lilly, Janssen, and Sanofi-Genzyme; Co-Scientific Director (consulting fee): Cor-Evitas (Corrona) Psoriasis Registry; Investigator: Dermavant, AbbVie, Corrona Psoriasis Registry, Dermira, Cara, and Novartis.

ABSTRACT 43

Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 (TYK2) Inhibitor, Compared With Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Integrated Laboratory Parameter Results From the Phase 3 POETYK PSO-1 and PSO-2 Trials

Diamant Thaçi, MD,[1] Kenneth B Gordon, MD,[2] Melinda Gooderham, MD,[3] Bruce Strober, MD, PhD,[4] Neil J Korman, MD, PhD,[5] Subhashis Banerjee, MD,[6] Elizabeth Colston, MD, PhD,[6] Jonghyeon Kim, PhD,[6] John Throup, PhD,[6] Akimichi Morita, MD, PhD[7]

[1]University of Lübeck, Lübeck, Germany; [2]Medical College of Wisconsin, Milwaukee, WI, USA; [3]Probity Medical Research, Waterloo, ON, Canada; [4]Yale University, New Haven, CT, and Central Connecticut Dermatology, Cromwell, CT, USA; [5]Case Western Reserve University and University Hospitals, Cleveland, OH, USA; [6]Bristol Myers Squibb, Princeton, NJ, USA; [7]Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan

BACKGROUND: TYK2, an intracellular kinase, mediates signaling of key cytokines (IL-23, IL-12, and Type I interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral agent, selectively inhibits TYK2 via an allosteric mechanism by uniquely binding to the regulatory domain; this mechanism is in contrast to inhibitors of JAK 1/2/3 that bind to the conserved active site in the TYK2 domain. Deucravacitinib was significantly more efficacious than placebo or apremilast and well tolerated in patients with moderate to severe plaque psoriasis in 2 phase 3 trials, POETYK PSO-1 and PSO-2.

OBJECTIVES: To compare effects of deucravacitinib versus placebo and versus apremilast on multiple laboratory parameters using integrated data from the 2 trials.

METHODS: POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) were double-blind, 52-week trials that randomized patients with moderate to severe plaque psoriasis (BSA involvement ≥10%, PASI ≥12, sPGA ≥3) 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily. Placebo patients were switched to deucravacitinib at Week 16 and apremilast patients who failed to meet trial-specific efficacy thresholds (PSO-1: PASI 50; PSO-2: PASI 75) were switched to deucravacitinib at Week 24. Changes from baseline levels of standard hematologic parameters (lymphocytes, neutrophils, platelets, and hemoglobin) and chemistry parameters, including lipids (total cholesterol, high-density lipoprotein cholesterol, and triglycerides) and creatine phosphokinase (CPK) in the blood, were evaluated. Shifts in CTCAE (version 5.0) severity grade of laboratory parameter abnormalities between baseline and Week 16 were assessed. Integrated data from PSO-1 and PSO-2 are presented.

RESULTS: A total of 666 and 1020 patients were randomized in PSO-1 and PSO-2, respectively, and were included in this analysis. Overall, no clinically meaningful changes from baseline levels were observed in any laboratory parameter over the placebo-controlled period from Weeks 0–16 (4 relevant parameters known to change with JAK 1/2/3 inhibition are shown in the Figure). There were no shifts from grade ≤2 to ≥3 in cholesterol, neutrophils, or platelets in deucravacitinib-treated patients through Week 16; shifts in CPK and triglycerides were low and similar across treatment arms (<1.8%). Overall, there were no clinically relevant changes from baseline

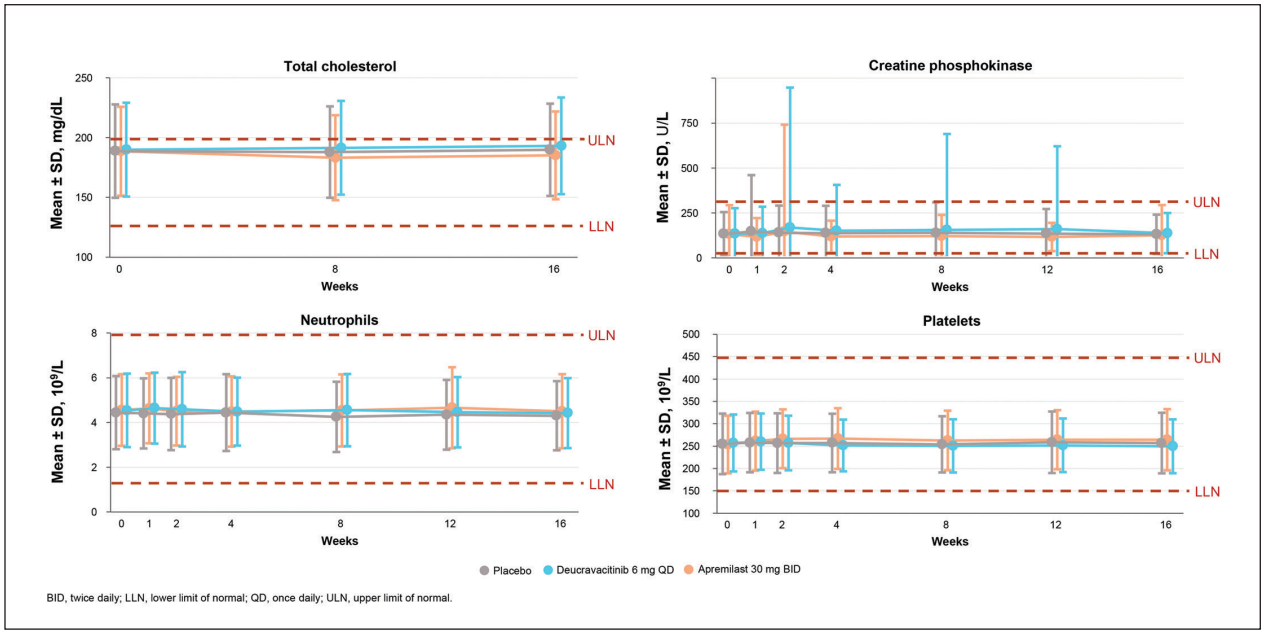


FIGURE: Selected Laboratory Parameters of Interest (Integrated), Weeks 0-16

levels and no cumulative trends observed up to Week 52. The majority of patients remained within normal range throughout the trials, and shifts of ≥2 CTCAE grades from baseline were balanced overall and infrequent for all treatment groups.

CONCLUSIONS: Deucravacitinib treatment did not result in clinically significant laboratory parameter abnormalities in 2 large phase 3 trials in psoriasis, suggesting that routine laboratory monitoring during deucravacitinib treatment may not be warranted.

FUNDING: These clinical trials were sponsored by Bristol Myers Squibb.

ACKNOWLEDGMENTS: Writing and editorial assistance were provided by Lisa Feder, PhD, of Peloton Advantage, LLC, an OPEN Health company, Parsippany, NJ, USA, funded by Bristol Myers Squibb

DISCLOSURES: DT: Advisory board, principal investigator, and lecture fees: AbbVie, Almirall, Amgen, Biogen Idec, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DS Pharma, Eli Lilly, Galapagos, Galderma, Janssen-Cilag, Leo Pharma, Novartis, Pfizer, Regeneron, Roche-Posay, Samsung, Sandoz-Hexal, Sanofi, and UCB. KBG: Grant support and consulting fees: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Novartis, and UCB; Consulting fees: Amgen, Almirall, Dermira, Leo Pharma, Pfizer, and Sun Pharma. MG: Advisory board, principal investigator, and lecture fees: AbbVie, Galderma, Leo Pharma, Pfizer, and Regeneron; Advisory board and lecture fees: Actelion; Principal investigator and consulting fees: Akros Pharma; Advisory board, principal investigator, lecture fees, and consulting fees: Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Novartis, Sanofi Genzyme, and Valeant; Principal investigator: Arcutis, Bristol Myers Squibb, Dermira, GlaxoSmithKline, MedImmune, Merck, Roche, and UCB; Principal investigator and lecture fees: Glenmark. BS: Honoraria or consultation fees: AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, Equillium, GlaxoSmithKline, Immunic Therapeutics, Janssen, Leo Pharma, Maruho, Meiji Seika Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, and Ventyxbio; Speaker: AbbVie, Janssen, Lilly, and Sanofi Genzyme; Scientific co-director (consulting fee): CorEvitas' (Corrona) Psoriasis Registry; Investigator: AbbVie, Cara, CorEvitas' (Corrona) Psoriasis Registry, Dermavant, Eli Lilly/Dermira, and Novartis. NJK: Advisory board, consulting fees: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis, Principia, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB; Grant support/Principal investigator: AbbVie, Amgen, Argenx, Bristol Myers Squibb, Celgene, Chemocentryx, Eli Lilly, Galderma, Kyowa Hakko Kirin, Leo Pharma, Menlo, Principia, Prothena, Rhizen, Syntimmune, Trevi, and Xbiotech; Speaker: AbbVie, Eli Lilly, Janssen, Novartis, Regeneron, and Sanofi Genzyme. SB, EC, JK, JT: Employees and shareholders: Bristol Myers Squibb. AM: Grant/research support, consultant, speakers bureau: AbbVie, Boehringer Ingelheim,Bristol Myers Squibb, Celgene, Eisai, Eli Lilly, Janssen, Kyowa Hakko Kirin, Leo Pharma, Maruho, Mitsubishi Tanabe, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB, and Ushio.

ABSTRACT 44

Long-term Efficacy and Safety in Participants Who Achieved Skin Clearance in an Open-Label Study of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion

Mark G. Lebwohl, MD[1]; Jerry Bagel, MD[2]; Cula N. Svidzinski, MD[1]; Abby Jacobson, MS, PA-C[3]

[1]Icahn School of Medicine at Mount Sinai, New York, NY; [2]Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ; [3]Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

BACKGROUND: Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is approved to treat plaque psoriasis in adults. In this post hoc analysis, we assessed long-term efficacy, symptom control, and safety in 44 participants who achieved skin clearance (investigator's global assessment [IGA] score of 0) at or before week 16 in an open-label study of HP/TAZ (NCT02462083).

OBJECTIVE: To evaluate the long-term efficacy and safety of HP/TAZ in participants with psoriasis who achieved IGA score of 0 in a 52-week open-label study.

METHODS: Participants in the open-label study received HP/TAZ once-daily. At week 8, participants who achieved treatment success (IGA 0 or 1) stopped treatment and were reevaluated monthly through 52 weeks; those who did not achieve treatment success continued HP/TAZ. Twenty-four continuous weeks of treatment were allowed if participants achieved ≥1-grade improvement in IGA from baseline at week 12, with monthly reevaluation. If at any point IGA ≥2 was achieved, HP/TAZ was resumed, otherwise, HP/TAZ was discontinued.

RESULTS: Among participants who stopped therapy at treatment success, percentages of participants who did not relapse or require retreatment at <29, <57, and <85 days after HP/TAZ cessation were 81.2%, 68.7%, and 59.4%, respectively. Participants with none-to-mild itch at baseline were more likely to achieve none-to-mild itch scores post-baseline (50%) compared with participants with moderate-to-severe baseline itch (13.6%). More than half of participants with both none-to-mild and moderate-to-severe baseline dryness achieved a maximum post-baseline dryness score of none-to-mild dryness (62.5% vs 50%). Of the 95.5% of participants with none-to-mild baseline burning/stinging, a majority (61.9%) maintained a maximum post-baseline burning/stinging score of none-to-mild. Adverse events were reported by 24 (57.1%) of participants, of which only 1 (2.4%) was serious. Only 2 participants discontinued HP/TAZ due to adverse events. The maximum incidence of skin atrophy occurred at week 24 (2/35; 5.7%), of striae at week 2 (3/44; 6.8%), of telangiectasias at

week 24 (2/35; 5.7%), and of folliculitis at week 8 (3/41; 7.3%).

CONCLUSIONS: Participants who achieved skin clearance with HP/TAZ maintained high rates of efficacy through 52 weeks, measured by treatment success and symptom severity scores, with no new safety concerns. These data support the use of HP/TAZ to treat psoriasis to clear skin, particularly given the low rates of adverse events leading to treatment discontinuation.

FUNDING: This study was sponsored by Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

ABSTRACT 45

Efficacy of Brodalumab vs Ustekinumab by Prior TNFα Inhibitor Exposure: Post Hoc Analysis of Two Phase 3 Psoriasis Studies

Alan Menter, MD[1]; Erin Boh, MD, PhD, FAAD[2]; George Michael Lewitt, MD[3]; Abby Jacobson, MS, PA-C4

[1]Baylor Scott & White, Dallas, TX; 2Tulane University School of Medicine, New Orleans, LA; 3Illinois Dermatology Institute, Chicago, IL; [4]Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

BACKGROUND: Brodalumab, a fully human anti–interleukin-17 receptor A monoclonal antibody, antagonizes inflammatory cytokines involved in psoriasis pathogenesis.

OBJECTIVE: This post hoc analysis of two phase 3 psoriasis studies (AMAGINE-2/-3) evaluates the efficacy of brodalumab vs ustekinumab (an anti–interleukin-12/-23 monoclonal antibody) in individuals who were rescued with brodalumab or continued ustekinumab, stratified by prior treatment with tumor necrosis factor α (TNFα) inhibitors.

METHODS: In AMAGINE-2/-3, after a 12-week induction phase, patients received maintenance treatment as follows: brodalumab-treated patients were rerandomized to brodalumab 210 mg every 2 weeks (Q2W); ustekinumab-treated patients continued to receive ustekinumab; and those receiving placebo switched to brodalumab 210 mg Q2W. At week 16, patients with inadequate response to ustekinumab (single static physician's global assessment [sPGA] of ≥3 or persistent sPGA of 2 over ≥4 weeks) were eligible for rescue with brodalumab 210 mg Q2W. Patients who responded adequately to ustekinumab at week 16 continued to receive ustekinumab; after week 16, patients on ustekinumab with an inadequate response remained on ustekinumab. Psoriasis area and severity index 75%, 90%, and 100% response rates (PASI 75, 90, and 100) are reported for patients who were rescued with 36 weeks of brodalumab 210 mg Q2W or continued ustekinumab after inadequate response, stratified by TNFα inhibitor treatment before entering the study (no prior TNFα inhibitor experience, prior TNFα inhibitor nonfailure, or prior TNFα inhibitor failure).

RESULTS: At week 52, after 36 weeks of retreatment, PASI 75, 90, and 100 response rates were 73%, 58%, and 36% for patients rescued with brodalumab (N=124) and 62%, 26%, and 5% for patients who continued ustekinumab (N=149), respectively. Among patients with no prior TNFα inhibitor experience, observed PASI 75, 90, and 100 response rates at week 52 were 89%, 71%, and 46% (brodalumab rescue) and 75%, 34%, and 8% (ustekinumab), respectively. Among those who responded to prior TNFα inhibitor treatment, PASI 75, 90, and 100 response rates were 93%, 71%, and 43% (brodalumab rescue) and 71%, 25%, and 4% (ustekinumab), respectively. Corresponding response rates for patients who failed prior TNFα inhibitor treatment were 58%, 50%, and 25% (brodalumab rescue) and 53%, 13%, and 0% (ustekinumab).

CONCLUSIONS: Patients with psoriasis who were rescued with 36 weeks of retreatment with brodalumab demonstrated higher response rates than those receiving ustekinumab, regardless of prior TNFα inhibitor treatment. Brodalumab may be a safe and effective treatment after inadequate response to previous biologics.

ABSTRACT 46

Psoriasis Area and Severity Index Component Scores in Clinical Trials of Brodalumab

Mark Lebwohl, MD[1]; Lawrence Green, MD[2]; Scott Drew, DO, FAOCD[3]; Abby Jacobson, MS, PA-C[4]

[1]Icahn School of Medicine at Mount Sinai, New York, NY; [2]George Washington University School of Medicine, Washington, DC; [3]Dermatology Associates of Mid-Ohio, Marion, OH; [4]Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

BACKGROUND: The psoriasis area and severity index (PASI) measures severity and extent of psoriasis in 4 body components (head and neck, upper extremities, trunk, and lower extremities; Feldman S, et al. *Ann Rheum Dis* 2005).

OBJECTIVE: To conduct a post hoc analysis of PASI component scores of patients with moderate-to-severe psoriasis in phase 3 clinical studies of the interleukin-17 receptor A antagonist brodalumab.

METHODS: Data were analyzed from three double-blind, placebo- or active-comparator–controlled studies (AMAGINE-1/-2/-3; Lebwohl M, et al. N Engl J Med 2015; Papp KA, et al. Br J Dermatol 2016). Pooled PASI component scores were analyzed from patients receiving brodalumab 210 mg every 2 weeks (Q2W) or placebo and from patients receiving continuous brodalumab 210 mg Q2W or ustekinumab (AMAGINE-2/-3) through 12 weeks.

RESULTS: Mean PASI component scores were similar among groups at baseline, ranging from ~2 (head and neck) to ~9 (lower extremities). In multiple imputation analyses, significantly lower mean (SE) scores were observed at week 12 with brodalumab 210 mg Q2W (N=1458) compared with placebo (N=844) for head and

neck (0.2 [0.013] vs 1.4 [0.045]; *P*<0.0001), upper extremities (0.5 [0.029] vs 3.5 [0.079]; *P*<0.0001), trunk (0.6 [0.041] vs 4.9 [0.132]; *P*<0.0001), and lower extremities (1.2 [0.064] vs 8.2 [0.170]; *P*<0.0001). In as-observed analyses, significantly lower mean (SE) scores were observed with continuous brodalumab (N=339) compared with ustekinumab (N=590) at week 12 for head and neck (0.2 [0.027] vs 0.3 [0.023]; *P*=0.0164), upper extremities (0.4 [0.057] vs 0.7 [0.046]; *P*=0.0004), trunk (0.6 [0.089] vs 1.1 [0.075]; *P*<0.0001), and lower extremities (1.3 [0.132] vs 2.2 [0.131]; *P*<0.0001).

CONCLUSIONS: Brodalumab was associated with lower PASI scores compared with placebo and ustekinumab across body components.

ABSTRACT 47

Long-Term Safety and Efficacy of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion in Patients with Clinically Meaningful Improvement in Plaque Psoriasis

Andrew Alexis, MD, MPH[1]; James Del Rosso, DO, FAOCD[2]; Tina Bhutani, MD, MAS[3]; Kim Papp, MD, PhD[4]; Abby Jacobson, MS, PA-C[5]

[1]Department of Dermatology, Weill Cornell Medical College, New York, NY; [2]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV; [3]UCSF Psoriasis and Skin Treatment Center, San Francisco, CA; [4]Probity Medical Research and K. Papp Clinical Research, Waterloo, Ontario, Canada; [5]Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

BACKGROUND: Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is approved to treat plaque psoriasis in adults. The product of investigator's global assessment and affected body surface area (IGA×BSA) is a measure of psoriasis severity; a ≥75% improvement from baseline (IGA×BSA-75) is considered a clinically meaningful improvement in skin clearance.

OBJECTIVE: This post hoc analysis of two phase 3 trials (NCT02462070 and NCT02462122) and a 52-week open-label study (NCT02462083) evaluated the efficacy and safety of HP/TAZ as measured by IGA×BSA-75 and signs/symptoms of psoriasis in participants who achieved IGA×BSA-75 at or before week 12.

METHODS: In the phase 3 trials, participants were randomized 2:1 to either HP/TAZ once daily or vehicle lotion, with a primary endpoint of treatment success at week 8 (IGA score of clear [0] or almost clear [1]) and follow-up assessment at week 12. Similarly, in the open-label study, all participants received HP/TAZ once daily for 8 weeks; those who achieved treatment success stopped treatment and were reevaluated monthly through 52 weeks, whereas those who did not achieve treatment success at week 8 continued to apply HP/TAZ. Participants were allowed 24 continuous weeks of HP/TAZ if they achieved ≥1-grade improvement in IGA from baseline at week 12, with monthly reevaluation for achievement of IGA 0/1. Subsequent decisions to continue or discontinue treatment at each monthly evaluation were repeated for 1 year. If at any point IGA ≥2 was achieved, HP/TAZ was resumed; if IGA 0/1 was achieved, HP/TAZ was discontinued.

RESULTS: In a pooled analysis of participants who achieved IGA×BSA-75 at or before week 12 from the phase 3 trials (HP/TAZ, n=140; vehicle, n=19) and open-label study (n=254), a numerically higher proportion of participants receiving HP/TAZ maintained IGA×BSA-75 vs those receiving vehicle at week 8 (82.1% vs 73.7%) and week 12 (73.1% vs 68.4%). At week 8, most participants receiving HP/TAZ or vehicle reported no itching (71.1% vs 73.7%), dryness (68.1% vs 78.9%), or burning/stinging (85.9% vs 94.7%), with similar results at week 12. In the open-label study, 63.3% of participants who achieved IGA×BSA-75 by week 12 maintained IGA×BSA-75 at week 52. Rates of skin atrophy, striae, telangiectasias, and folliculitis were low throughout the study, and absent in all participants at week 52.

CONCLUSIONS: HP/TAZ was associated with long-term skin clearance in participants who achieved clinically meaningful improvement in psoriasis at week 12, with no new safety concerns.

ABSTRACT 48

Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Efficacy by Baseline Disease Characteristics and Demographics in Two Pivotal Phase 3 Trials

Leon Kircik, MD[1,2], Linda Stein Gold, MD[3], James Del Rosso, DO, FAOCD[4], Seemal R. Desai, MD, FAAD[5,6], Brad P. Glick, DO, MPH, FAAD[7], Howard Sofen, MD[8], David S. Rubenstein, MD, PhD[9], Anna M. Tallman, PharmD[9], Janine Fournier MS, PharmD[9], Philip M. Brown MD, JD[9]

[1]Skin Sciences PLLC, Louisville, KY, USA, [2]Icahn School of Medicine at Mount Sinai, New York, NY, USA, [3]Henry Ford Health System, Detroit, MI, USA, [4]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV, USA, [5]University of Texas Southwestern Medical Center, Dallas, TX, USA, [6]Innovative Dermatology, Plano, TX, USA, [7]Herbert Wertheim College of Medicine, Florida International University, Miami, FL, USA, [8]David Geffen UCLA School of Medicine, Los Angeles, CA, USA, 9Dermavant Sciences, Inc., Morrisville, NC, USA

CONTACT INFORMATION: Leon Kircik, wedoderm@yahoo.com; Linda Stein Gold, LSTEIN1@hfhs.org; James Del Rosso, jqdelrosso@yahoo.com; Seemal R. Desai, seemald@yahoo.com; Brad P. Glick, spinsking1103@aol.com; Howard Sofen, hsofen@ucla.edu; David S. Rubenstein, david.rubenstein@dermavant.com; Anna M. Tallman, anna.tallman@dermavant.com; Janine Fournier, janine.fournier@dermavant.com; Philip M. Brown, phil.brown@dermavant.com

LEAD AUTHOR INFORMATION:
Name: Leon Kircik
Degree: MD
Institution: Icahn School of Medicine at Mount Sinai, New York, NY; Skin Sciences PLLC, Louisville, KY
Address: Icahn School of Medicine
5 E. 98th St., 5th Fl.,
New York,
NY 10029, USA

Skin Sciences, PLLC
1169 Eastern Pkwy Ste 2310,
Louisville,
KY 40217, USA
Phone: (502) 456-2783
Email: wedoderm@yahoo.com

BACKGROUND: Tapinarof cream 1% once daily (QD) demonstrated statistically significant efficacy versus vehicle at 12 weeks and was well tolerated in adults with mild to severe plaque psoriasis in two identical, randomized, double-blind phase 3 trials: PSOARING 1 (N=510) and PSOARING 2 (N=515).

OBJECTIVE: To present results for the primary efficacy endpoint of Physician Global Assessment (PGA) response (0 or 1 and ≥2-grade improvement from baseline) at week 12 by baseline characteristics (PGA score, percentage body surface area [%BSA] affected, duration of disease) and demographics (sex, age, race, and country of enrollment [US, Canada]) using pooled data from PSOARING 1 and 2.

METHODS: In PSOARING 1 and 2, conducted in the US and Canada, adults with baseline PGA score ≥2 and BSA involvement ≥3 to ≤20% were randomized 2:1 to tapinarof cream 1% or vehicle QD for 12 weeks. The pooled analysis included the intention-to-treat population assigned to tapinarof 1% QD (n=683) or vehicle (n=342) in PSOARING 1 and 2.

RESULTS: Overall, mean baseline PGA score, %BSA affected, duration of psoriasis, and demographics were comparable across treatment groups and studies. Most patients (82%) had a PGA score of 3 (moderate), 57% had psoriasis >10 years, and 26% had ≥10% BSA affected; 57% were male, 86% aged <65 years, 85% Caucasian, and 76% enrolled in the US. PGA response was 19.9% vs 5.8% (in patients with baseline PGA=2, mild), 40.1% vs 6.4% (baseline PGA=3, moderate), and 36.3% vs 4.7% (baseline PGA=4, severe) in patients treated with tapinarof 1% vs vehicle, respectively. By baseline %BSA affected, PGA response was 38.6% vs 5.1% (baseline BSA <10%) and 35.6% vs 9.3% (baseline BSA ≥10%); and by baseline duration of disease, PGA response was 34.8% vs 7.8% (baseline duration <5 years), 36.9% vs 4.1% (baseline duration 5–10 years), and 39.3% vs 6.5% (baseline duration >10 years) in patients treated with tapinarof 1% vs vehicle, respectively. In addition, PGA response in tapinarof 1% vs vehicle groups was consistent across sex, age, race, and country of enrollment.

CONCLUSION: Tapinarof cream 1% QD was consistently efficacious and well tolerated irrespective of baseline PGA score, %BSA affected, duration of psoriasis, sex, age, race, and country of enrollment, supporting its use across a broad spectrum of disease severity and patient populations.

FUNDING SUPPORT: Dermavant Sciences, Inc.

DISCLOSURES: L.K. has served as a consultant/speaker/investigator/advisory board member for Abbott Laboratories, AbbVie, Ablynx, Aclaris, Acambis, Allergan, Inc., Almirall, Amgen, Inc., Anacor Pharmaceuticals, Anaptys, Arcutis, Arena, Assos Pharma, Astellas Pharma US, Inc., Asubio, Bausch Health, Berlex Laboratories (Bayer HealthCare Pharmaceuticals), Biogen-Idec, Biolife, Biopelle, Bristol Myers Squibb, Boehringer Ingleheim, Breckinridge Pharma, Cassiopea, Centocor, Inc., Cellceutix, Cipher, Coherus, Colbar, Combinatrix, Connetics Corporation, Coria, Dermavant Sciences, Inc., Dermira, Dermik Laboratories, Dow Pharmaceutical Sciences, Inc., Dr. Reddy's Lab, Dusa, Embil Pharmaceuticals, Eli Lilly, EOS, Exeltis, Ferndale Laboratories, Inc., Foamix, Ferrer, Galderma, Genentech, Inc., GlaxoSmithKline, plc, Glenmark, Health Point Ltd, Idera, Incyte, Intendis, Innocutis, Innovail, Isdin, Johnson & Johnson, Kyowakirin, Laboratory Skin Care, Inc., LEO Pharma, L'Oreal, 3M, Maruho, Medical International Technologies, Merck, Medicis Pharmaceutical Corp., Merz, Nano Bio, Novartis AG, Noven Pharmaceuticals, Nucryst Pharmaceuticals Corp, Obagi, Onset, OrthoNeutrogena, PediaPharma, Pfizer, Promius, PuraCap, PharmaDerm, QLT, Inc, Quinnova, Quatrix, Regeneron, Sanofi, Serono (Merck Serono International SA), SkinMedica, Inc., Stiefel Laboratories, Inc., Sun Pharma, Taro, TolerRx, Triax, UCB, Valeant Pharmaceuticals Intl, Warner-Chilcott, XenoPort, and ZAGE. L.S.G. has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from Arcutis, Amgen, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, LEO Pharma, Ortho Dermatologic, and UCB Biopharma. J.D.R. is an advisor and research investigator for Dermavant Sciences, Inc. S.R.D. serves as a consultant and investigator for Dermavant Sciences, Inc. In addition, he serves in multiple other leadership and industry roles unrelated to this product.B.P.G. has served as an investigator/speaker/advisor for AbbVie, Brickell Biotech, Celgene, ChemoCentryx, Corrona Registry PSO, Corrona Registry AD, Dermavant Sciences, Inc, Dermira, Eli Lilly, Janssen, Novartis, Ortho Dermatologics, Pfizer, Prose Registry, Regeneron, Sanofi-Genzyme, and Sun Pharma. H.S. has served as scientific adviser and/or clinical study investigator for AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi-Genzyme, Sun Pharma, and UCB. D.S.R., A.M.T., J.F., and P.M.B. are employees of Dermavant Sciences, Inc., with stock options.

ABSTRACT 49

Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Long-Term Extension Trial of a Novel Therapeutic Aryl Hydrocarbon Receptor Modulating Agent

Bruce Strober, MD, PhD, FAAD[1], Linda Stein Gold, MD[2], Robert Bissonnette, MD, FRCPC[3], April W. Armstrong, MD, MPH[4], Andrew Blauvelt, MD, MBA[5], Leon Kircik, MD[6,7], Philip M. Brown, MD, JD[8], Anna M. Tallman, PharmD[8], Mark Lebwohl, MD[7]

[1]Yale University, New Haven & Central Connecticut Dermatology Research, Cromwell, CT, USA, [2]Henry Ford Health System, Detroit, MI, USA, [3]Innovaderm Research Inc., Montreal, QC, Canada, [4]Keck School of Medicine at University of Southern California, Los Angeles, CA, USA, [5]Oregon Medical Research Center, Portland, OR, USA, [6]Skin Sciences PLLC, Louisville, KY, USA, [7]Icahn School of Medicine at Mount Sinai, New York, NY, USA, [8]Dermavant Sciences, Inc., Morrisville, NC, USA

Contact information: Bruce Strober, brucestrober30@me.com; Linda Stein Gold, LSTEIN1@hfhs.org; Robert Bissonnette, rbissonnette@innovaderm.com; April Armstrong, april.armstrong@med.usc.edu/aprilarmstrong@post.harvard.edu; Andrew Blauvelt, ablauvelt@oregonmedicalresearch.com; Leon Kircik, wedoderm@yahoo.com; Philip M. Brown, phil.brown@dermavant.com; Anna M. Tallman, anna.tallman@dermavant.com; Mark Lebwohl, mark.lebwohl@mssm.edu/lebwohl@aol.com

Lead Author Information:
Name: Bruce Strober
Degree: MD, PhD, FAAD
Institution: Yale University, New Haven & Central Connecticut Dermatology Research, Cromwell, CT
Address: Yale University, New Haven, CT
333 Cedar Street, LC1 501
PO Box 208059
New Haven, CT 06520-8059, USA

Central Connecticut Dermatology Research, Cromwell, CT
1 Willowbrook Rd #2,
Cromwell, CT 06416, USA
Phone: (860) 322-2222
Email: brucestrober30@me.com

BACKGROUND: In two double-blind, 12-week pivotal trials (PSOARING 1 and 2), tapinarof cream 1% once daily (QD) demonstrated significant efficacy versus vehicle and was well tolerated in adults with mild to severe plaque psoriasis. Tapinarof also maintained efficacy after a 12-week phase-2b trial, warranting investigation of a potential remittive effect.

OBJECTIVE: To present the results of PSOARING 3, a long-term extension trial designed to assess the safety and efficacy of tapinarof (including duration of remittive effect off therapy and durability of response on therapy) during repeated, intermittent treatment, based on individual patient Physician Global Assessment (PGA) score.

METHODS: Eligible PSOARING 1 and 2 completers could enroll in PSOARING 3 for 40 weeks of open-label treatment followed by 4 weeks' follow-up. Patients entering with PGA≥1 received tapinarof 1% QD until disease clearance (PGA=0/clear). Patients entering with or achieving PGA=0 discontinued treatment and were monitored for remittive effect (off therapy maintenance of PGA=0 or 1). Patients with disease worsening (PGA≥2) were re-treated until PGA=0. Efficacy endpoints included median time from PGA=0 to first PGA≥2 and proportion of patients with PGA=0/1 after treatment.

RESULTS: 91.6% of eligible patients (n=763) enrolled in PSOARING 3. Common treatment-emergent adverse events, which were mostly mild/moderate and at application sites, were folliculitis (22.7%), contact dermatitis (5.5%), and upper respiratory tract infection (4.7%). Incidence/severity of folliculitis and contact dermatitis remained stable and was associated with low discontinuation rates (1.2% and 1.4%, respectively). Efficacy continued to improve beyond the 12-week pivotal trials. Overall, 40.9% (n=312) of patients achieved complete disease clearance (PGA=0) at least once and 58.2% (n=302) entering with PGA≥2 achieved PGA=0/1. Consistent efficacy was observed, despite intermittent treatment and regardless of prior treatment with tapinarof or vehicle in the pivotal trials. Overall, 10.4% (n=79) had PGA=0 and 31.6% (n=240) had PGA=0/1 at entry; at Week 40, 16.9% (n=126) had PGA=0 and 44.3% (n=330) had PGA=0/1. Median duration of remittive effect off therapy was ~4 months (115 days) for patients entering with PGA=0 (n=79). Among patients entering with or achieving PGA=0 (n=312), mean duration of remittive effect off therapy was >4 months (130 days). Durability of response with no tachyphylaxis for up to 52 weeks was demonstrated.

CONCLUSION: Tapinarof cream 1% QD, a non-steroidal psoriasis therapy, was well tolerated long-term, consistent with the previously reported pivotal trials. A high rate of complete disease clearance, ~4-month remittive effect off therapy, no tachyphylaxis, and consistent efficacy irrespective of intermittent treatment are key attributes of tapinarof, confirmed by these data.

FUNDING SUPPORT: Dermavant Sciences, Inc.

DISCLOSURES: B.S. has served as an honorary consultant/speaker/scientific director/investigator for AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Boehringer Ingelheim, Bristol Myers-Squibb, Cara, Celgene, Corrona Psoriasis Registry, Dermavant Sciences, Inc., Dermira, Equillium, GlaxoSmithKline, Janssen, Leo, Eli Lilly, Meiji Seika Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi-Genzyme, Sun Pharma, and UCB Pharma. L.S.G. has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from Arcutis, Amgen, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, LEO Pharma, Ortho Dermatologic, and UCB Biopharma. R.B. has served as a consultant/advisory board member/speaker/investigator, and/or receives honoraria/grants from Almirall, Amgen, AnaptysBio, Arcutis, Arena Pharma, Aristea, Asana BioSciences, Bausch Health, Bellus Health, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, CARA, Dermavant Sciences, Inc., Eli Lilly,

EMD Serono, Escalier, Evidera, Galderma, GlaxoSmithKline, Incyte, Inmagene Bio, Janssen, Kiniksa, Kyowa Kirin, LEO Pharma, Nimbus, Novan, Pfizer, Ralexar, RAPT, Regeneron, Respivant, Sanofi Genzyme, Sienna, Target RWE, and UCB Biopharma. R.B. is an employee and shareholder of Innovaderm Research. A.W.A. is a research investigator and/or scientific advisor to AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Dermira, EPI, Incyte, Janssen, LEO Pharma, Lilly, Modmed, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Biopharma. A.B. has served as a scientific adviser and/or clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. L.K. has served as a consultant/speaker/investigator/advisory board member for Abbott Laboratories, AbbVie, Ablynx, Aclaris, Acambis, Allergan, Inc., Almirall, Amgen, Inc., Anacor Pharmaceuticals, Anaptys, Arcutis, Arena, Assos Pharma, Astellas Pharma US, Inc., Asubio, Bausch Health, Berlex Laboratories (Bayer HealthCare Pharmaceuticals), Biogen-Idec, Biolife, Biopelle, Bristol Myers Squibb, Boehringer Ingleheim, Breckinridge Pharma, Cassiopea, Centocor, Inc., Cellceutix, Cipher, Coherus, Colbar, Combinatrix, Connetics Corporation, Coria, Dermavant Sciences, Inc., Dermira, Dermik Laboratories, Dow Pharmaceutical Sciences, Inc., Dr. Reddy's Lab, Dusa, Embil Pharmaceuticals, Eli Lilly, EOS, Exeltis, Ferndale Laboratories, Inc., Foamix, Ferrer, Galderma, Genentech, Inc., GlaxoSmithKline, plc, Glenmark, Health Point Ltd, Idera, Incyte, Intendis, Innocutis, Innovail, Isdin, Johnson & Johnson, Kyowakirin, Laboratory Skin Care Inc., LEO Pharma, L'Oreal, 3M, Maruho, Medical International Technologies, Merck, Medicis Pharmaceutical Corp., Merz, Nano Bio, Novartis AG, Nven Pharmaceuticals, Nucryst Pharmaceuticals Corp, Obagi, Onset, OrthoNeutrogena, PediaPharma, Pfizer, Promius, PuraCap, PharmaDerm, QLT, Inc., Quinnova, Quatrix, Regeneron, Sanofi, Serono (Merck Serono International SA), SkinMedica, Inc., Stiefel Laboratories, Inc., Sun Pharma, Taro, TolerRx, Triax, UCB, Valeant Pharmaceuticals Intl, Warner-Chilcott, XenoPort, and ZAGE. P.M.B., and A.M.T. are employees of Dermavant Sciences, Inc., with stock options. M.L. has received grants, and/or is a consultant for AbbVie, Amgen, Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Aristea Therapeutics, Arrive Technologies, Avotres, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Inc., Dr. Reddy's Laboratories, Eli Lilly, Evelo Biosciences, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd, Incyte, Janssen Research & Development, LEO Pharma, LLC, Meiji Seika Pharma, Mindera, Ortho Dermatologics, Pfizer, Regeneron, Seanergy, UCB, Inc., and Verrica.

ABSTRACT 50

Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Additional Efficacy Outcomes From a Long-Term Extension Trial

Linda Stein Gold, MD[1], Benjamin Ehst, MD, PhD[2], Laura K. Ferris, MD, PhD[3], Philip M. Brown, MD, JD[4], David S. Rubenstein, MD, PhD[4], Anna M. Tallman, PharmD[4], Jerry Bagel, MD, MS[5]

[1]Henry Ford Health System, Detroit, MI, USA, 2Oregon Medical Research Center, Portland, OR, USA, [3]UPMC Department of Dermatology, Pittsburgh, PA, USA, [4]Dermavant Sciences, Inc., Morrisville, NC, USA, [5]Psoriasis Treatment Center of New Jersey, East Windsor, NJ, USA

Contact information: Linda Stein Gold, LSTEIN1@hfhs.org; Benjamin Ehst, behst@oregonmedicalresearch.com; Laura K. Ferris, ferrislk@upmc.edu; Philip M. Brown, phil.brown@dermavant.com; David S. Rubenstein, david.rubenstein@dermavant.com; Anna M. Tallman, anna.tallman@dermavant.com; Jerry Bagel, dreamacres1@aol.com

Lead Author Information:
Name: Linda Stein Gold
Degree: MD
Institution: Henry Ford Health System, Detroit, MI
Address: 3031 West Grand Blvd,
Detroit, MI 48202, USA
Phone: Office (248) 661-8764, Cell (248) 884-5356
Email: LSTEIN1@hfhs.org

BACKGROUND: Tapinarof cream 1% once daily (QD) was efficacious and well tolerated versus vehicle in adults with mild to severe plaque psoriasis in two double-blind, 12-week phase 3 trials (PSOARING 1 and 2). The proportion of patients who achieved ≥1-grade improvement in Physician Global Assessment (PGA) score from baseline at Week 12 was higher in the tapinarof group versus vehicle in PSOARING 1 (74.5% vs 35.6%) and PSOARING 2 (80.3% vs 30.6%).

OBJECTIVE: To report additional efficacy results from PSOARING 3, the long-term efficacy (LTE) trial assessing tapinarof during intermittent treatment based on PGA score.

METHODS: Eligible PSOARING 1 and 2 completers could enroll for 40 weeks of open-label tapinarof 1% QD and 4 weeks' follow-up in PSOARING 3. Patients entering with PGA≥1 were treated until they achieved PGA=0. Patients entering with or achieving PGA=0 discontinued tapinarof until PGA≥2, then were re-treated until they achieved PGA=0.

RESULTS: 91.6% (n=763) of eligible patients enrolled in PSOARING 3. Efficacy improved beyond the 12-week pivotal trial outcomes and was maintained over time. In PSOARING 1 and 2, overall mean baseline body surface area (BSA) affected was 7.6–7.9% and Psoriasis Area Severity Index (PASI) was 8.9–9.1. PSOARING 3 baseline mean BSA affected was 4.7% (3.3% and 7.3% for patients previously treated with tapinarof and vehicle, respectively), and mean PASI score was 4.8 (3.3 and 7.7 with tapinarof and vehicle, respectively). At Week 40, significant improvements

beyond those in the pivotal trials were observed. Overall mean improvement from baseline in BSA affected was –2.0%; PASI75 and PASI90 responses were 29.4% and 17.5%, respectively (beyond the PASI75 of 36.1% and 47.6% and PASI90 of 18.8% and 20.9% in PSOARING 1 and 2, respectively). No new safety signals were observed.

CONCLUSION: Continued improvements beyond 12 weeks and durable responses/no tachyphylaxis were observed with tapinarof cream 1% QD across additional efficacy outcomes, which, together with previously reported high rates of complete disease clearance (PGA=0) and ~4-month remittive effect off therapy, differentiate tapinarof from other topical therapies.

Funding Support: Dermavant Sciences, Inc.

Disclosures: L.S.G. has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from Arcutis, Amgen, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, LEO Pharma, Ortho Dermatologic, and UCB Biopharma. B.E. has served as a consultant and/or receives honoraria/grants from AbbVie, Bristol Myers Squibb, Eli Lilly, Evelo Biosciences, Janssen, Novartis, Ortho Dermatologics, Pfizer, Sun Pharma, and UCB. L.K.F. is an investigator for AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, Galderma, Janssen, Novartis, Regeneron and UBC, and a consultant for AbbVie, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, Janssen, Pfizer, and Sun Pharma. P.M.B., D.S.R., and A.M.T. are employees of Dermavant Sciences, Inc., with stock options. J.B. has received research funds payable to Psoriasis Treatment Center and/or speaking/consultant fees from AbbVie, Amgen, Arcutis Biotherapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Celgene Corporation, Corrona LLC, Dermavant Sciences Inc., Dermira/UCB, Eli Lilly, Glenmark Pharmaceuticals Ltd, Janssen Biotech, Kadmon Corporation, LEO Pharma, Lycera Corp, Menlo Therapeutics, Novartis, Pfizer, Regeneron Pharmaceuticals, Sun Pharma, Taro Pharmaceutical Industries Ltd, UCB, and Valeant Pharmaceuticals.

ABSTRACT 51

Patient Satisfaction with Tapinarof Cream 1% Once Daily for Plaque Psoriasis in a Long-Term Extension Trial

Jerry Bagel, MD, MS[1], Linda Stein Gold, MD[2], James Del Rosso, DO, FAOCD[3], Neal Bhatia, MD[4], Sandy Johnson, MD, FAAD[5], Paul Yamauchi, MD, PhD[6], Angela Y. Moore, MD[7], Anna M. Tallman, PharmD[8]

Affiliations: [1]Psoriasis Treatment Center of New Jersey, East Windsor, NJ, USA, [2]Henry Ford Health System, Detroit, MI, USA, [3]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV, USA, [4]Therapeutics Clinical Research, San Diego, CA, USA, [5]Johnson Dermatology, Fort Smith, AR, USA, [6]Dermatology Institute & Skin Care Center, Santa Monica, CA, USA, [7]Arlington Center for Dermatology, Arlington Research Center, Arlington, TX, USA, [8]Dermavant Sciences, Inc., Morrisville, NC, USA

Contact information: Jerry Bagel, dreamacres1@aol.com; Linda Stein Gold, LSTEIN1@hfhs.org; James Del Rosso, jqdelrosso@yahoo.com; Neal Bhatia, dsbconsulting37@gmail.com; Sandy Johnson, drsandy@johnsondermatology.com; Paul Yamauchi, paulyamauchi@yahoo.com; Angela Y. Moore, acdermacderm@gmail.com; Anna M. Tallman, anna.tallman@dermavant.com

Lead Author Information:
Name: Jerry Bagel
Degree: MD, MS
Institution: Psoriasis Treatment Center of New Jersey, NJ
Address: 59 One Mile Road Ext, East Windsor, NJ 0852, USA
Phone: (609) 443-4500
Email: dreamacres1@aol.com

BACKGROUND: Low patient satisfaction with psoriasis therapies has a significant impact on disease management and is an important barrier to optimal care. Tapinarof cream 1% once daily (QD) demonstrated significant efficacy in two 12-week pivotal phase 3 trials (PSOARING 1 and PSOARING 2) of 1,025 adults with mild to severe plaque psoriasis. The proportion of patients who achieved ≥1-grade improvement in PGA score from baseline at Week 12 was higher in the tapinarof group versus vehicle in PSOARING 1 (74.5% vs 35.6%) and PSOARING 2 (80.3% vs 30.6%). Tapinarof 1% was well tolerated as demonstrated by favorable patient-reported local tolerability and investigator-assessed irritation scores, including sensitive skin areas.

OBJECTIVE: To report Patient Satisfaction Questionnaire results from PSOARING 3, the open-label long-term extension trial.

METHODS: Eligible patients completing PSOARING 1 or 2 could enroll for up to 40 weeks of open-label treatment with tapinarof cream 1% QD in PSOARING 3. Patient Satisfaction Questionnaire responses were assessed at Week 40 or early termination. The questionnaire was designed to assess patient satisfaction with tapinarof efficacy, formulation elegance, application ease, impact on daily life, and preference for tapinarof versus prior psoriasis therapies.

RESULTS: 91.6% (n=763) of eligible patients completing PSOARING 1 or 2 elected to enroll in PSOARING 3. Patient Satisfaction Questionnaires were completed by 78.5% of patients. Patients consistently reported high satisfaction rates across all parameters. A high proportion of patients either strongly agreed or agreed that they: could easily manage their psoriasis with tapinarof (85.8%); were satisfied with how well tapinarof worked (83.6%); felt that tapinarof cleared their skin and prevented psoriasis from coming back (62.9%); were satisfied with the look and feel of tapinarof (87.7%); felt that tapinarof was not greasy (89.0%); considered tapinarof easy to apply (96.3%); were satisfied with the time spent applying tapinarof (93.2%); and would use tapinarof again or continue using it, if available (82.5%). For patients who reported prior use of other topical drugs to treat psoriasis, 81.7% considered tapinarof to be more effective, 65.3% considered tapinarof to be easier to use, and 81.1% preferred tapinarof to other topical drugs used. For patients who reported prior use of systemic drugs to treat psoriasis, 55.3% felt that tapinarof was more

effective, 63.8% considered tapinarof to be easier to use, and 67.8% preferred tapinarof to prior systemic drugs.

CONCLUSION: Patient satisfaction data from PSOARING 3 demonstrated consistently high rates of satisfaction and positive perceptions of tapinarof cream 1% QD across all patient-relevant parameters, including satisfaction with tapinarof efficacy, formulation elegance, ease of application, impact on daily life, and preference for tapinarof versus prior psoriasis therapies.

FUNDING SUPPORT: Dermavant Sciences, Inc.

DISCLOSURES: J.B. has received research funds payable to Psoriasis Treatment Center and/or speaking/consultant fees from AbbVie, Amgen, Arcutis Biotherapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Corrona LLC, Dermavant Sciences, Inc., Dermira/UCB, Eli Lilly, Glenmark Pharmaceuticals Ltd, Janssen Biotech, Kadmon Corporation, LEO Pharma, Lycera Corp, Menlo Therapeutics, Novartis, Pfizer, Regeneron, Sun Pharma, Taro Pharmaceutical Industries Ltd, UCB, and Valeant Pharmaceuticals. L.S.G. has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from Arcutis, Amgen, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, LEO Pharma, Ortho Dermatologic, and UCB Biopharma. J.D.R. is a consultant and research investigator for Dermavant Sciences, Inc. N.B. is a consultant with honorarium and an investigator for Dermavant Sciences, Inc. S.J. is an advisor, and/or speaker, and/or editor, and/or involved in clinical trials for AbbVie, Aclaris, AFMC, Allergan, Amgen, Candela Syneron, Cassiopea, Celgene, Chemocentryx, Dermavant Sciences, Inc., Dermira, Foamix, Gage, Galderma, GSK, Journal of Arkansas Medical Society, LEO, Eli Lilly, National Psoriasis Foundation, Nielsen, Novartis, Practical Dermatology, Regeneron, Sanofi Genzyme, Skin Medical, TARGET Therapeutics, and the University of Pennsylvania. P.Y. has served as an investigator and/or speaker and/or consultant for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., EPI Health, Incyte, Janssen, Lilly, Leo, Novartis, Pfizer, Sun Pharma, and UCB. A.Y.M. has served as an investigator for Dermavant Sciences, Inc. A.M.T. is an employee of Dermavant Sciences, Inc., with stock options.

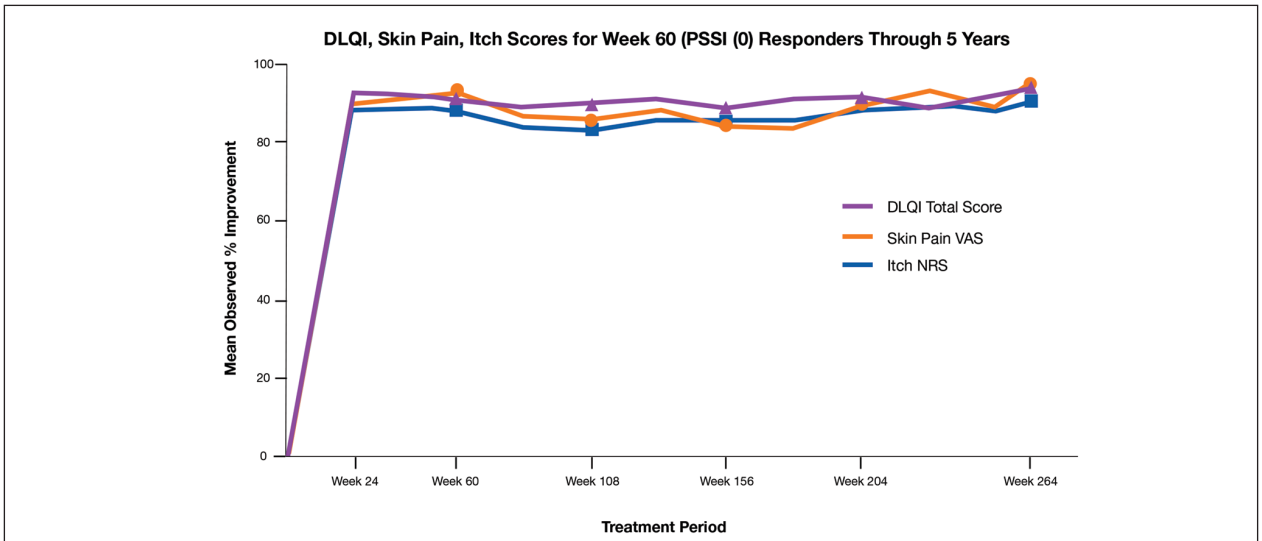
ABSTRACT 52

Ixekizumab-Treated Patients With Complete Scalp Psoriasis Clearance by Week 60 Demonstrate Substantial Improvements in Patient Reported Outcomes Through Five Years

Alexander Egeberg,[1] MD, PhD, alexander.egeberg@gmail.com;
Jason Hawkes[2] MD, MS, jehawkes@ucdavis.edu;
Terri Ridenour,[3] MBA, BSN, ridenour_terri_lynn@lilly.com;
Yan Wang,[4] MD, PhD, wangy111@yahoo.com;
Najwa Somani,[3] MD, somani_najwa@lilly.com;
Russel Burge,[3,5] PhD, burge_russel_thomas@lilly.com;
Kyoungah See,[3] PhD, see_kyoungah@lilly.com;
Missy McKean-Matthews,[6] MS, mckean_matthews_missy@network.lilly.com;
April Armstrong[7] MD, MPH, aprilarmstrong@post.harvard.edu

[1]Gentofte Hospital, Hellerup, Denmark; [2]University of California, Davis, CA, USA; [3]Eli Lilly and Company, Indianapolis, IN, USA; [4]Alnylam Pharmaceuticals Inc., Cambridge, MA, USA; [5]University of Cincinnati, Cincinnati, OH, USA; [6]Syneos Health, Raleigh, NC, USA; [7]Department of Dermatology, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA

BACKGROUND: An estimated 50–80% of patients with psoriasis report scalp involvement. Scalp psoriasis is difficult



Mean-observed % improvement in Dermatology Life Quality Index (DLQI) total score, skin pain-visual analogue scale (VAS), and itch numeric rating scale (NRS) through 5 years of ixekizumab plaque psoriasis treatment. Analysis was performed on patients from the long-term extension period of the UNCOVER 1 & 2 trials reporting scalp psoriasis at baseline who recorded a Psoriasis Scalp Severity Index (PSSI) score of 0 at week 60.

FIGURE. Key Results

to treat and disproportionately impacts patient quality of life due to appearance, flaking, and often severe pruritis.

OBJECTIVE: This post-hoc analysis of an integrated population from the phase-3 UNCOVER 1 & 2 trials examines clinical and patient-reported outcomes from long-term Ixekizumab (IXE) treatment of moderate-to-severe plaque psoriasis, with a specific focus on the scalp.

METHODS: Data were integrated from the randomized, double-blinded phase 3 UNCOVER 1 & 2 trials, through Week 60 and up to Week 264 of the long-term extension period (LTEP). Patients who continuously received the label IXE dose, exhibited a static Physician's Global Assessment score of 0 or 1 at Week 12, and completed 60 weeks of treatment, were eligible to enter the LTEP. During the LTEP, patients received 80 mg IXE every12 weeks, 4 weeks, or 2 weeks, with the option to escalate dosing per investigator's discretion. The analysis population included patients from the 5-year LTEP with baseline scalp psoriasis who recorded a Psoriasis Scalp Severity Index (PSSI) score of 0 at Week 60. Patient-reported outcomes (mean observed % improvement from baseline in Dermatology Life Quality Index [DLQI] total score, skin pain visual analogue scale [VAS], and itch numeric rating scale [NRS]) were measured throughout the LTEP, including at Week 60 and years 2, 3, 4, and 5. Descriptive statistics were applied to investigate clinical (PSSI) and patient reported (itch NRS, skin pain VAS, and DLQI total score) outcomes.

RESULTS: By Week 60 of the trials, 167 (88.4%) of 189 patients recording scalp psoriasis at baseline had achieved a PSSI (0) response. At Week 60, these responders reported a 91.3% mean observed improvement from baseline in DLQI total score, a 93.3% improvement in skin pain VAS, and an 88.2% improvement in itch NRS. This improvement was maintained throughout the 5-year LTEP, with mean observed % improvement from baseline remaining at or above 89.1% for DLQI total score, 83.5% for skin pain VAS, and 83.8% for itch NRS between weeks 60 and 264. At Week 264 (study end), mean observed % improvement from baseline in Week 60 PSSI (0) responders was 94.3% for DLQI total score, 95.2% for skin pain VAS, and 90.8% for itch NRS.

CONCLUSIONS: In this study, the majority (nearly 9 out of 10) of patients with moderate-to-severe plaque psoriasis who recorded scalp psoriasis at baseline achieved complete clearance (PSSI [0]) of their scalp psoriasis with IXE treatment at week 60. Week 60 PSSI (0) responders also experienced substantial improvements in patient-reported quality of life, itch, and skin pain outcomes. With continued IXE treatment, these improvements were sustained over a period of 5 years. These results underscore the high efficacy and long-term durability of IXE for plaque psoriasis, including difficult to treat areas such as the scalp.

DISCLOSURES: Study was sponsored by Eli Lilly and Company. Abstract previously presented at European Academy of Dermatology and Venereology (EADV), 2021

ABSTRACT 53

Ixekizumab Improves Nail Psoriasis in Patients With Nail Psoriasis, Enthesitis and Joint Involvement

Christopher T Ritchlin[1], M.D., M.P.H, christopher_ritchlin@urmc.rochester.edu
Lars E Kristensen[2], MD, PhD, lars.erik.kristensen@regionh.dk
Bruce E Strober[3], MD, PhD, brucestrober30@me.com
Rebecca J Bolce[4], MSN, Rebecca.Bolce@lilly.com
Jeffrey Lisse[4], MD, lisse_jeffrey_r@lilly.com
Jennifer M Pustizzi[4], PharmD, jennifer.pustizzi@lilly.com
Najwa Somani[4], MD, somani_najwa@lilly.com
Christophe Sapin[4], MSc, sapin_christophe@lilly.com
Joseph F Merola[5], MD, MMSc, jfmerola@bwh.harvard.edu

[1]Allergy, Immunology, and Rheumatology, University of Rochester Medical Center, Rochester, NY, USA [2]Muscoloskeletal Statistics Unit, The Parker Institute, Bispebjerg and Frederiksberg Hospital, Copenhagen, Denmark; Department of Rheumatology, Odense University Hospital, Denmark, [3] University of Connecticut, Farmington, Connecticut; Probity Medical Research, Waterloo, Ontario, Canada, [4]Eli Lilly and Company, Indianapolis, IN, USA, [5]Department of Medicine, Division of Rheumatology, and Department of Dermatology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA.

BACKGROUND: In SPIRIT head-to-head (H2H) study, ixekizumab (IXE) demonstrated superiority vs adalimumab (ADA) using a combined endpoint of ACR 50/PASI 100. Significantly more patients (pts) achieved resolution of nail psoriasis with IXE treatment compared to ADA. Little is known about the dynamics of resolution of articular and extra-articular manifestations of Psoriatic Arthritis (PsA) relative to nail psoriasis resolution, important clinical parameters of disease.

OBJECTIVE: To show the impact of IXE vs ADA in the resolution of both nail psoriasis and enthesitis, and both nail psoriasis and joint involvement.

METHODS: SPIRIT-H2H (NCT03151551) was a 52 week, multicenter, randomized, open-label, parallel-group, assessor-blinded study evaluating the efficacy and safety of IXE vs ADA in PsA. Participants were randomized (1:1) to approved-label dosing of IXE or ADA. Nail psoriasis was measured using Nail Psoriasis Severity Index (NAPSI). Enthesitis was measured using Leeds Enthesitis Index (LEI). Joint involvement was measured by tender/swollen joint count (TJC/SJC) scores. Non-responder imputation method was used for missing data. Statistical significance was assessed using Fisher's exact tests.

RESULTS: Overall, 368 pts (IXE N=191, ADA N=177) out of 565 had a baseline NAPSI >0 (table 1). No major imbalance was found between IXE- and ADA-treated pts. In pts with both NAPSI >0 and LEI >0 at baseline, IXE treatment resulted in a higher proportion of pts with complete resolution of 1) nail psoriasis (IXE=57.4%, ADA=42.4%, p=0.047), and 2) both nail psoriasis and enthesitis (IXE=38.9%, ADA=22.8%, p=0.022) compared

TABLE 1. Baseline demographics and disease characteristics

	Without nail psoriasis (n=197)		With nail psoriasis (n=368)	
	IXE (n=92)	*ADA (n=105)*	*IXE (n=191)*	*ADA (n=177)*
Gender (n (%), male)	43 (46.7%)	49 (46.7%)	119 (62.3%)	100 (56.5%)
Age (years ± SD)	47.6 ± 12.7	47.2 ± 11.8	47.5 ± 11.7	48.9 ± 12.6
Duration of PsA (mean ± SD, years)	6.3 ± 7.3	6.0 ± 5.6	8.6 ± 8.5	8.0 ± 8.4
TJC (mean ± SD)	16.8 ± 11.2	20.3 ± 15.4	20.2 ± 13.2	22.0 ± 15.4
SJC (mean ± SD)	8.9 ± 7.2	10.0 ± 6.7	10.7 ± 7.6	11.1 ± 8.8
Presence of enthesitis (n (%), LEI>0)	51 (55.4%)	54 (51.4%)	108 (56.5%)	92 (52.0%)
Presence of dactylitis (n (%), LDI-B>0)	11 (12.0%)	15 (14.3%)	31 (16.2%)	43 (24.3%)

TABLE 2. Summary of results from patients with baseline scores >0 in NAPSI and LEI

		Week 24		Week 52	
Baseline status	**Efficacy outcomes**	*IXE*	*ADA*	*IXE*	*ADA*
NAPSI and LEI > 0	*N*	108	92	108	92
	Nails[a]	57.4%*	42.4%	69.4%	56.5
	Enthesitis[b]	62%	60.9%	64.8%	67.4%
	Nails & Enthesitis[c]	38.9%*	22.8%	48.1%	43.5%
NAPSI > 0	*N*	191	177	191	177
	Nails[a]	60.7%*	49.7%	71.2%	62.1%
	TJC=0	35.6%*	24.3%	38.7%	34.5%
	Nails[a] *& TJC=0*	23.6%*	14.1%	29.3%	27.1%
	SJC=0	60.7%	58.8%	69.1%	65.5%
	Nails[a] *& SJC=0*	40.8%	31.1%	51.3%	49.2%

[a]Nail resolution measured by NAPSI=0 [b]Enthesitis resolution measured by LEI=0

[c]Combined resolution of nail (NAPSI=0) and enthesitis (LEI=0)

*=p<0.05 vs ADA treatment (Fisher's exact test)

to ADA treatment at week 24 (Table 2). Increased proportions of pts with complete resolution of nail psoriasis (IXE=69.4%, ADA=56.5%, p=0.077), and complete resolution of both nail psoriasis and enthesitis involvement (IXE=48.1%, ADA=43.5%, p=0.570) were seen in IXE-treated pts by week 52 (Table 2). A similar number of pts achieved complete resolution of enthesitis alone with either IXE or ADA treatments at weeks 24 and 52 (Table 2). In pts with NAPSI >0 at baseline, IXE treatment resulted in a higher proportion of pts with complete resolution of 1) nail psoriasis (IXE=60.7%, ADA=49.7%, p=0.036), 2) tender joint involvement, TJC=0 (IXE=35.6%, ADA=24.3%, p=0.023), and 3) both nail psoriasis and tender joint involvement (IXE=23.6%, ADA=14.1%, p=0.024) compared to ADA treatment at week 24 (Table 2). Increased proportions of pts with complete resolution of nail psoriasis (IXE=71.2%, ADA=62.1%, p=0.076), tender joint involvement, TJC=0 (IXE=38.7%, ADA=34.5%, p=0.449) and both nail resolution and tender joint involvement (IXE=29.3%, ADA=27.1%, p=0.645) were seen in IXE-treated pts at week 52 (Table 2).

CONCLUSION: IXE treatment resulted in a higher proportion of pts achieving complete resolution of both nail psoriasis and enthesitis, and both nail psoriasis and TJC compared to ADA treatment in the SPIRIT H2H trial.

DISCLOSURES: This study was funded by Dermira, a wholly-owned subsidiary of Eli Lilly and Company. This study was previously presented at Congress of Clinical Rheumatology West – 2021.

ABSTRACT 54

Long-Term Continuous Use of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion in Patients With Plaque Psoriasis

Lawrence Green, MD[1]; Alice B. Gottlieb, MD, PhD[2]; Mona Shahriari, MD[3]; Abby Jacobson, MS, PA-C4

[1]George Washington University School of Medicine, Washington, DC; [2]Icahn School of Medicine at Mt. Sinai, New York, NY; [3]Central Connecticut Dermatology, Cromwell, CT; [4]Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

BACKGROUND: The efficacy and safety of fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) was demonstrated in a 52-week, long-term, open-label study (NCT02462083) of participants with psoriasis. However, participants in this study varied in the duration of HP/TAZ treatment needed.

OBJECTIVES: To evaluate long-term efficacy and safety outcomes for participants with first treatment success (investigator's global assessment [IGA] of clear [0] or almost clear [1]) after 8 weeks (n=111) or ≥16 weeks (n=89) of continuous HP/TAZ treatment in a post hoc analysis of the open-label study.

METHODS: All participants received HP/TAZ once daily for 8 weeks. Participants who achieved treatment success at week 8 stopped treatment and were reevaluated monthly through 52 weeks. Participants were allowed up to 24 continuous weeks of treatment if they achieved ≥1-grade improvement in IGA from baseline at week 12, with monthly reevaluation. If at any point IGA ≥2 was achieved, HP/TAZ was resumed; otherwise, HP/TAZ was discontinued.

RESULTS: There was no significant difference between participants with 8 vs ≥16 weeks of continuous treatment who achieved IGA 0/1 at week 52 (46.6% vs 30.8%; P=0.122). Despite similar baseline body surface area (BSA) involvement, significantly more participants with 8 vs ≥16 weeks of continuous treatment maintained BSA involvement of ≤3% for ≥1 year (66.1% vs 30.8%; P<0.001). The percentage of participants with 8 weeks of continuous treatment who reported none-or-mild itching and none-or-mild dryness increased from 51.4% and 55.9% (baseline) to 91.4% and 96.6% (week 52), respectively. Similarly, the percentage of participants with ≥16 weeks of continuous treatment who reported none-or-mild itching and none-or-mild dryness increased from 49.4% and 51.7% (baseline) to 92.3% and 89.7% (week 52), respectively. Rates of none-or-mild burning/stinging remained similar from baseline through week 52 for both groups. Incidences of skin atrophy, striae, telangiectasias, and folliculitis were low and were absent in all participants by week 52. Rates of application-site dermatitis, pruritus, pain, and irritation were also low. Overall, adverse event rates were similar between groups.

CONCLUSIONS: Continuous HP/TAZ, including through 24 weeks, was associated with skin clearance, improvement in signs and symptoms of psoriasis, and low rates of skin reactions. Participants with 8 weeks of continuous treatment may have more responsive disease, which could explain greater maintenance of disease control observed relative to those with ≥16 continuous weeks.

ABSTRACT 55

Sustained Treatment Effect of Spesolimab Over 12 Weeks for Generalized Pustular Psoriasis Flares; Results From the Effisayil 1 Study

Boni Elewski[1] (belewski@uabmc.edu),

Jonathan Barker[2] (jonathan.barker@kcl.ac.uk),

Ulrich Mrowietz[3] (umrowietz@dermatology.uni-kiel.de),
Shinichi Imafuku[4] (dermatologist@mac.com),

Jinhua Xu[5] (xjhhsyy@163.com),

Na Hu[6] (na.hu@boehringer-ingelheim.com),

Manuel Quaresma[7] (manuel.quaresma@boehringer-ingelheim.com),

Christian Thoma[8] (christian.thoma@boehringer-ingelheim.com),

Hervé Bachelez[9,10] (herve.bachelez@orange.fr)

[1]University of Alabama School of Medicine, Birmingham, AL, USA; [2]St John's Institute of Dermatology, Guy's Hospital, London, UK; [3]Psoriasis-Center, Department of Dermatology, University Medical Center Schleswig-Holstein, Campus Kiel, Kiel, Germany; [4]Department of Dermatology, Faculty of Medicine, Fukuoka University, Fukuoka, Japan; [5]Department of Dermatology, Huashan Hospital, Fudan University, Shanghai, People's Republic of China ; [6]Boehringer Ingelheim (China) Investment Corporation Limited, Shanghai, People's Republic of China; [7]Boehringer Ingelheim International GmbH, Ingelheim, Germany; [8]Boehringer Ingelheim International GmbH, Biberach, Germany; [9]Service de Dermatologie, Assistance Publique-Hôpitaux de Paris Hôpital Saint-Louis, Paris, France; [10]INSERM U1163, Imagine Institute of Genetic of Diseases, Université de Paris, Paris, France

BACKGROUND: Generalized pustular psoriasis (GPP) is a rare, life-threatening autoinflammatory disease (Gooderham MJ, et al. Expert Rev Clin Immunol 2019) (Navarini AA, et al. *J Eur Acad Dermatol Venereol* 2017) (Choon SE, et al. *BMJ Open* 2021). In Effisayil 1 (NCT03782792), a double-blind, randomized, placebo-controlled study in patients presenting with a GPP flare, spesolimab, an anti-interleukin-36 receptor antibody, led to rapid clearance (within 1 week) of pustular and skin lesions (Bachelez H, et al. 6th World Psoriasis & Psoriatic Arthritis Conference, 2021).

OBJECTIVES: Here, we explore the effects of spesolimab over the 12-week study duration, based on observed case analysis.

METHODS: Patients (N=53) were randomized to receive a single intravenous dose of spesolimab 900 mg (n=35) or placebo (n=18) on Day 1. Per protocol, 12 (34.3%) in the spesolimab group and 15 (83.3%) in the placebo group were eligible to receive an open-label dose of spesolimab at Day 8 for persistent symptoms.

RESULTS: Of patients initially randomized to spesolimab, 61.8% and 84.4% achieved a GPPGA pustulation subscore of 0, and 50.0% and 81.3% a GPPGA total score of 0/1 by Weeks 1 and 12, respectively. Of patients initially randomized to placebo who received open-label spesolimab at Day 8, 83.3% and 80.0% had a GPPGA pustulation subscore of 0, and 72.2% and 93.3% had a GPPGA total score of 0/1 by Weeks 2 (1-week post-spesolimab) and 12, respectively. After Day 8, 32 and 17 patients randomized to spesolimab and placebo, respectively, completed the 12-week follow-up period, during which four and two patients, required rescue treatment with spesolimab for a new flare episode.

CONCLUSION: Spesolimab demonstrated rapid clinical improvements, which were sustained over 12 weeks. These data further support spesolimab as a potential therapeutic option for patients with a GPP flare.

This encore was originally presented at the American Academy of Dermatology (2022), 25 Mar to 29 Mar 2022.

FUNDING: This study was funded by Boehringer Ingelheim.

ACKNOWLEDGMENT: OPEN Health Communications (London, UK) provided writing, editorial support and formatting assistance for the original presentation contracted and funded by Boehringer Ingelheim.

DISCLOSURES: BE is an investigator for AbbVie, Anaptys- Bio, Boehringer Ingelheim, Bristol Myers Squibb, Amgen (previously Celgene), Incyte, Leo, Eli Lilly, Merck, Novartis, Pfizer, Regeneron, Sun, Valeant (Ortho dermatology), and Vanda and a consultant for Boehringer Ingelheim, BMS, Amgen (previously Celgene), Leo, Lilly, Menlo, Novartis, Valeant (Ortho dermatology), and Verrica. JB declares having attended advisory boards and/or received consultancy fees and/or spoken at sponsored symposia, and/or received grant funding from AbbVie, Almirall, Amgen, AnaptysBio, Boehringer Ingelheim, Bristol-Meyers-Squibb, Celgene, Janssen, LEO Pharma, Lilly, Novartis, Pfizer, Samsung, Sienna, Sun Pharma, UCB. UM has received grants/honoraria as an investigator and/or consultant from Abbvie, Almirall, Amgen, Biogen Idec, Boehringer Ingelheim, Celgene, Centocor, Dr Reddy's, Eli Lilly and Company, Foamix, Formycon, Forward Pharma, Janssen, Leo Pharma, Medac, MSD, Miltenyi Biotech, Novartis, VBL, and Xenoport. SI has served as a consultant and/or paid speaker for and/or accepted a research grant from and/or participated in clinical trials sponsored by companies including Maruho, Celgene, Kyowa-Kirin, Leo and Novartis. JX declares receiving grants, consulting fees, and/or speaker's fees from AbbVie, Bayer, Boehringer Ingelheim, Kyowa Kirin, La Roche-Posay China, Novartis, Pfizer Inc and Sanofi. NH, MQ and CT are employees of Boehringer Ingelheim. HB declares paid consulting activities for AbbVie, Almirall, BIOCAD, Boehringer Ingelheim, Celgene, Dermavant, Janssen, Kyowa-Kirin, LEO Pharma, Lilly, Mylan, Novartis, UCB, and Xion Pharmaceuticals, grant support from Boehringer Ingelheim, Janssen, LEO Pharma, Novartis, and Pfizer, and participation on a data safety monitoring board/advisory board from Avillion. The study was supported and funded by Boehringer Ingelheim. The authors meet the criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE). The authors did not receive payment related to the development of the poster. Boehringer Ingelheim was given the opportunity to review the abstract for medical and scientific accuracy as well as intellectual property considerations.

ABSTRACT 56

Current Treatments for Generalized Pustular Psoriasis: A Systematic Literature Review

Luis Puig[1] (LPuig@santpau.cat), Hideki Fujita[2] (fujita.hideki@nihon-u.ac.jp), Diamant Thaçi[3] (diamant.thaci@uksh.de), Min Zheng[4] (minz@zju.edu.cn), Craig Leonardi[5] (craig.leonardi@centralderm.com), Ana Cristina Hernandez Daly[6] (ana_cristina.hernandez@boehringer-ingelheim.com), Jonathan Barker[7] (jonathan.barker@kcl.ac.uk)

[1]Hospital de la Santa Creu i Sant Pau (HSCSP), Barcelona, Spain. [2]Nihon University, Tokyo, Japan. [3]Universitat Zu Luebeck, Lubeck, Germany. [4]Department of Dermatology, Second Affiliated Hospital, Zhejiang University, School of Medicine, Hangzhou, Zhejiang, China. [5]Central Dermatology, St. Louis, MO, USA. [6]Boehringer Ingelheim International GmbH, Ingelheim, Germany. [7] St John's Institute of Dermatology, Guy's Hospital, London, UK.

BACKGROUND: Generalized pustular psoriasis (GPP) is a rare, potentially life-threatening autoinflammatory skin disease, characterized by recurrent flares of widespread pustules. No therapies are currently approved specifically for GPP in Europe or the USA.

OBJECTIVES: We report results of a systematic literature review (SLR) of current published literature on GPP to understand the efficacy, safety, quality of life, economic burden, and the use of current treatments in clinical practice.

METHODS: The SLR search protocol was prospectively logged in the PROSPERO database (CRD42021215437) and specified detailed search and eligibility criteria for study inclusion. Searches were conducted in February 2021 in Embase and PubMed databases to capture outcomes in all studies reported between 1980–2021 in all patients of any age group, gender, and ethnicity with GPP. No restrictions were made to the searches in terms of intervention, comparator, study design, geography, or languages of the publications included. The initial searches yielded 1,427 publications, which were screened for eligibility based on titles and abstracts by two independent reviewers using the eligibility criteria. From this, 341 publications were then reviewed in full text to determine eligibility for final extraction. Any discrepancies in opinion were reconciled by an independent reviewer. The data extractions were conducted by the reviewers and independently quality checked.

RESULTS: In total, 114 eligible publications passed both rounds of screening and were included in the final review, with results extracted from 13 trials (11 open-label [9 in Japan]; 1 double-blind; 1 unblinded), 15 retrospective studies, 1 prospective study, 51 case studies or reports, and 34 other study types. A wide, but ill-defined, range of therapies for GPP were identified, the most commonly reported were infliximab, ustekinumab, secukinumab, methotrexate, acitretin, and cyclosporin. Psoriasis Area and Severity Index score was the most frequently reported efficacy outcome, with treatments showing a limited improvement from baseline. Overall, treatments were found to be tolerable, with few serious adverse events reported in the short duration of the included studies.

CONCLUSIONS: There is no clear standard of care for GPP. Current therapies based on evidence from small open-label studies and case studies show limited efficacy but are not suitable life-long treatment due to their adverse event profile and existing contraindications. This is the first SLR on GPP to include publications in all languages over a 40-year period. Results should be interpreted with caution, since despite the wide search criteria, the GRADE criteria determined the included studies were of low or very low quality. There is a lack of clinical trial data and approved therapies (except in Japan) to support clinicians with effective and consistent GPP management.

This encore was originally presented at the European Academy of Dermatology and Venereology congress in 2021.

FUNDING: This study was funded by Boehringer Ingelheim.

ACKNOWLEDGMENT: OPEN Health Communications (London, UK) provided writing, editorial support and formatting assistance for the original presentation, contracted and funded by Boehringer Ingelheim.

DISCLOSURES: LP has received consultancy/speaker's honoraria from and/or participated in clinical trials sponsored by Abbvie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Celgene, Gebro, Janssen, JS BIOCAD, Leo-Pharma, Lilly, Merck-Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, Sandoz, Samsung-Bioepis, Sanofi, and UCB. HF has received honoraria or fees for serving on advisory boards, as a speaker and as a consultant, as well as grants as an investigator from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Chugai Pharmaceutical, Esai, Eli Lily, Janssen, Japan Blood Products Organization, JMEC, Kaken, Kyorin, Kyowa Kirin, Leo Pharma, Maruho, Mitsubishi-Tanabe, Nihon Pharmaceutical, Novartis, Sanofi, Sun Pharma, Taiho, Torii, UCB, and Ushio. DT declares having attended advisory boards and/or received consultancy fees and/or receiving grants as an investigator from AbbVie, Almirall, Amgen, Beiersdorf, BMS, Boehringer Ingelheim, DS-Pharma, Eli Lilly, Galapagos, GSK, Janssen-Cilag, LEO Pharma, Maruho, Medac, MorphoSys, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Samsung, Sandoz, Sanofi, Sun Pharma, and UCB. MZ declares receiving grants, consulting fees and/or speaker's fees from AbbVie, Boehringer Ingelheim, Janssen-Cilag, LEO Pharma China, Novartis, Pfizer and Xian-Janssen. CL has received honoraria or fees for serving on advisory boards, as a speaker and as a consultant, as well as grants as an investigator from AbbVie, Actavis, Amgen, Boehringer Ingelheim, Celgene, Coherus, Dermira, Eli Lilly, Galderma, Janssen, Merck, Novartis, Pfizer, LEO Pharma, Sandoz, Stiefel, UCB, Vitae and Wyeth. ACHD is an employee of Boehringer Ingelheim International GmbH, Ingelheim, Germany. JB declares having attended advisory boards and/or received consultancy fees and/or spoken at sponsored symposia, and/or received grant funding from AbbVie, Almirall, Amgen, AnaptysBio, Boehringer Ingelheim, Bristol-Meyers-Squibb, Celgene, Janssen, LEO Pharma, Lilly, Novartis, Pfizer, Samsung, Sienna, Sun Pharma, UCB.

ABSTRACT 57

Bimekizumab Versus Secukinumab in Plaque Psoriasis: Psoriasis Symptoms and Impacts Measure (P-SIM) Responses Accompanying Achievement of Complete Skin Clearance in The Phase 3b BE RADIANT Trial

Alice B. Gottlieb,[1] Richard G. Langley,[2] Richard B. Warren,[3] Mark Lebwohl,[1] Boni Elewski,[4] Luke Peterson,[5] Markus Kaspar,[6] Natalie Nunez Gomez,[7] Valerie Ciaravino,[8] Matthias Augustin[9]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]Division of Clinical Dermatology and Cutaneous Science Dalhousie University, Halifax, NS, Canada; [3]Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; [4]Department of Dermatology, University Hospitals of Cleveland, Case Western Reserve University, Cleveland, OH, USA; [5]UCB Pharma, Raleigh, NC, USA; [6]UCB Pharma, Monheim, Germany; [7]UCB Pharma, Monheim, Germany; [8]UCB Pharma, Colombes, France; [9]Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

BACKGROUND: The P-SIM, a novel, validated, patient-reported outcome tool, captured psoriasis symptoms in bimekizumab (BKZ) clinical trials (Gottlieb AB, et al. *Dermatol Ther* 2020).

OBJECTIVE: To report achievement of a score of 0 on the P-SIM, indicating no symptom, for itching, skin pain, and scaling in patients with moderate to severe plaque psoriasis treated with bimekizumab or secukinumab over 48 weeks.

METHODS: BE RADIANT randomized patients 1:1 to: BKZ 320mg every 4 weeks (wks)(Q4W); secukunimab (SEC) 300mg weekly to Wk4, then Q4W. From Wk16, BKZ patients received either BKZ Q4W or Q8W (Reich K, et al. *N Eng J Med* 2021). We report proportions of patients achieving PASI90(Wk4)/PASI100(Wk48), and scores of 0 (no symptom) for itching, skin pain, and scaling P-SIM items alongside nominal p-values (non-responder imputation), in the intention-to-treat population and maintenance set (received ≥1 BKZ/SEC dose at Wk16 or later).

RESULTS: Mean baseline P-SIM scores for BKZ Q4W (N=373) vs SEC (N=370) were itching, 6.6 vs 6.8; skin pain, 4.5 vs 4.8; scaling, 6.7 vs 6.8. From Wk16, N=147 patients received BKZ Q4W; BKZ Q8W, N=215; SEC, N=354. At Wk4, the proportions of patients (intention-to-treat) achieving P-SIM=0 with BKZ vs SEC were itching, 32.2% vs 24.2% (p=0.004); skin pain, 69.3% vs 56.0% (p<0.001); scaling, 45.5% vs 21.3% (p<0.001). Differences were consistent with Wk4 PASI90 responses (35.9% vs 17.6%). At Wk48, the proportions (maintenance set) for BKZ Q4W/Q4W and Q4W/Q8W vs SEC were itching, 58.7% and 64.1% vs 50.1% (p=0.074 and p=0.001); skin pain, 75.2% and 81.8% vs 73.2% (p=0.291 and p=0.038); scaling, 71.9% and 73.3% vs 52.0% (both p<0.001). Differences were consistent with Wk48 PASI100 results (73.5% and 66.0% vs 48.3%) (Reich K, et al. *N Eng J Med* 2021).

CONCLUSIONS: At Wk4 and Wk48, more patients reported no itching, skin pain, and scaling with BKZ (Q4W or Q8W) vs SEC using the P-SIM, consistent with differences in PASI responses.

FUNDING: This study was funded by UCB Pharma. Medical writing support was provided by Costello Medical.

REFERENCES:

1. Gottlieb AB et al. Dermatol Ther (Heidelb) 2020;10:1255–72; 2. Reich K et al. *N Eng J Med* 2021;385:142–52, NCT03536884.

LEAD AUTHOR INFORMATION: Alice B. Gottlieb MD, PhD: alicegottliebderm@gmail.com; please send correspondence to taylor-marie.vasil@costellomedical.com

DISCLOSURES: AG: Honoraria as an advisory board member and consultant for Anaptyps Bio, Avotres Therapeutics, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sun Pharma, UCB Pharma, and XBiotech (only stock options); research/educational grants (paid to Mount Sinai Medical School) from Boehringer Ingelheim, Incyte, Janssen, Novartis, Sun Pharma, UCB Pharma, and XBiotech. RGL: Principal Investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; provided lectures for AbbVie, Amgen, Celgene, LEO Pharma, Merck, Novartis, and Pfizer. RBW: Received consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB Pharma; received research grants to his institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, and UCB Pharma; honoraria from Astellas, DiCE, GSK, and Union. ML: Employee of Mount Sinai and receives research funds from: Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB, Inc., and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitatation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. BE: Received research support as funding to Case Western Reserve University from AbbVie, AnaptysBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Incyte, Leo, Eli Lilly, Merck, Menlo, Novartis, Pfizer, Regeneron, Sun Pharma, Valeant and Vanda; Consultant (honoraria) from Arcutis, Boehringer Ingelheim, BMS, Celgene, LEO Pharma, Eli Lilly, Menlo, Novartis, Pfizer, Sun Pharma, UCB, Valeant and Verrica. LP: Employee and shareholder of UCB Pharma. MK and VC: Employees of UCB Pharma. NNG: Employee and shareholder of UCB Pharma. MA: Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, and Xenoport.

ABSTRACT 58

Complete Skin Clearance for Patients With Moderate to Severe Plaque Psoriasis: The Relationship Between Improvements in Psoriasis Area and Severity Index and Health Related Quality of Life

Andrew Blauvelt,[1] Mark Lebwohl,[2] Alice B. Gottlieb,[2] Matthias Augustin,[3] Luis Puig,[4] Paolo Eusebi,[5] Christopher Cioffi,[6] Balint Szilagyi,[7] Susanne Wiegratz,[7] Lars Iversen[8]

[1]Oregon Medical Research Center, Portland, OR, USA; [2]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]Institute for Health Services Research in Dermatology and Nursing (IVDP), University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany; [4]Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Barcelona, Spain; [5]UCB Pharma, Brussels, Belgium; [6]UCB Pharma, Raleigh, NC, USA; [7]UCB Pharma, Monheim, Germany; [8]Department of Dermatology, Aarhus University Hospital, Aarhus, Denmark

LEAD AUTHOR INFORMATION: Andrew Blauvelt MD, MBA: ablauvelt@oregonmedicalresearch.com; please send correspondence to taylor-marie.vasil@costellomedical.com

BACKGROUND: Psoriasis can place a significant burden on patients' health-related quality of life (HRQoL);

it is important to understand the relationship between different levels of clinical response and impact on HRQoL (Blauvelt A, et al. *J Drugs Dermatol* 2020). Here, we assessed the impact of improvements in Psoriasis Area and Severity Index (PASI) on the achievement of Dermatology Life Quality Index (DLQI) 0/1 (no impact of skin disease on the patient's life).

OBJECTIVES: To evaluate the importance of complete skin clearance for patients with moderate to severe plaque psoriasis and to assess the impact of specific, incremental improvements in the PASI on the achievement of a score of 0 or 1 in the DLQI.

METHODS: These analyses used data from the initial 16-week periods of the BE SURE, BE VIVID, BE READY, and BE RADIANT bimekizumab (BKZ) in plaque psoriasis phase 3/3b trials, pooled across all trial visits and treatments (Warren RB, et al. *N Engl J Med* 2021; Reich K, et al. Lancet 2021; Gordon KG, et al. *Lancet* 2021; Reich K, et al. *N Engl J Med* 2021).

A mixed-effects logistic regression model assessed the relationship between skin clearance and DLQI0/1. Estimated DLQI0/1 responses are reported with 95% confidence intervals (CI) for patient subgroups, defined according to specific PASI percentage improvements.

RESULTS: These analyses included 2,223 randomized patients (BKZ: 1,362; placebo: 169; ustekinumab: 163; adalimumab: 159; secukinumab: 370). Mean baseline PASI=20.4; mean baseline DLQI=10.7.

The estimated percentage of patients achieving DLQI0/1 was 85.5% (95% CI: 83.3%, 87.4%) with PASI improvement=100%, 78.6% (75.9%, 81.0%) with PASI improvement=95%, 69.5% (66.5%, 72.3%) with PASI improvement=90%, 58.6% (55.4%, 61.8%) with PASI improvement=85%, 46.8% (43.6%, 50.1%) with PASI improvement=80%, and 35.4% (32.3%, 38.5%) with PASI improvement=75%.

CONCLUSIONS: Incremental PASI improvements translate to higher rates of DLQI0/1. These data highlight the importance of complete skin clearance for patients with plaque psoriasis and suggest that for patients who respond to treatment, but do not achieve complete skin clearance, residual disease may still negatively impact HRQoL.

FUNDING: These studies were funded by UCB Pharma. Medical writing support was provided by Costello Medical.

REFERENCES:

1. Blauvelt A et al. J Drugs Dermatol 2020;19(5):487–92; 2. Warren RB et al. *N Engl J Med* 2021;385:130–41, NCT03412747; 3. Reich K et al. *Lancet* 2021;397:487–98, NCT03370133; 4. Gordon KG et al. *Lancet* 2021;397:475–86, NCT03410992; 5. Reich K et al. *N Engl J Med* 2021;385:142–52, NCT03536884.

DISCLOSURES: AB: Served as a scientific advisor and/or clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, EcoR1, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, and Vibliome; ML: Employee of Mount Sinai and receives research funds from: Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB, Inc., and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitatation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. ABG: Honoraria as an advisory board member and consultant for Anaptyps Bio, Avotres Therapeutics, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sun Pharma, UCB Pharma, and XBiotech (only stock options); research/educational grants (paid to Mount Sinai Medical School) from Boehringer Ingelheim, Incyte, Janssen, Novartis, Sun Pharma, UCB Pharma, and XBiotech. MA: Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, and Xenoport. LP: Received consultancy/speaker's honoraria from and/or participated in trials sponsored by AbbVie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Gebro, Janssen, JS BIOCAD, LEO Pharma, Merck-Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, SamsungBioepis, Sandoz, Sanofi Genzyme, and UCB Pharma. PE: Former employee of UCB Pharma. CC: Employee and shareholder of UCB Pharma. BS: Employee of UCB Pharma. SW: Employee of UCB Pharma. LI: Served as a consultant and/or paid speaker for and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Regranion, Samsung-Bioepis, UCB Pharma, and Union Therapeutics.

ABSTRACT 59

Guselkumab Efficacy and Safety Through 5 Years Among Psoriasis Patients With and Without Metabolic Syndrome at Baseline: Results From VOYAGE 1 and VOYAGE 2

Joseph F. Merola,[1*] Diamant Thaçi,[2] Olivia Choi,[3] Daphne Chan,[3] Ya-Wen Yang,[4] Megan Miller,[5] Yin You,[5] Shu Li,[5] Andrew Blauvelt,[6] Luis Puig[7]

[1]Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA; [2]University of Luebeck, Luebeck, Germany; [3]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [4]Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Horsham, PA, USA; [5]Janssen Research & Development, LLC, Spring House, PA, USA; [6]Oregon Medical Research Center, Portland, OR, USA; [7]Hospital de la Santa Creu i Sant Pau, Autonomous University of Barcelona, Barcelona, Spain

*Presenting author

BACKGROUND: The phase 3 - VOYAGE 1 and 2 studies have demonstrated long-term efficacy and safety of guselkumab (GUS, an interleukin-23 p19 subunit inhibitor) in patients with moderate to severe psoriasis.
OBJECTIVE: To evaluate the long-term efficacy and safety of GUS among patients with and without metabolic syndrome (MetS).
METHODS: Post hoc analyses were conducted among GUS-treated patients (GUS, placebo→GUS, adalimumab→GUS) from VOYAGE 1 and 2 with and without MetS at baseline. MetS was defined as ≥3 of the following: body mass index >30 kg/m2; triglycerides ≥150 mg/dL; high-density lipoprotein (HDL) cholesterol <40/<50 mg/dL (men/women); blood pressure ≥130/85 mmHg; and fasting glucose ≥110 mg/dL. Psoriasis Area and Severity Index (PASI) 90, PASI 100, Investigator's Global Assessment scores of cleared/minimal or cleared (IGA 0/1, IGA 0) through Week 252 were assessed using observed data after applying treatment failure rules. Body weight, blood pressure, and safety through Week 264 were evaluated.
RESULTS: At baseline, 19.4% (334/1721) of patients met criteria for MetS. Although numerically lower proportions of patients with MetS (vs. without MetS, respectively) achieved PASI 90 (77.7%; 83.4%); IGA 0/1 (76.6%; 85.2%); PASI 100 (48.4%; 53.9%); and IGA 0 (50.8%; 56.1%) at Week 252, high levels of efficacy in both groups was observed and maintained over time from Week 100 to Week 252. Mean weight and blood pressure of patients with and without MetS remained stable over time. Safety through Week 264 was generally similar in patients with and without MetS.
CONCLUSIONS: GUS demonstrated high efficacy and durability through 5 years of treatment regardless of baseline MetS status. In addition, among patients with and without MetS, mean weight and blood pressure remained stable over 5 years and no new safety signals were identified.
DISCLOSURES: J.F. Merola has served as a consultant and/or investigator for AbbVie, Arena, Biogen, Bristol-Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma. D. Thaçi has received honoraria for participation on ad boards, as a speaker, and for consultancy from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Dignity, Eli Lilly, Galapagos, GlaxoSmithKline, Janssen, LEO Pharma, Merck Sharp & Dohme, Morphosys, Novartis, Pfizer, Regeneron Pharmaceuticals, Sandoz-Hexal, Sanofi, and UCB Pharma, and has received research grants from Celgene and Novartis. O. Choi and D. Chan are employees of Janssen Scientific Affairs, LLC, Y.-W. Yang is an employee of Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, and M. Miller, Y. You, and S. Li are employees of Janssen Research & Development, LLC; employees own stock in Johnson & Johnson, of which Janssen is a subsidiary. A. Blauvelt has served as a scientific advisor/investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, EcoR1, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, Leo, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, and Vibliome. L. Puig has served as a consultant/speaker and/or participated in clinical trials and has received honoraria/consultation fees and/or grants/research support from Abbvie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Fresenius-Kabi, Janssen, JS BIOCAD, Leo-Pharma, Lilly, Mylan, Novartis, Pfizer, Regeneron, Roche, Samsung-Bioepis, Sandoz, Sanofi, and UCB.

ABSTRACT 60

Malignancy Rates Through 5 Years of Follow-Up in Guselkumab-treated Patients With Moderate to Severe Psoriasis: Results From the VOYAGE 1 and 2 Trials and Comparisons to General Populations

Andrew Blauvelt,[1*] Richard G. Langley,[2] Vincent Ho,[3] Katelyn Rowland,[4] Daphne Chan,[4] Megan Miller,[5] Yin You,[5] Jenny Yu,[5] Ya-Wen Yang,[6] Mark Lebwohl[7]

[1]Oregon Medical Research Center, Portland, OR, USA; [2]Dalhousie University, Halifax, Nova Scotia, Canada; [3]Department of Dermatology and Skin Science, University of British Columbia, Vancouver, BC, Canada; [4]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [5]Janssen Research & Development, LLC, Spring House, PA, USA; [6]Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Horsham, PA, USA; [7]Icahn School of Medicine at Mount Sinai, New York, NY, USA

*Presenting author

BACKGROUND : Surveillance of malignancy risk among patients receiving long-term immunomodulatory treatment remains an important safety objective.
OBJECTIVE: To report malignancy rates in patients with moderate to severe psoriasis treated with guselkumab for up to 5 years versus a representative psoriasis registry population and the general US population.
METHODS: Cumulative rates of malignancies/100 patient-years (PY) were evaluated in 1721 guselkumab-treated patients from VOYAGE-1&2. Overall rates of malignancies excluding nonmelanoma skin cancer (NMSC) were compared with rates among patients eligible for systemic therapy from the Psoriasis Longitudinal Assessment and Registry (PSOLAR; 2007-2014; N=12,093; >40,000 PY) (Papp K, et al. *J Drugs Dermatol.* 2015). Standardized incidence ratios (SIRs; 95%CI) comparing rates of malignancies excluding NMSC and cervical cancer in situ between guselkumab-treated psoriasis patients and the general US population using Surveillance, Epidemiology, and End Results data (2000-2017) were calculated, adjusting for age, sex, and race.
RESULTS: Of 1721 guselkumab-treated patients included in VOYAGE-1&2 (7166PY of follow-up), 24 had NMSC (0.34/100PY) and 32 had malignancies excluding NMSC (0.45/100PY). For comparison, the rate of malignancies excluding NMSC was 0.68/100PY in PSOLAR (Papp K, et al. *J Drugs Dermatol.* 2015). The rate of malignancies (excluding NMSC/cervical cancer in situ) in guselkumab-treated patients was generally consistent with that expected in the general US population [SIR(95%CI)=0.93(0.64-1.31)]; the most commonly

reported malignancies in guselkumab-treated patients were breast [n=6; SIR=1.47(0.54-3.20)], colorectal [n=5; SIR=1.54(0.50-3.59)], melanoma [n=4; SIR=1.32 (0.36-3.39)], and prostate [n=4; SIR=0.59(0.16-1.50)].

CONCLUSIONS: Through 5 years of treatment of psoriasis patients with guselkumab in VOYAGE-1&2, NMSC and other malignancy rates were low. Malignancy rates (excluding NMSC) were generally consistent with rates expected in the general US population and observed in the PSOLAR registry.

DISCLOSURES: A. Blauvelt: Scientific adviser/investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, Leo, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. R. G. Langley: served and has received compensation in the form of grant funding and/or honoraria as principal investigator for and is on the scientific advisory board or has served as a speaker for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sun Pharma, and UCB. V. Ho: Advisory board participant, investigator, and/or speaker for AbbVie, Eli Lilly, Novartis, Janssen, and Sanofi. D. Chan, K. Rowland: Employees of Janssen Scientific Affairs, LLC (a subsidiary of Johnson & Johnson), and own Johnson & Johnson stock/stock options. M. Miller, Y. You, J. Yu: Employees of Janssen Research & Development, LLC (a subsidiary of Johnson & Johnson), and own Johnson & Johnson stock/stock options. Y.-W. Yang: Employee of Janssen Pharmaceutical Companies of Johnson & Johnson; owns Johnson & Johnson stock/stock options. M. Lebwohl: Employee of Mount Sinai and receives research funds from: Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB, Inc., and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Arena Pharmaceuticals, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Brickell Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, CorEvitas, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica.

ABSTRACT 61

Safety of Guselkumab in Patients With Moderate-to-Severe Psoriasis: Pooled Analyses Across Clinical Studies

Mark Lebwohl, MD[1*], Katelyn Rowland, MS, ARNP[2], Megan Miller, MPH[3], Ya-Wen Yang, MD[4], Jenny Yu, MS, MD[3], Yin You[3], Daphne Chan, MS[2] Richard G. Langley, MD[5]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [3]Janssen Research & Development, LLC, Spring House/Horsham, PA, USA; [4]Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Horsham, PA, USA; [5]Dalhousie University, Halifax, Nova Scotia, Canada

*Presenting author

BACKGROUND: Studies of guselkumab in plaque psoriasis have established a favorable safety profile for the drug.

OBJECTIVES: To evaluate the cumulative safety experience in psoriasis using pooled safety data from phase 2/3 studies of guselkumab (CNTO1959PSO2001, CNTO1959PSO3001/3002, CNTO1959PSO3003, CNTO1959PSO3004, CNTO1959PSO3006, and CNTO1959PSO3009). (Gordon KB, et al. *N Engl J Med* 2015; Blauvelt A, et al. J Am Acad Dermatol 2017; Reich K, et al. *J Am Acad Dermatol* 2017; Langley RG, et al. *Br J Dermatol* 2018; Reich K, et al. *Lancet* 2019; Ferris LK, et al. *J Dermatol Treat* 2020; Ohtsuki M, et al. J Dermatol 2018; Reich K, et al. Br J Dermatol 2021).

METHODS: Safety data were summarized for the placebo-controlled (week 0 to16 in CNTO1959PSO2001, CNTO1959PSO3001/3002, and CNTO1959PSO3006) and end-of-reporting (week 0 to 40 for CNTO1959PSO3006; week 16 to 44 for CNTO1959PSO3003; week 0 to 52 for CNTO1959PSO2001 and CNTO1959PSO3004; week 0 to 56 for CNTO1959PSO3009; and through week 264 for CNTO1959PSO3001/3002) periods. Pooled data were adjusted by exposure per 100 patient-years of follow-up [100PY]).

RESULTS: During the placebo-controlled period, 544 patients received placebo (165 PY) and 1220 received guselkumab (378 PY). Adverse event (AE) rates were similar for placebo (341.12/100PY) and guselkumab (345.63/100PY); corresponding serious AE (SAE) rates were 6.66/100PY and 6.34/100PY. Infection rates were 83.61/100PY (placebo) and 95.92/100PY (guselkumab). Serious infections occurred at rates of 1.21/100PY and 1.06/100PY in the placebo and guselkumab groups, respectively. The rate was 0.26/100PY for both nonmelanoma skin cancer (NMSC) and malignancies other than NMSC in the guselkumab group (none in the placebo group). Through the end-of-reporting period (n=2891 patients; 8662 PY), rates remained low for guselkumab-treated patients: 169.02/100PY (AE), 5.26/100PY (SAE), 65.92/100PY (infections), and 0.88/100PY Serious infections . Other AEs of interest rates were 0.43/100PY (malignancies), 0.35/100PY (NMSC), and 0.33/100PY (Major Adverse Cardiac Events). In guselkumab-treated

patients, there were no reported active tuberculosis or opportunistic infections; no serum sickness-like/anaphylactic reactions related to guselkumab were reported.

CONCLUSIONS: Pooled analyses confirm the established safety profile of guselkumab for patients treated for up to 5 years.

DISCLOSURES: Mark Lebwohl: An employee of Mount Sinai and receives research funds from: Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB, Inc., and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Arena Pharmaceuticals, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Brickell Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, CorEvitas, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. Katelyn Rowland, Daphne Chan: An employee of Janssen Scientific Affairs, LLC, and owns stocks in Johnson & Johnson. Megan Miller, Jenny Yu, and Yin You: An employee of Janssen Research & Development, LLC, and owns stocks in Johnson & Johnson. Ya-Wen Yang: An employee of Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, and owns stocks in Johnson & Johnson. Richard G. Langley: Served/received compensation in the form and or Honoria as Principle I investigator for/or on the scientific advisory board/ or served as a speaker for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Janssen, LEO Pharma, Eli Lilly, Merck, Novartis, Pizer, Sun Pharmaceutical, and UCB Pharma

ABSTRACT 62

Social Relationships, Sexual Difficulty, and the Impact of Treatment With Guselkumab Versus Adalimumab in Men and Women With Psoriasis: Results From VOYAGE 1 and 2

April Armstrong, MD, MPH[1*], Yi-hsuan Liu, PhD[2], Ya-Wen Yang, PhD[3], Ru-fong Cheng, MD[4], Megan Miller, MPH[5], Luis Puig, MD, PhD[6], Kim A. Papp, MD, PhD[7], Jenny E. Murase, MD[8], Pablo Fernández-Peñas, MD[9], Chenglong Han, MD, PhD[2]

[1]Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; [2]Janssen Global Services, LLC, Raritan, NJ/Malvern, PA, USA; [3]Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Horsham, PA, USA; [4]Women's Health, Office of the Chief Medical Officer, Johnson & Johnson, New Brunswick, NJ, USA; [5]Janssen Research & Development, LLC, Spring House, PA, USA; [6]Hospital de la Santa Creu i Sant Pau, Autonomous University of Barcelona, Barcelona, Spain; [7]K Papp Clinical Research and Probity Research, Inc., Waterloo, ON, Canada; [8]University of California San Francisco, San Francisco, CA, USA and Palo Alto Foundation Medical Group, Mountain View, CA, USA; [9]Sydney Medical School, Department of Dermatology, Westmead Hospital, Westmead, New South Wales, Australia

*Presenting author:

BACKGROUND: In psoriasis patients social relationship difficulty and sexual difficulty has been reported.

OBJECTIVES: To evaluate the impact of guselkumab or adalimumab on social relationship difficulty and sexual difficulty in psoriasis patients.

METHODS: Patients received guselkumab Week 0, Week 4, then every eight weeks (Q8W) versus placebo (Week 16→guselkumab) or adalimumab for moderate-to-severe plaque-type psoriasis. (Blauvelt A, et al. *J Am Acad Dermatol* 2017; Reich K, et al. *J Am Acad Dermatol* 2017). Social relationship difficulty and sexual difficulty were measured using Dermatology Life Quality Index questions 8 and 9, respectively, under the personal relationship domain. Psoriasis Area and Severity Index (PASI) was used to assess the severity.

RESULTS: At baseline, patients with higher PASI scores tended to have greater social relationship difficulty and sexual difficulty, with females reporting greater impairment than males across most PASI scores. After treatment, the proportion of males and females having social relationship difficulty or sexual difficulty declined from baseline to Week 24 with greater improvements in PASI response. Across groups at baseline, 31.2% to 34.9% of males and 38.9% to 44.1% of females had social relationship difficulty. At Week 16, greater improvements in social relationship difficulty were achieved with guselkumab and adalimumab versus placebo in males (placebo 26.7%, guselkumab 2.6%, adalimumab 6.0%; both $p<0.001$) and females (placebo 28.5%, guselkumab 3.0%, adalimumab 11.7%; both $p<0.001$). At Week 24, greater improvements in social relationship difficulty were achieved with guselkumab versus adalimumab in males (guselkumab 1.5%, adalimumab 5.5%; $p<0.001$) and females (guselkumab 3.8%, adalimumab 14.1%; $p<0.001$). Similar patterns were observed for sexual difficulty in males and females.

CONCLUSIONS: Social relationship difficulty and sexual difficulty improved as PASI improved. Despite differences at baseline, males and females with psoriasis treated with guselkumab or adalimumab reported significantly greater improvement in social relationship difficulty and sexual difficulty at W16 versus placebo. The effect of guselkumab on social relationship difficulty and sexual difficulty was maintained and was greater versus adalimumab at Week 24.

DISCLOSURES: April Armstrong has served as a Research investigator and/or consultant to AbbVie, Janssen, Lilly, Leo, Novartis, UCB, Ortho Dermatologics, Dermira, KHK, Sanofi, Regeneron, Sun Pharma, BMS, Dermavant, and Modernizing Medicine. Yi-hsuan Liu and Chenglong Han are employees of Janssen Global services, LLC. Ya-Wen Yang is an employee of Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson; employees own stock in Johnson & Johnson, of which Janssen is a subsidiary. Ru-fong Cheng is an employee of Women's Health, Office of the Chief Medical Officer, Johnson & Johnson. Megan Miller is an employee of Janssen Research & Development, LLC. Luis Puig has served consultant/speaker and/or participated in clinical trials and has received honoraria/consultation fees and/or grants/research support from Abbvie, Almirall, Amgen, Baxalta,

Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Fresenius-Kabi, Janssen, JS BIOCAD, Leo-Pharma, Lilly, Mylan, Novartis, Pfizer, Regeneron, Roche, Samsung-Bioepis, Sandoz, Sanofi, and UCB. Kim A. Papp received clinical research grants and/or honoraria as a consultant, and/or speaker, and/or investigator, and/or scientific officer, and/or advisory board member, and/or Steering Committee member for AbbVie, Akros, Amgen, Anacor, Arcutis, Astellas, Avillion, Bausch Health/Valeant, Baxalta, Boehringer Ingelheim, Bristol-Myers Squibb, Can-Fite Biopharma, Celgene, Coherus, Dermavant, Dermira, Dow Pharma, Eli Lilly, Evelo, Galapagos, Galderma, Gilead, GSK, Incyte, Janssen, Kyowa Hakko Kirin, Leo, Medimmune, Meiji Seika Pharma, Merck (MSD), Merck- Serono, Mitsubishi Pharma, Moberg Pharma, Novartis, Pfizer, PRCL Research, Regeneron, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda and UCB. Jenny E. Murase has served on Advisory Boards for Sanofi/Genzyme, UCB, Leo Pharma, Eli Lilly; as a consultant for UpToDate; and as a non-branded Speaker for Regeneron and UCB. Pablo Fernández-Peñas has received clinical research grants and/or honoraria as a consultant, and/or speaker, and/or investigator, and/or scientific officer, and/or advisory board member, and/or Steering Committee member for AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, CSL, Eli Lilly, Eisai, Galderma, GlaxoSmithKline, Janssen, Jiangsu Hengrui, Kyowa Hakko Kirin, La Roche Posay, LEO Pharma, Merck (MSD), Merck- Serono, miRagen, Novartis, Oncosec, Pfizer, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, and UCB Pharma.

ABSTRACT 63

Patient Demographics and Disease Characteristics of Psoriasis Patients From The US Ixekizumab Customer Support Program

[1]Alice B. Gottlieb, MD, PhD, [2,3]Russel Burge, PhD,[2]William N. Malatestinic, PharmD, MBA, [2]Baojin Zhu, PhD, [2]Jiaying Guo, PhD, [4]Julie McCormack, MA, [4]Miriam Kimel, PhD, [2]Scott A. Lawrence, PhD

[1]Icahn School of Medicine at Mt Sinai, New York, NY; United States, [2] Eli Lilly and Company, Indianapolis, IN, United States, [3]University of Cincinnati, Cincinnati, OH, United States, [4]Evidera, Bethesda, MD

CORRESPONDING AUTHOR: [1]Alice B. Gottlieb

BACKGROUND: Ixekizumab (IXE), a highly selective interleukin (IL)-17A monoclonal antibody, has been approved for treatment of psoriasis (PsO). No large US databases capture key clinical, quality of life (QOL), or patient-reported outcome (PRO) data shortly after treatment initiation, nor do they add to our understanding of patient needs and expectations, influencing decisions to stay on therapy. Data collection from IXE PsO patients in the US Taltz customer support program (CSP) was initiated to fill this gap, allowing key physician and patient related IXE questions focused on clinical, QOL, and PRO measures to be answered.

TABLE 1. Breakdown of patient screening, enrollment and exclusions

Patient breakdown (November 13, 2020 to December 17, 2021)		
Number of participants screened	**830**	**100.0%**
Inclusion and exclusion status	**N**	**% Screened**
Met inclusion criteria	**621**	**74.8%**
Did not complete consent form[1]	68	11.0%
Did not consent to participate[2]	14	2.3%
Consented to participate	539	86.8%
Did not meet inclusion criteria	**188**	**22.7%**
Taltz initiated ≥ 8 day (revised exclusion)	92	48.9%
Treated with Taltz before enrolling in the Taltz Customer Support Program	62	33.0%
Taltz initiated > 3 days (initial exclusion)	30	16.0%
Less than 18 years in most states, 19 years in Alabama & Nebraska, and 21 in Mississippi	2	1.1%
Did not have access to a smartphone/iPhone or computer with internet access to complete a web-based survey	2	1.1%
Missing data to determine eligibility	21	2.5%

[1]Did not complete consent form: the potential participant did not check either consent or do not consent (i.e., closed out of the survey)

[2]Did not consent to participate': the potential participant checked a box that they do not consent ("I do not consent to partipate")

TABLE 2. Baseline Patient Demographics and Clinical Characteristics

Characteristic	N=528	
Age	Mean (SD)	47.6 (±12.1)
Gender	Female	334 (63.4%)
	Male	193 (36.6%)
Duration of Psoriasis (Years)	n	525
	Mean (SD)	16.4 (±13.9)
PREPI Category[1]	n	525
	Very few patches (Score =0)	17 (3.2%)
	A few patches (Score =1, 2)	163 (31.1%)
	Scattered patches (Score =3, 4)	90 (17.1%)
	More scattered patches (Score =5-10)	133 (25.3%)
	Extensive patches (Score =11-20)	71 (13.5%)
	Very extensive patches (Score >20)	51 (9.7%)
Itch NRS[2]	n	517
	Mean (SD)	5.3 (±2.7)
Skin Pain NRS[3]	n	517
	Mean (SD)	4.3 (±2.8)
PROMIS® Short Form v1.0 - Sleep-Related Impairement[4]	n	514
	Mean (SD)	10.3 (±4.4)
DLQI Total Score[5]	n	513
	Mean (SD)	9.8 (±6.9)
Patient Global Assessment of Disease Severity (PatGA), 0 (Clear) to 5 (Severe)	n	512
	Score = 0	14 (2.7%)
	Score = 1	54 (10.6%)
	Score = 2	76 (14.8%)
	Score = 3	146 (28.5%)
	Score = 4	110 (21.5%)
	Score = 5	112 (21.9%)
Patient Importance Questionnaire (PIQ) 1: Psoriasis is clear or almost clear	n	516
	Not at all important =0	3 (0.6%)
	Slightly important = 1	8 (1.6%)
	Somewhat important = 2	31 (6.0%)
	Moderately important = 3	89 (17.3%)
	Extremely important = 4	385 (74.6%)
PSQ 2: Psoriasis clears quickly	n	516
	Not at all important =0	4 (0.8%)
	Slightly important = 1	20 (3.9%)
	Somewhat important = 2	105 (20.4%)
	Moderately important = 3	173 (33.5%)
	Extremely important = 4	214 (41.5%)

CONTINUED ON NEXT PAGE

TABLE 2. continued

PIQ 3: Psoriasis stays clear or almost clear while taking medication	n	516
	Not at all important =0	3 (0.6%)
	Slightly important = 1	6 (1.2%)
	Somewhat important = 2	20 (3.9%)
	Moderately important = 3	119 (23.1%)
	Extremely important = 4	368 (71.3%)
PIQ 4: Skin is not itchy	n	516
	Not at all important =0	8 (1.6%)
	Slightly important = 1	9 (1.7%)
	Somewhat important = 2	37 (7.2%)
	Moderately important = 3	96 (18.6%)
	Extremely important = 4	366 (70.9%)
PIQ 5: Skin is not painful	n	515
	Not at all important =0	7 (1.4%)
	Slightly important = 1	12 (2.3%)
	Somewhat important = 2	35 (6.8%)
	Moderately important = 3	96 (18.6%)
	Extremely important = 4	365 (70.9%)
PIQ 6: No unwanted effects (side effects)	n	517
	Not at all important =0	4 (0.8%)
	Slightly important = 1	13 (2.5%)
	Somewhat important = 2	65 (12.6%)
	Moderately important = 3	160 (31.0%)
	Extremely important = 4	275 (53.2%)
PSQ 7: Medication is easy to use	n	517
	Not at all important =0	12 (2.3%)
	Slightly important = 1	30 (5.8%)
	Somewhat important = 2	107 (20.7%)
	Moderately important = 3	157 (30.4%)
	Extremely important = 4	211 (40.8%)
PSQ 8: Medication is convenient to use	n	517
	Not at all important =0	10 (1.9%)
	Slightly important = 1	37 (7.2%)
	Somewhat important = 2	106 (20.5%)
	Moderately important = 3	164 (31.7%)
	Extremely important = 4	200 (38.7%)

[1]PREPI Category: Patients were instructed to take the palm of their hand and determine how many palms would cover their PsO patches

[2]Itching severity due to psoriasis in the past 24 hours selecting a number from 0-10, 10 being the worst itch imaginable

[3]Pain severity due to psoriasis in the past 24 hours selecting a number from 0-10, 10 being the worst pain imaginable

[4]PROMIS® Short Form v1.0 - Sleep-Related Impairment Scale from 1 (Not at all) to 5 (Very much)

[5]DLQI Total Score ranges from 0 to 30; higher scores reflect more impaired quality of life

OBJECTIVES: This abstract describes baseline characteristics of 528 IXE CSP patients and IXE treatment attributes.
METHODS: This is a 24-week prospective, observational study of commercially-insured patients enrolled in the US CSP program for IXE Treatment. CSP enrollment decisions were independent of this study. Enrollees were included based on IXE initiation ≤7 days, and >18 years old. Participants were required to access the internet to fill in questionnaires at baseline and Weeks 2, 4, 8, 12, and 24. Demographic and clinical characteristics; Pain Numeric Rating Scale (NRS) and Itch NRS; PROMIS® Short Form v1.0 -Sleep-Related Impairment; Dermatology Life Quality Index (DLQI); Patient Global Assessment of Disease Severity (PatGA); Patient Report of Extent of Psoriasis Involvement (PREPI) (Finlay and Khan, Clin Exp Dermatol.1994; Dommasch, et al. *Br J Dermatol.* 2010) and patient importance questionnaires (PIQ) were collected. Descriptive statistics are reported.
RESULTS: A total of 830 CSP enrollees were screened (Table 1). Of those, 528 patients were included in this study. The majority were female (63.4%), average of 47.6 (±12.1) years with PsO for 16.4 (±13.9) years. Based on the PREPI score, most patients reported "A few patches" (Score 1,2) (n=163, 31.1%), followed by "More scattered patches" (Score=5-10) (n=133, 25.3%) of psoriatic lesions (Table 2). The most common comorbidities included psoriatic arthritis (PsA) (n=287, 54.7%), obesity (n=184, 35.1%), anxiety (n=175, 33.3%), hypertension (n=157, 29.9%) and depression (n=134, 25.5%). The majority of patients (n=504, 96.0%) had used medications for PsO in the past two years, with 34.9% of patients using biologics most recently before initiating IXE. Average DLQI score was 9.8 (±6.9) (Table 2). Prior to IXE therapy initiation, skin clearance was the most important therapy feature, and "extremely important" to 74.6% of patients (PIQ1, Table 2).
CONCLUSIONS: Data collected from this CSP program indicate that this patient population has similar demographic, disease history, prior biologic use, and baseline PROs to those observed from clinical trials (Gordon, et al. N Engl J Med. 2016). Thus, utilizing the IXE US CSP appears to be a relevant approach for collecting real world data on IXE PsO patients.

REFERENCES:

Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. *Clin Exp Dermatol.* 1994 May;19(3):210-6. doi: 10.1111/j.1365-2230.1994.tb01167.x. PMID: 8033378

Dommasch ED, Shin DB, Troxel AB, Margolis DJ, Gelfand JM. Reliability, validity and responsiveness to change of the Patient Report of Extent of Psoriasis Involvement (PREPI) for measuring body surface area affected by psoriasis. *Br J Dermatol.* 2010 Apr;162(4):835-42. doi: 10.1111/j.1365-2133.2009.09589.x. Epub 2009 Nov 10. PMID: 19906216; PMCID: PM

Gordon KB, Blauvelt A, Papp KA, Langley RG, Luger T, Ohtsuki M, Reich K, Amato D, Ball SG, Braun DK, Cameron GS, Erickson J, Konrad RJ, Muram TM, Nickoloff BJ, Osuntokun OO, Secrest RJ, Zhao F, Mallbris L, Leonardi CL; UNCOVER-1 Study Group; UNCOVER-2 Study Group; UNCOVER-3 Study Group. Phase 3 Trials of Ixekizumab in Moderate-to-Severe Plaque Psoriasis. *N Engl J Med.* 2016 Jul 28;375(4):345-56. doi: 10.1056/NEJMoa1512711. Epub 2016 Jun 8. PMID: 27299809.

FUNDING: Funded by Eli Lilly and Company.

ABSTRACT 64

Pooled Efficacy and Safety Results From the DERMIS-1 and DERMIS-2 Phase 3 Trials of Once-Daily Roflumilast Cream 0.3% by Baseline Body Surface Area

Linda Stein Gold[1], Jerry Bagel[2], James Del Rosso[3], Lawrence J. Green[4], Mark Lebwohl[5], Leon H. Kircik[6], Amy Feng[7], Scott Snyder[7], Robert C. Higham[7], Patrick Burnett[7], David R. Berk[7]

[1]Henry Ford Medical Center, Detroit, MI, USA; [2]Psoriasis Treatment Center of Central New Jersey, Windsor, NJ, USA; [3]JDR Dermatology Research Center, Las Vegas, NV, USA; [4]George Washington University School of Medicine, Rockville, MD, USA; [5]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [6]Icahn School of Medicine at Mount Sinai, New York, NY, Indiana Medical Center, Indianapolis, IN, Physicians Skin Care, PLLC, Louisville, KY, and Skin Sciences, PLLC, Louisville, KY, USA; [7]Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

BACKGROUND: Roflumilast cream 0.3% is a selective and potent phosphodiesterase-4 inhibitor under investigation as a once-daily treatment for psoriasis.
OBJECTIVES: Here we describe pooled efficacy and safety results from two identical Phase 3 randomized controlled trials of roflumilast cream (DERMIS-1: NCT04211363 and DERMIS-2: NCT04211389) analyzed by baseline body surface area (BSA) affected (<5%, 5%-10%, or >10%).
METHODS: Patients (≥2 years) with psoriasis involving 2-20% BSA were randomized to roflumilast (n=576) or vehicle (n=305) for 8 weeks.
RESULTS: Overall, significantly more roflumilast- vs. vehicle-treated patients achieved the primary efficacy endpoint of Investigator Global Assessment (IGA) Success (Clear or Almost Clear IGA status plus ≥2-grade improvement from baseline) at Week 8 (39.9% vs. 6.5%; $P<0.0001$). More roflumilast-treated patients achieved IGA Success at Week 8 with generally consistent rates (36.5%-46.7% with roflumilast vs. 1.8%-8.5% with vehicle) across all BSA categories ($P<0.0001$ for all). Differences favoring roflumilast were also observed for percentages achieving 75% reduction in Psoriasis Area Severity Index (38.1%-47.8% with roflumilast vs. 1.8%-9.4% with vehicle) across all BSA categories. Percentages with baseline Worst Itch-Numeric Rating Scale ≥4 achieving a 4-point reduction favored roflumilast ($P\leq0.0001$ for all BSA subgroups). Overall incidence of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation were low with similar rates between roflumilast and vehicle. Local tolerability was highly favorable on patient and investigator assessments.
CONCLUSION: Once-daily roflumilast cream 0.3% provided improvement across multiple efficacy endpoints and favorable safety and tolerability in patients with psoriasis across two Phase 3 trials regardless of baseline BSA.

ABSTRACT 65

Pooled Efficacy and Safety Results From the DERMIS-1 and DERMIS-2 Phase 3 Trials of Once-Daily Roflumilast Cream 0.3% for Treatment of Chronic Plaque Psoriasis

Mark Lebwohl[1], Melinda J. Gooderham[2], Scott T. Guenthner[3], H. Chih-ho Hong[4], Leon H. Kircik[5], Angela Y. Moore[6], Matthew Zirwas[7], Amy Feng[8], Robert C. Higham[8], Patrick Burnett[8], David R. Berk[8]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]SkiN Centre for Dermatology, Probity Medical Research and Queen's University, Peterborough, ON, Canada; [3]The Indiana Clinical Trials Center, PC, Plainfield, IN, USA; [4]University of British Columbia, Vancouver, BC, and Probity Medical Research, Surrey, BC, Canada; [5]Icahn School of Medicine at Mount Sinai, New York, NY, Indiana Medical Center, Indianapolis, IN, Physicians Skin Care, PLLC, Louisville, KY, and Skin Sciences, PLLC, Louisville, KY, USA; [6]Arlington Research Center, Arlington, TX, USA, Baylor University Medical Center, Dallas, TX, USA; [7]Dermatologists of the Central States, Probity Medical Research, and Ohio University, Bexley, OH, USA; [8]Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

BACKGROUND: Roflumilast cream 0.3% is a selective, highly potent phosphodiesterase-4 inhibitor being investigated as a nonsteroidal, once-daily treatment for psoriasis.

OBJECTIVES: Here we describe pooled efficacy and safety results from two identical Phase 3 randomized controlled trials of roflumilast cream (DERMIS-1: NCT04211363 and DERMIS-2: NCT04211389).

METHODS: Patients with psoriasis involving 2-20% of body surface area (aged ≥2 years) were randomized to roflumilast (n=576) or vehicle (n=305) for 8 weeks.

RESULTS: Significantly greater percentages of roflumilast-treated versus vehicle-treated patients achieved the primary efficacy endpoint, Investigator Global Assessment (IGA) Success (Clear or Almost Clear IGA plus ≥2-grade improvement from baseline) at Week 8 (39.9% vs. 6.5%; $P<0.0001$) and had IGA of Clear/Almost Clear at Week 8 (48.0% vs. 9.5%; $P<0.0001$). Statistically significant differences favoring roflumilast were observed for multiple secondary endpoints at Week 8: percentages of patients achieving intertriginous-IGA Success (69.7% vs. 16.1%; $P=0.0025$), percentages achieving 75% reduction in Psoriasis Area Severity Index (40.3% vs. 6.5%; $P<0.0001$), and percentages with baseline Worst Itch-Numeric Rating Scale (WI-NRS) ≥4 achieving a 4-point reduction (68.5% vs. 31.3%; $P<0.0001$). Differences in WI-NRS for roflumilast- versus vehicle-treated patients were significant as early as 2 weeks (38.4% vs. 21.6%; $P<0.001$). Overall incidence of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation were low and similar between roflumilast and vehicle. Local tolerability was highly favorable on patient and investigator assessments.

CONCLUSION: Once-daily roflumilast cream 0.3% provided superior improvement across multiple efficacy endpoints by Week 8 and favorable safety and tolerability in patients with psoriasis in two Phase 3 trials.

ABSTRACT 66

Efficacy and Safety of Once-Daily Roflumilast Cream 0.3% in Patients With Knee/Elbow Involvement: Pooled Results From Phase 3 Trials (DERMIS-1 and DERMIS-2)

Laura K. Ferris[1], Zoe D. Draelos[2], Adelaide A. Hebert[3], Charles W. Lynde[4], David M. Pariser[5], Kim A. Papp[6], Paul S. Yamauchi[7], Amy Feng[8], Robert C. Higham[8], Patrick Burnett[8], David R. Berk[8]

[1]University of Pittsburgh, Department of Dermatology, Pittsburgh, PA, USA; [2]Dermatology Consulting Services, High Point, NC, USA; [3]UT Health McGovern Medical School, Houston, TX, USA; [4]Lynderm Research Inc., Markham, ON, Canada; 5Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, VA, USA; 6Probity Medical Research and K Papp Clinical Research, Waterloo, ON, Canada; 7David Geffen School of Medicine at UCLA, Los Angeles, and Dermatology Institute & Skin Care Center, Inc., Santa Monica, CA, USA; 8Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

BACKGROUND: Roflumilast cream 0.3% is a selective and potent phosphodiesterase-4 inhibitor under investigation as a once-daily treatment for psoriasis. Psoriatic plaques on the knees/elbows can be challenging to treat due to thicker stratum corneum, which impedes topical absorption.

OBJECTIVES: We present pooled efficacy results from a post-hoc analysis of the subgroup of patients with knee and/or elbow involvement from two identical Phase 3 randomized controlled trials of roflumilast (DERMIS-1: NCT04211363 and DERMIS-2: NCT04211389).

METHODS: Patients (≥2 years) with psoriasis involving 2-20% of body surface area were randomized to roflumilast (n=576) or vehicle (n=305) for 8 weeks. Three-quarters (76.3%) of patients had knee/elbow involvement at baseline (roflumilast: n=446 [77.4%]; vehicle: n=226 [74.1%]).

RESULTS: More roflumilast-treated than vehicle-treated patients achieved the primary efficacy endpoint of Investigator Global Assessment (IGA) Success (Clear or Almost Clear IGA status plus ≥2-grade improvement from baseline) at Week 8 (41.2% vs. 5.1%; $P<0.0001$). Almost half (48.6%) of roflumilast-treated patients with knee/elbow involvement achieved IGA of Clear/Almost Clear at Week 8 versus 7.6% of vehicle-treated patients ($P<0.0001$). At all post-baseline timepoints, more roflumilast-treated patients with knee/elbow involvement and baseline Worst Itch-Numeric Rating Scale ≥4 achieved a ≥4-point reduction ($P<0.0001$). Overall incidence of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation were low with similar rates between roflumilast and vehicle. Local tolerability was highly favorable on patient and investigator assessments.

CONCLUSION: Once-daily roflumilast cream 0.3% provided improvement across multiple efficacy endpoints in psoriasis patients with knee/elbow involvement in two Phase 3 trials.

ABSTRACT 67

Long-term Safety and Efficacy of Roflumilast Cream 0.3% in Patients With Chronic Plaque Psoriasis: Interim Results From A 24-week, Phase 3 Open-label Study

Kim A. Papp[1], David N. Adam[2], Melinda J. Gooderham[3], Lawrence J. Green[4], Mark Lebwohl[5], Angela Y. Moore[6], David M. Pariser[7], Amy Feng[8], Robert C. Higham[8], Patrick Burnett[8], David R. Berk[8]

[1]Probity Medical Research and K Papp Clinical Research, Waterloo, ON, Canada; [2]CCA Medical Research, Probity Medical Research and Temerty Faculty of Medicine, University of Toronto, Toronto, ON, Canada; [3]SkiN Centre for Dermatology, Probity Medical Research and Queen's University, Peterborough, ON, Canada; [4]George Washington University School of Medicine, Washington, DC, USA; [5]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [6]Arlington Research Center, Arlington, TX, and Baylor University Medical Center, Dallas, TX, USA; [7]Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, VA, USA; [8]Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

BACKGROUND: Roflumilast cream is a selective, highly potent phosphodiesterase-4 inhibitor under investigation as a non-steroidal, once-daily treatment for psoriasis. A phase 3, 24-week, open-label extension (DERMIS-OLE; NCT04286607) is being conducted in patients (aged ≥2 years) with psoriasis who successfully completed a prior roflumilast cream trial (Cohort-1) and patients (aged ≥2-17 years) naïve to roflumilast/vehicle (Cohort-2).

OBJECTIVES: Explain the safety and efficacy results in this phase 3, 24-week, open-label safety trial of roflumilast cream for the treatment of psoriasis.

METHODS: We present interim results from Cohort-1, comprising 264 patients from two 8-week phase 3 studies.

RESULTS: As of December 2020, 84.1% of Cohort-1 completed the trial, 3.8% were ongoing, and 12.1% discontinued. One (0.4%) patient discontinued due to an adverse event (AE). Overall, 69 (26.1%) patients experienced a treatment-emergent AE; most were mild or moderate. One AE was considered likely treatment-related and 3 were possibly related; none were serious. Investigator tolerability assessments demonstrated ≥96.3% of patients had "no evidence of irritation" at each visit. At Week 24 of the OLE, key efficacy results were: 50.0% of patients had Investigator Global Assessment (IGA) status of Clear/Almost Clear, >75% of patients with intertriginous-IGA of at least Mild (≥2) at Baseline achieved intertriginous-IGA Success, 43.8% of patients had 75% reduction on the Psoriasis Area and Severity Index, and 62.4% of patients achieved 4-point improvement on the Worst Itch-Numeric Rating Scale from a baseline of ≥4. With cumulative treatment up to 32 weeks (including parent trial), safety and tolerability were consistent with the previous phase 2, 52-week trial.

CONCLUSION: In this long-term safety trial, roflumilast cream demonstrated excellent tolerability with no unexpected AEs and effectively maintained Clear/Almost Clear skin.

ABSTRACT 68

Cutaneous Absorption of Combined Topical Halobetasol Propionate and Tazarotene Treatment

Linda Stein Gold,[1] Emil A. Tanghetti,[2] Adam J. Friedman,[3] Abby Jacobson[4]

[1]Henry Ford Health System, West Bloomfield, MI; [2]Center for Dermatology and Laser Surgery, Sacramento, CA; [3]George Washington School of Medicine and Health Sciences, Washington, DC; [4]Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

BACKGROUND: Adequate cutaneous permeation is essential for topical therapeutics to achieve optimal bioavailability. Some patients with psoriasis require the use of multiple topical agents simultaneously. However, topical layering may impede the permeation of active agents. Moreover, it may be challenging for patients to adhere to such regimens.

OBJECTIVES: To review the cutaneous permeation of halobetasol propionate (HP) and tazarotene (TAZ) in the context of the clinical efficacy of fixed-combination HP/TAZ lotion for plaque psoriasis.

METHODS: Percutaneous permeation of HP 0.05% cream, TAZ 0.1% cream, and HP 0.01%/TAZ 0.045% lotion across human donor tissue was assessed via liquid chromatography-mass spectrometry of receptor phase samples collected over 24 hours.

RESULTS: Receptor phase concentrations at 24 hours were greater with TAZ alone (0.010%) compared with TAZ layered over HP (0.002%). Residual TAZ in the epidermis was lower with TAZ alone (7.60%) versus TAZ layered over HP cream (8.99%). Conversely, dermal deposition of TAZ was greatest with TAZ alone (3.80%) versus under-layered HP cream with TAZ (2.26%). Compared with fixed-combination HP/TAZ, residual epidermal TAZ was lower with TAZ application alone (10.80% vs 18%, respectively). In another analysis, residual HP in the epidermis was lower with HP alone (1.72%) vs HP/TAZ (4.97%) and dermal deposition of HP was also lower with HP monad vs HP/TAZ (3.34% vs 6.82%).

CONCLUSIONS: The layered application of separate HP and TAZ topicals may result in lower-than-expected drug bioavailability. Conversely, the ability of fixed-combination HP/TAZ to permeate skin may enhance its bioavailability and could contribute to the higher rates of treatment success at week 8 compared with monads in clinical studies of plaque psoriasis (HP/TAZ: 52.5%; HP: 33.3%; TAZ: 18.6%). The convenience of a combination topical compared with layering may also encourage treatment adherence. Considering the permeation data and its clinical efficacy, fixed-combination HP/TAZ is a practical and effective alternative to topical layering for patients requiring dual topical therapy.

ABSTRACT 69

Prevalence, Severity, and Impact of Fatigue in Psoriasis Patients With and Without Self-reported Psoriatic Arthritis

Khattri, Saakshi, MD,[1] Yang, YW, MD,[2] Fitzgerald, Timothy, PhD,[3] Janak, Judson, PhD,[4] Teneralli, Rachel E., PhD, MS,[3] Sima, Adam, PhD,[4] Lesser, Elizabeth, MS,[4] Merola, Joseph F., MD, MMSc,[5]

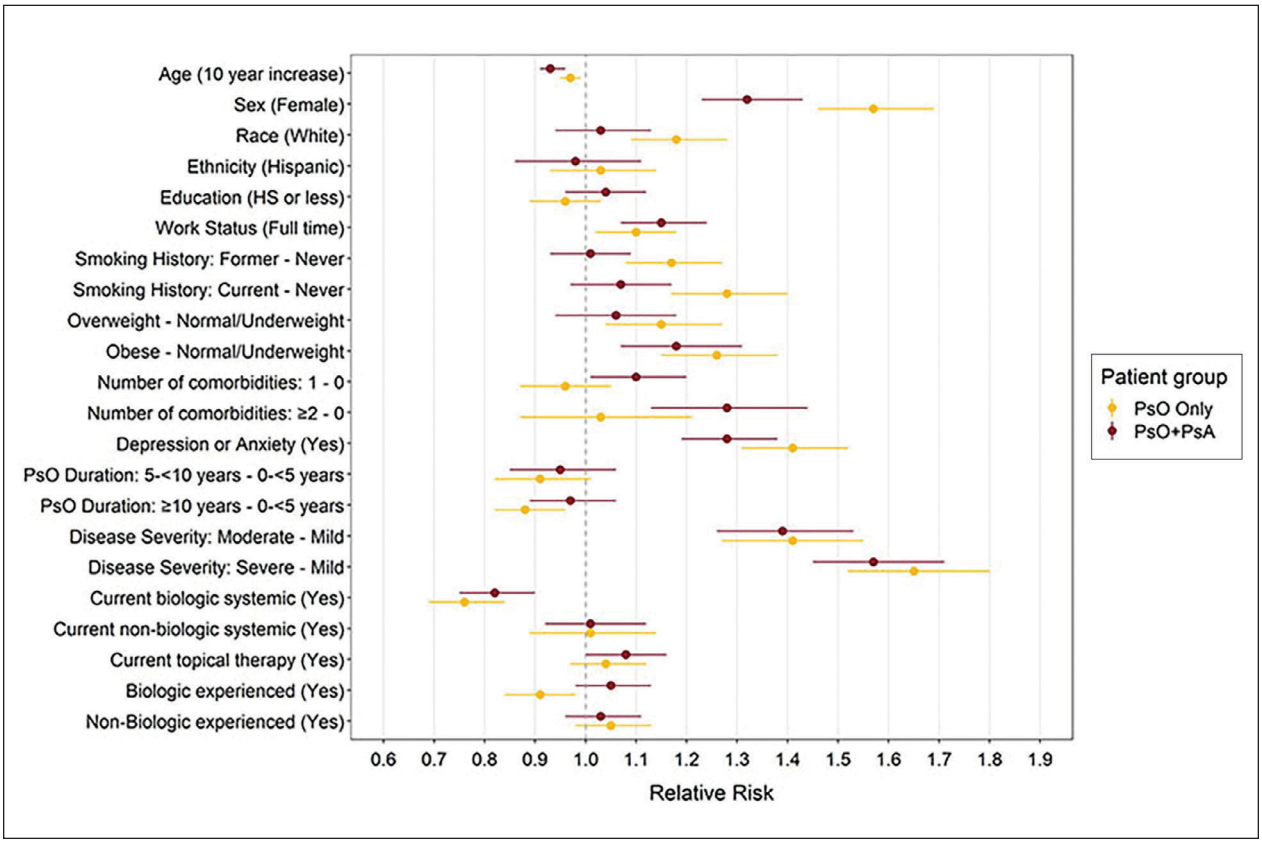
[1]Mt. Sinai Medical Center, New York, NY; [2]Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, LLC, Horsham, PA, USA; [3]Janssen Scientific Affairs, LLC, Horsham, PA; [4]CorEvitas, LLC, Waltham, MA; [5]Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA

BACKGROUND: Fatigue is commonly reported both in plaque psoriasis (PsO) patients (pts) and psoriatic arthritis (PsO+PsA) pts), however is not as well-characterized in the PsO-only patient population. Few studies delineate differences between these two patient populations; therefore, a need exists to better understand fatigue in PsO and PsO+PsA pts independently.

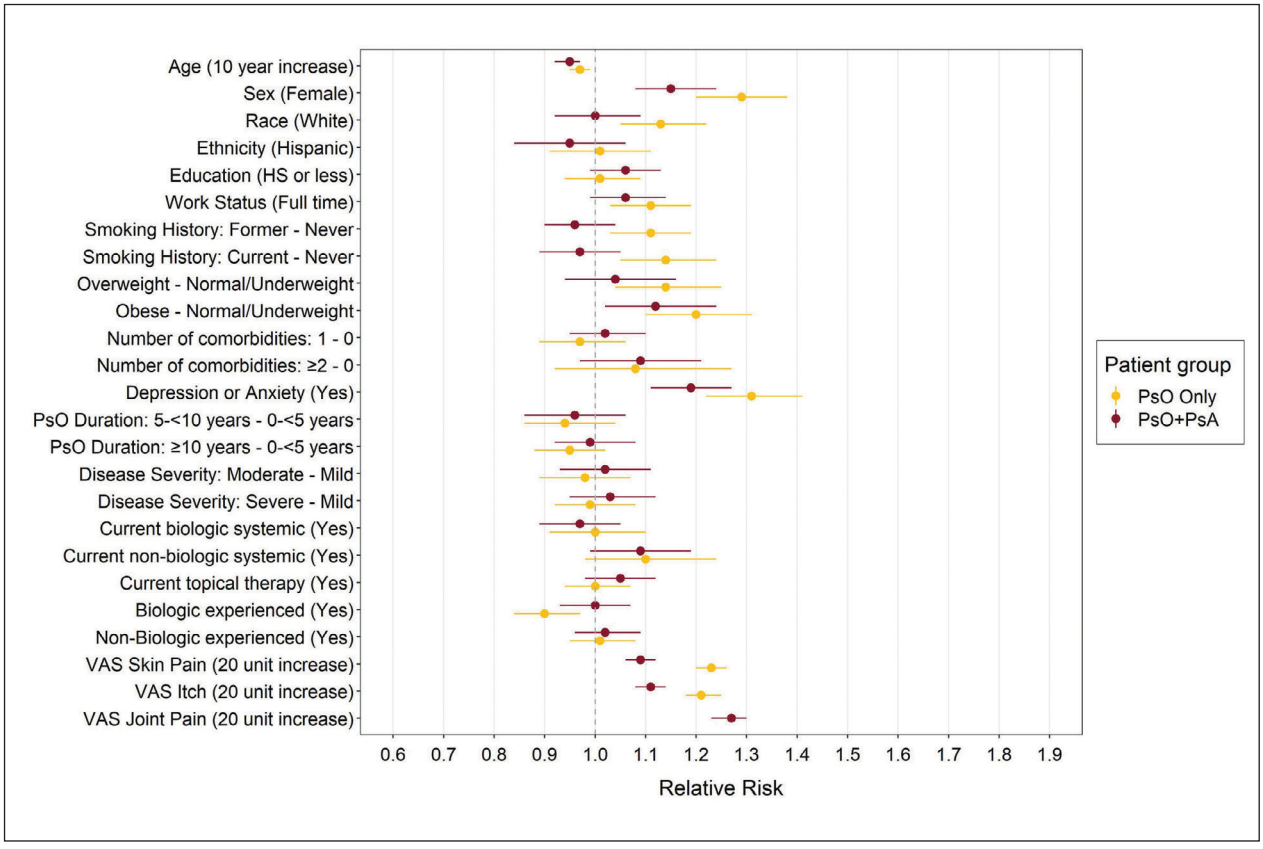
OBJECTIVES: Determine the prevalence of fatigue and assess factors associated with severity of fatigue among patients with PsO or PsO+PsA.

METHODS: Pts with PsO and PsO+PsA enrolled in the CorEvitas Psoriasis Registry from 4/2015-8/2021 were included in this cross-sectional analysis. Pt-reported fatigue was assessed on a Visual Analog Scale (VAS; 0-100), and associated pt factors including sociodemographics, disease characteristics, treatments, itch, skin pain, and joint pain (PsO+PsA only) were assessed. Moderate to severe fatigue was defined as VAS-F ≥50, and pt-reported symptoms were scaled to a 20-unit increase. Poisson regression models estimated relative risks (RR) and 95% confidence intervals (CI) for each factor. Two models were evaluated; one that adjusted for all factors excluding pt-reported symptoms and the other adjusted for all factors. Concordance (C) statistics were reported to compare model fit.

RESULTS: 13,702 pts were included [PsO (n=8,894;65%) and PsO+PsA (n=4,808;35%)]. The prevalence of fatigue for pts with PsO was 28% and 41% for PsO+PsA. Generally, factors associated with fatigue were similar across both groups but some unique differences such as joint pain (RR=1.27; (CI) 1.23-1.30) in PsO+PsA pts were identified. When pt-reported symptoms were excluded for PsO, female sex (RR=1.57;1.46-1.69), current smoker (RR=1.28; 1.17-1.40), obesity (RR=1.26; 1.15-1.38), history of depression/anxiety (RR=1.41; 1.27-1.55), moderate PsO disease activity (RR=1.41; 1.27-1.55), and severe PsO disease activity (RR=1.65; 1.52-1.80) were associated with ≥20% higher risk of fatigue. Current biologic treatment



MODEL 1. Adjusted Relative Risk Models for all Factors Excluding Patient-reported Symptoms



MODEL 2. Adjusted Relative Risk Models for all Factors Including Patient-reported Symptoms

of ≥3 months was associated with a lower risk of fatigue (RR=0.76; 0.69-0.84). In Model 2, also in PsO only pts, female sex (RR=1.29; 1.20-1.39), obesity (RR=1.20; 1.10-1.31), history of depression/anxiety (RR=1.31; 1.22-1.41), skin pain (RR=1.21; 1.19-1.23), and itch (RR=1.21; 1.18-1.25) conferred at least 20% higher risk of fatigue. The lower associated risk of current biologic treatment of ≥3 months was no longer meaningful (RR=1.00; 0.91-1.10). The addition of patient symptom information improved model fit [C-statistic (Model 2): 0.79; (0.78-0.80) vs. (Model 1) 0.68 (0.67-0.70)].

CONCLUSIONS: PsO pts with PsA reported a higher prevalence of fatigue; however, PsO only pts also reported a meaningful burden of fatigue. A deeper understanding of unresolved patient-reported symptoms, and how targeted interventions can address these symptoms to reduce associated fatigue not fully explained by disease activity and biologic therapies, is warranted.

ACKNOWLEDGEMENTS: Support for third-party writing assistance for this poster, furnished by Michelle D. Karpman, PhD, and Leslie A. Whitehead of CorEvitas, LLC, was provided by Janssen Scientific Affairs, Horsham, PA, USA. This study is sponsored by CorEvitas, LLC. CorEvitas has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, Arena, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, Eli Lilly and Company, Genentech, Gilead, GSK, Janssen, Leo Pharma, Novartis, Ortho Dermatologics, Pfizer Inc., Regeneron, Sanofi, Sun and UCB. The authors would like to thank all the investigators, their clinical staff, and patients who participate in the CorEvitas Psoriasis Registry.

DISCLOSURES: SK, Speakers bureau: Eli Lilly, Janssen, UCB, AbbVie, Research: Pfizer, Bristol-Myers Squibb, Leo Pharma, Advisory Board/consultant: AbbVie, UCB, Janssen, Eli Lilly; JEM, consultant and/or investigator for Amgen, Bristol-Myers Squibb, AbbVie, Dermavant, Eli Lilly, Novartis, Janssen, UCB, Sanofi, Regeneron, Sun Pharma, Biogen, Pfizer and Leo Pharma; YY, Employee of Janssen Global Medical Affairs and shareholder of Johnson & Johnson, LLC; TF, RT, employees of Janssen Scientific Affairs and shareholders of Johnson & Johnson, LLC; JJ employee and shareholder, CorEvitas, LLC; AS, EL employees of CorEvitas, LLC.

ABSTRACT 70

Long-Term Effectiveness of Guselkumab on Disease Severity in the Corevitas Psoriasis Registry

Strober, Bruce E., MD, PhD,[1] Fitzgerald, Timothy, PhD,[2] Janak, Judson, PhD,[3] Rowland, Katelyn, MS, ARNP,[2] Choi, Olivia, MD, PhD,[2] Chan, Daphne, PhD,[2] Marchese, Maya, MS,[3] Teneralli, Rachel E., PhD, MS,[2] Kang, Hyung-Joo, MS,[3] Armstrong, April W., MD, MPH,[4]

[1]Yale University School of Medicine, New Haven, CT, Central Connecticut Dermatology, Cromwell, CT; [2]Janssen Scientific Affairs, LLC, Horsham, PA; [3]CorEvitas, LLC, Waltham, MA; [4]University of Southern California, Los Angeles, CA

BACKGROUND: Guselkumab is an IL-23 inhibitor approved for moderate-to-severe plaque PsO and active PsA (Tremfya [guselkumab], 2021). In clinical trials, guselkumab has demonstrated improvement in disease activity through five years (Voyage 1 and Voyage 2) (Reich K. et al, *Br J Dermatol.* 2021 Dec;185(6):1146-1159). However, studies are needed to determine the long-term effectiveness of guselkumab in the real-world practice setting.

OBJECTIVE: Evaluate the long-term effectiveness of guselkumab on disease activity among real-world patients with moderate to severe plaque psoriasis in the CorEvitas Psoriasis Registry who were persistent on guselkumab for 18-24 months.

METHODS: Patients enrolled in the CorEvitas Psoriasis Registry between July 2017 and September 2021 who met the following criteria were included in this study: diagnosis of plaque psoriasis; ≥18 years of age; moderate to severe disease activity as measured by (Body Surface Area (BSA) ≥3% and Investigator's Global Assessment (IGA) ≥3) at index visit; persistent guselkumab use for ≥18 months; and a clinical visit 18-24 months post initiation of guselkumab. Disease activity outcomes of interest were achievement of: 'clear' or 'almost clear' skin (IGA 0/1), ≥90% decrease on Psoriasis Area and Severity Index (PASI90), and National Psoriasis Foundation (NPF) Target Response (BSA≤1%). Results are summarized by descriptive statistics.

RESULTS: 183 patients were included in this study (Figure 1) with a mean duration of guselkumab use of 20.5 months (SD [standard deviation]=1.9). Most patients were biologic-experienced (n=106; 58%) with a mean age of 50 years, White (n=147; 80%), male (n=108; 59%) and had a mean disease duration of 16 years (SD=13.4). Nearly half (n=87, 48%) of the patients who initiated guselkumab were also on topical agents. The majority of patients achieved clinically meaningful skin clearance: IGA 0/1 (n=126; 69% [95% Confidence Interval (CI): 62%, 76%]), PASI90 (n=105; 58% [95% CI: 50%, 65%]), and NPF Target Response (n=122; 67% [95% CI: 60%, 74%]).

CONCLUSIONS: These findings demonstrated meaningful improvements in skin clearance were achieved for patients with 18-24 months of persistent use of guselkumab. These results highlight the importance of understanding individual patient characteristics associated with long-term persistence and durable long-term effectiveness.

REFERENCES:

Tremfya [guselkumab], Prescribing Information for Psoriasis; Janssen Biotech, Inc.; 2021. Accessed 2/14/22; https://www.tremfya.com

Reich K, Gordon KB, Strober BE, Armstrong AW, Miller M, Shen YK, You Y, Han C, Yang YW, Foley P, Griffiths CEM. Five-year maintenance of clinical response and health-related quality of life improvements in patients with moderate-to-severe psoriasis treated with guselkumab: results from VOYAGE 1 and VOYAGE 2. Br J Dermatol. 2021 Dec;185(6):1146-1159. doi: 10.1111/bjd.20568. Epub 2021 Sep 8. PMID: 34105767.

ABSTRACT 71

Efficacy After Patients Switched to Guselkumab From Adalimumab: VOYAGE 1 Results

Jennifer Soung, MD[1] Victor Czerkasij, MA, MSN, FNP-C[2] Jeffrey Pawlikowski, PhD[3] Katelyn Rowland, MS, ARNP[3] Daphne Chan, PhD[3] Yin You, MS[4] Jeffrey Crowley, MD[5]

[1]Southern California Dermatology, Inc, Santa Ana, CA, USA; [2]Skin Cancer & Cosmetic Dermatology Centers, Cleveland, TN, USA; [3]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [4]Janssen Research & Development, LLC, Spring House, PA, USA; [5]Bakersfield Dermatology and Skin Cancer Medical Group, Bakersfield, CA, USA.

BACKGROUND: Over the past two decades, biologic agents have dramatically improved the treatment and clinical outcomes of patients with psoriasis and psoriatic arthritis (Brownstone ND, et al *Biologics* 2021). However, even with the introduction of this important class of medications, it is inevitable that patients may not respond or may fail to achieve an optimal or sustained response to any treatment over time. Thus, it is important to have additional clinical data to inform treatment decisions so patients and clinicians can achieve the desired clinical outcomes.

OBJECTIVE: In VOYAGE 1, guselkumab (GUS), a fully human monoclonal antibody that binds the p19 subunit of interleukin-23, demonstrated superiority to adalimumab (ADA) at Week 16 (Psoriasis Area and Severity Index score from baseline [PASI 90]: 73% vs 50%, respectively) through Week 48 (76% vs 48%) in adults with moderate to severe plaque psoriasis (Blauvelt A, et al *J Am Acad Dermatol* 2017). Here, we present a post hoc analysis to further evaluate efficacy outcomes in ADA patients with an inadequate (PASI <75% improvement from baseline) or partial (PASI ≥75% to <90% improvement from baseline) response to ADA after 48 weeks of treatment, who switched to GUS at Week 52.

METHODS: VOYAGE 1 was a Phase 3, randomized, double-blind, placebo (PBO)- and active-comparator–controlled study that evaluated the efficacy and safety of GUS for 5 years. Patients were randomized to GUS 100 mg at Weeks 0/4, then every 8 weeks (q8w); or PBO at Weeks 0/4/12, then GUS 100 mg at Weeks 16/20, then

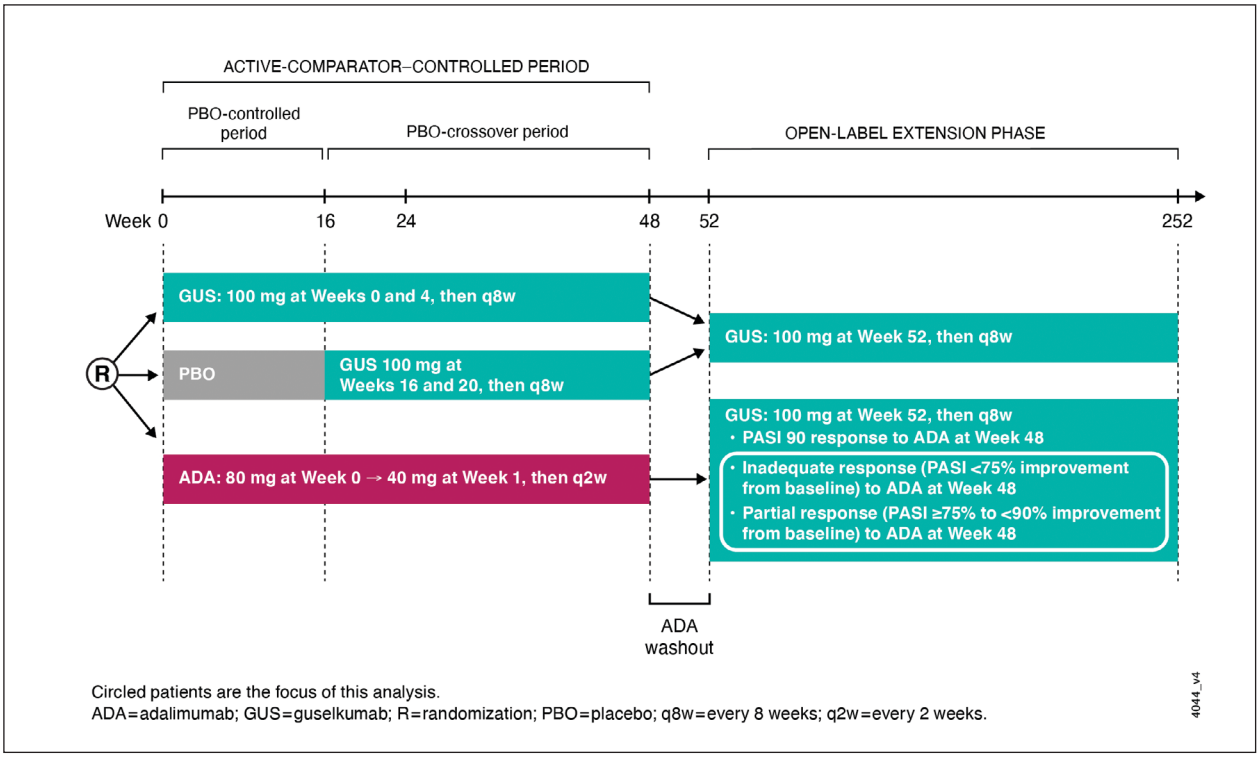


FIGURE. VOYAGE 1: Patients randomized to ADA could switch to GUS starting at Week 52

q8w; or ADA 80 mg at Week 0, 40 mg at Week 1, and 40 mg q2w through Week 47. Starting at Week 52, patients entered an open-label extension phase where patients initially randomized to ADA were switched, per study design, to receive GUS 100 mg q8w from Weeks 52–252 (Figure). Improvement in PASI response was evaluated through Week 252.

RESULTS: At Week 0, 334 patients were randomized to ADA, of whom 280 (84%) switched to GUS at Week 52. Among patients with inadequate (PASI <75% improvement from baseline) or partial (PASI ≥75% to <90% improvement from baseline) response to ADA at Week 48, 74% (87/118) and 43% (51/118) of patients achieved PASI 90 and complete clearance (PASI 100) at Week 100, respectively. These responses were well maintained through Week 252, with 74% (78/105) and 42% (44/105) of patients achieving PASI 90 and PASI 100, respectively.

CONCLUSIONS: The majority of patients with an inadequate or partial response to 1 year of ADA treatment had substantial improvements in skin clearance after switching to GUS. These improvements were sustained and durable throughout 4 years of GUS treatment.

ABSTRACT 72

Safety of Guselkumab in Patients With Psoriatic Disease: An Integrated Analysis of 11 Phase 2/3 Clinical Studies in Psoriasis and Psoriatic Arthritis

Bruce Strober,[1,2] Laura C. Coates,[3] Jenny Yu,[4] Katelyn Rowland,[5] Evan Leibowitz,[5] Megan Miller,[4] Alexa Kollmeier,[4] Shu Li,[4] Yanli Wang,[4] Daphne Chan,[5] Soumya D. Chakravarty,[5,6] Ya-Wen Yang,[7] May Shawi,[7] Mark Lebwohl,[8] Proton Rahman[9]

[1]Yale University, New Haven, CT, USA; [2]Central Connecticut Dermatology Research, Cromwell, CT, USA; [3]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK; 4Janssen Research & Development, LLC, Spring House, PA/San Diego, CA, USA; [5]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [6]Drexel University College of Medicine, Philadelphia, PA, USA [7]Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Horsham, PA, USA; [8]Icahn School of Medicine at Mount Sinai, New York, NY, USA; 9Craig L Dobbin Genetics Research Centre, Memorial University of Newfoundland, St. John's, Newfoundland, Canada

BACKGROUND: Guselkumab (GUS) is a fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin-23, inhibiting its function. GUS has been shown to have a favorable safety profile across Phase 2 and 3 studies conducted in adults with moderate to severe plaque psoriasis (PsO) and with active psoriatic arthritis (PsA).

OBJECTIVES: In this integrated analysis, safety data from 11 Phase 2/3 studies of GUS, including 7 in PsO (X-PLORE, VOYAGE 1, VOYAGE 2, NAVIGATE, ORION, ECLIPSE, Japanese registration) and 4 in PsA (Phase 2, DISCOVER-1, DISCOVER-2, COSMOS), were pooled to comprehensively evaluate the safety experience with GUS in a large population of patients (pts) with psoriatic disease.

METHODS: GUS was generally administered as 100-mg subcutaneous injections at Week (W)0, W4, then Q8W in PsO studies (additional doses included in X-PLORE; see Tables‡) and at W0, W4, then Q4W or Q8W in PsA studies. Pts randomized to placebo (PBO) crossed over to GUS Q8W at W16 in 5 PsO studies (X-PLORE, VOYAGE 1, VOYAGE 2, ORION, Japan registration) and to GUS Q4W or Q8W at W24 in PsA studies. Safety data were summarized for the PBO-controlled period (W0-16 in PsO; W0-24 in PsA) and through the end of the reporting period (up to 5 years in PsO; up to 2 years in PsA). Incidence rates of key safety events were integrated post hoc, adjusted for duration of follow-up, and reported per 100 pt-years (PY).

RESULTS: During the PBO-controlled periods, 1061 pts received PBO (395 PY) and 2257 received GUS (856 PY). Through the end of the reporting periods, 4399 GUS-treated pts (PsO: 2891; PsA: 1508) contributed 10,787 PY of follow-up (PsO: 8662 PY; PsA: 2125 PY). In PsO and PsA studies, pooled incidence rates of overall adverse events (AEs) were similar between GUS- and PBO-treated pts (Table 1). Rates of serious AEs (SAEs), AEs leading to study agent discontinuation, serious infections, malignancy, and major adverse cardiovascular events (MACE) were low and generally similar between GUS- and PBO-treated pts (Table 1). The rates of safety events evaluated remained consistent through the

TABLE 1. Overall AEs During PBO-controlled Period*

	PsO (W0-16)		PsA (W0-24)			Pooled PsO and PsA	
	PBO† (N=544)	GUS Q8W‡ (N=1220)	PBO† (N=517)	GUS Q8W (N=664)	GUS Q4W (N=373)	PBO† (N=1061)	Combined GUS (N=2257)
Total (median) PY	165 (0.3)	378 (0.3)	230 (0.5)	305 (0.5)	172 (0.5)	395 (0.3)	856 (0.3)
Number of events/100 PY (95% confidence interval)							
AEs	341 (314, 370)	346 (327, 365)	223 (204, 243)	233 (216, 250)	223 (201, 246)	254 (239, 271)	267 (256, 278)
SAEs	6.7 (3.3, 11.9)	6.3 (4.1, 9.4)	8.7 (5.3, 13.4)	4.9 (2.8, 8.1)	5.2 (2.4, 9.9)	7.1 (4.7, 10.2)	5.3 (3.8, 7.0)
AEs leading to study agent discontinuation	9.7 (5.5, 15.7)	5.0 (3.0, 7.8)	4.4 (2.1, 8.0)	3.6 (1.8, 6.4)	7.0 (3.6, 12.2)	4.8 (2.9, 7.5)	4.7 (3.3, 6.4)
Infections	83.6 (70.2, 98.8)	95.9 (86.3, 106.3)	64.0 (54.1, 75.2)	59.0 (50.7, 68.2)	62.6 (51.4, 75.6)	67.6 (59.8, 76.3)	70.3 (64.8, 76.2)
Serious Infections	1.2 (0.2, 4.4)	1.1 (0.3, 2.7)	3.0 (1.2, 6.3)	0.7 (0.08, 2.4)	1.7 (0.4, 5.1)	2.0 (0.9, 4.0)	0.9 (0.4, 1.8)
Malignancy§	0.00 (0.00, 1.82)	0.53 (0.06, 1.91)	0.44 (0.01, 2.43)	0.99 (0.20, 2.88)	0.00 (0.00, 1.74)	0.25 (0.01, 1.41)	0.47 (0.13, 1.20)
MACE◊	0.00 (0.00, 1.82)	0.26 (0.01, 1.47)	0.44 (0.01, 2.43)	0.33 (0.01, 1.83)	0.58 (0.01, 3.23)	0.25 (0.01, 1.41)	0.35 (0.07, 1.02)

* Includes pts in all treatment groups who discontinued study treatment early with the last study treatment (PBO or GUS) administered prior to W16/24 and who did not receive any study agent (PBO or GUS) at or after W16/24; all data including the final safety follow-up visit collected through up to 2 years were included in this period.

† Includes data prior to GUS exposure in PBO pts who switched from PBO to GUS.

‡ Also includes all GUS-treated pts in the Phase 2 X-PLORE study: N=250 pts randomized to GUS 5 mg at W0, W4, then Q12W; 15 mg Q8W; 50 mg at W0, W4, then Q12W; 100 mg Q8W; or 200 mg at W0, W4, then Q12W; or PBO with crossover to GUS 100 mg Q8W at W16.

§ Pt-level analysis of all reported malignancies, including nonmelanoma skin cancer.

◊ MACE was predefined as cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke and was identified based on clinical review.

TABLE 2. Overall AEs Through the End of the Reporting Period

	PsO	PsA			Pooled PsO and PsA
	Combined GUS Q8W*,‡ (N=2891)	Combined GUS Q8W (N=783)	Combined GUS Q4W (N=725)	Combined GUS† (N=1508)	Combined GUS (N=4399)
Total (median) PY	8662 (3.5)	1019 (1.1)	1106 (1.7)	2125 (1.2)	10,787 (1.7)
Events/100 PY (95% CI)					
AEs	169 (166, 172)	160 (152, 168)	133 (126, 140)	146 (141, 151)	152 (149, 154)
SAEs	5.3 (4.8, 5.8)	6.3 (4.8, 8.0)	5.2 (3.9, 6.7)	5.7 (4.7, 6.8)	5.0 (4.6, 5.4)
AEs leading to study agent discontinuation	1.6 (1.3, 1.9)	2.4 (1.5, 3.5)	3.1 (2.1, 4.3)	2.7 (2.1, 3.5)	1.7 (1.5, 2.0)
Infections	65.9 (64.2, 67.6)	43.5 (39.5, 47.7)	40.6 (36.9, 44.5)	42.0 (39.3, 44.8)	57.0 (55.5, 58.4)
Serious Infections	0.88 (0.69, 1.10)	1.67 (0.97, 2.67)	1.54 (0.90, 2.46)	1.60 (1.11, 2.24)	0.97 (0.80, 1.18)
Malignancy§	0.74 (0.57, 0.95)	0.39 (0.11, 1.01)	0.09 (0.00, 0.50)	0.24 (0.08, 0.55)	0.64 (0.50, 0.81)
MACE◊	0.33 (0.22, 0.48)	0.20 (0.02, 0.71)	0.27 (0.06, 0.79)	0.24 (0.08, 0.55)	0.29 (0.20, 0.41)

* Includes PsO pts originally randomized to PBO or adalimumab at baseline who crossed over and were treated with GUS.
† Includes PsA pts randomized to PBO who crossed over to GUS at W24.
‡ Also includes all GUS-treated pts in the Phase 2 X-PLORE study: N=250 pts randomized to GUS 5 mg at W0, W4, then Q12W; 15 mg Q8W; 50 mg at W0, W4, then Q12W; 100 mg Q8W; or 200 mg at W0, W4, then Q12W; or PBO with crossover to GUS 100 mg Q8W at W16.
§ Pt-level analysis of all reported malignancies, including nonmelanoma skin cancer.
◊ MACE was predefined as cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke and was identified based on clinical review.

end of the reporting period for GUS-treated pts (Table 2). No cases of Crohn's disease or ulcerative colitis were reported in GUS-treated pts. No serum sickness-like or anaphylactic reactions related to GUS were reported. No opportunistic infections (OIs) were reported in any GUS-treated PsO pts. Three cases of OI were reported in pooled PsA studies (0.14/100 PY; all post-W52 in DISCOVER-2). Across all studies, no cases of active tuberculosis were reported.

CONCLUSIONS: In the most comprehensive analysis of GUS safety to date, evaluating ~4400 pts with psoriatic disease followed for up to 5 years of treatment (10,787 PY of exposure), GUS demonstrated a favorable and consistent safety profile compared with previous reports. Safety event rates in GUS-treated pts were similar to those observed with PBO and remained stable throughout the long-term follow-up.

A SUPPLEMENT TO

cutis®

CUTANEOUS MEDICINE FOR THE PRACTITIONER