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25TH ANNUAL LAS VEGAS DERMATOLOGY SEMINAR

Abstract COMPENDIUM

LAS VEGAS, NEVADA
SEPTEMBER 19-21, 2024

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25TH ANNUAL
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ACNE AND ROSACEA

Abstract AR-01

Efficacy and Safety of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Participants with Moderate-to-Severe Acne: The Patient Journey

Hilary Baldwin, MD[1,2]; Julie C Harper, MD[3]; Joshua A Zeichner, MD[4]; Zoe D Draelos, MD[5]; Lawrence F Eichenfield, MD[6,7]; Michael Gold, MD[8]; Linda Stein Gold, MD[9]; Leon H Kircik, MD[4,10,11]; Alexis Relampagos, PharmD[12]; Eric Guenin, PharmD, PhD, MPH[12]

[1]The Acne Treatment and Research Center, Brooklyn, NY; [2]Robert Wood Johnson University Hospital, New Brunswick, NJ; [3]Dermatology & Skin Care Center of Birmingham, Birmingham, AL; [4]Icahn School of Medicine at Mount Sinai, New York, NY; [5]Dermatology Consulting Services, PLLC, High Point, NC; [6]University of California, San Diego School of Medicine, La Jolla, CA; [7]Rady Children's Hospital, San Diego, CA; [8]Tennessee Clinical Research Center, Nashville, TN; [9]Henry Ford Hospital, Detroit, MI; [10]Indiana University School of Medicine, Indianapolis, IN; [11]Physicians Skin Care, PLLC, DermResearch, PLLC, and Skin Sciences, PLLC, Louisville, KY; [12]Ortho Dermatologics*, Bridgewater, NJ

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

BACKGROUND: When treating acne, the main goal of treatment is to clear lesions quickly to manage and/or mitigate sequelae.[1] Topical clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (CAB) gel is the only fixed-dose, triple-combination formulation approved for acne treatment. In three published clinical studies of participants with moderate-to-severe acne, CAB gel demonstrated superior efficacy to vehicle and component dyads, with good safety/tolerability.[1,2]

OBJECTIVE: To present detailed efficacy and safety data from 5 clinical study patients to document their CAB treatment journey.

METHODS: In two phase 3 (NCT04214652, NCT04214639), double-blind, 12-week studies, participants aged ≥9 years with moderate-to-severe acne were randomized to once-daily CAB or vehicle gel. Endpoints included percentage of participants achieving treatment success (≥2-grade reduction from baseline in Evaluator's Global Severity Score and clear/almost clear skin) and percent change from baseline in inflammatory/noninflammatory lesion counts at week 12. Dosing compliance, treatment-emergent adverse events (TEAEs) and cutaneous safety/tolerability were also assessed. Descriptive data from each of the selected cases who completed 12 weeks of CAB treatment are summarized.

RESULTS: Participants (n=5) ranged from 13-32 years. At week 12, 3 achieved treatment success, 1 achieved a 2-grade reduction from severe to mild, and 1 achieved a 1-grade reduction from moderate to mild. Percent reductions from baseline to week 12 in inflammatory/noninflammatory lesion counts ranged from 74.7%-100%. No participants reported TEAEs or serious AEs. Some cutaneous safety and tolerability scores increased at weeks 2, 4, or 8, but generally decreased back to/below baselines levels by week 12, similar to the overall study populations. Most scores at week 12 were 0 (none) or 1 (mild), with only one participant reporting scores of 2 (moderate) for itching, burning, and stinging.

CONCLUSIONS: In the overall phase 3 clinical trials, fixed-dose, triple-combination CAB gel has demonstrated good efficacy, safety, and tolerability. All 5 cases presented here achieved substantial (>70%) acne lesion reductions, with 4/5 cases achieving treatment success or a 2-grade EGSS reduction by week 12. While patterns in cutaneous safety/tolerability were variable across cases, transient increases with CAB generally resolved to baseline values within two months of treatment. These clinical study cases reinforce the importance of patient education regarding efficacy and safety of acne treatment,1 including the importance of treatment adherence, managing patient expectations, and the potential for increased cutaneous effects, which are often transient.

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3. Stein Gold L, et al. Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel for moderate-to-severe acne: Efficacy and safety results from two randomized phase 3 trials. *J Am Acad Dermatol.* 2023;89:927-935.

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DISCLOSURES: HB: has served as advisor, served as investigator, and served on speakers bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. JH: has received honoraria from Almirall, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun Pharma. JZ: has served as advisor, consultant, or speaker for AbbVie, Allergan, Dermavant, Dermira, EPI Health, Galderma, Incyte, Johnson and Johnson, L'Oreal, Ortho Dermatologics, Pfizer, Procter and Gamble, Regeneron, Sun Pharma, UCB, Unilever, and Vyne. LE: has received honoraria for consulting services from AbbVie, BMS, Amgen, Arcutis, Dermata, Dermira, Dermavant, Eli Lilly, Forte Pharma, Galderma, Incyte, J&J, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi Genzyme, and Ortho Dermatologics; and study support (to institution) from AbbVie, Amgen, Bausch Health, Dermata, Dermira, Eli Lilly, Galderma, Incyte, Pfizer, Regeneron Pharmaceuticals, Inc., and Sanofi Genzyme. MG: has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. LSG: has served as investigator/consultant or speaker for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, Pfizer, Sun Pharma, UCB, Arcutis, and Lilly. LK: has served as either a consultant, speaker, advisor or an investigator for Allergan, Almirall, Epi Health, Galderma, Novartis, Ortho Dermatologics, and Sun Pharma. AR and EG: are employees of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

Abstract AR-02

Triple-Combination Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel for Acne: Clinical Efficacy and Application Characteristics

Zoe D Draelos, MD[1]; Linda Stein Gold, MD[2]; Leon H Kircik, MD[3-5]; Emil A Tanghetti, MD[6]; Alexis Relampagos, PharmD[7]; Eric Guenin, PharmD, PhD, MPH[7]

[1]Dermatology Consulting Services, PLLC, High Point, NC; [2]Henry Ford Hospital, Detroit, MI; [3]Icahn School of Medicine at Mount Sinai, New York, NY; [4]Indiana University School of Medicine, Indianapolis, IN; [5]Physicians Skin Care, PLLC, DermResearch, PLLC, and Skin Sciences, PLLC, Louisville, KY; [6]Center for Dermatology and Laser Surgery, Sacramento, CA; [7]Ortho Dermatologics*, Bridgewater, NJ

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

BACKGROUND: Triple-combination therapies for acne including an antibiotic, topical retinoid, and benzoyl peroxide (BPO) are among the most effective, with meta-analyses demonstrating greater efficacy with triple-combinations than dual-combinations or topical monotherapy.[1] However, this benefit may be offset by reduced adherence to a complicated treatment regimen.[2]

OBJECTIVE: Here, the clinical efficacy of fixed-dose clindamycin phosphate 1.2%/adapalene 0.15%/BPO 3.1% (CAB) gel is reviewed, and the ease of CAB application is compared with the layered application of its individual active ingredients.

METHODS: In a phase 2 (N=741) and two phase 3 (N=183; N=180), double-blind, randomized, 12-week studies, participants aged ≥9 years with moderate-to-severe acne were randomized to receive once-daily CAB or vehicle; the phase 2 study also included treatment arms containing dyad gels (BPO/adapalene; clindamycin phosphate/BPO; clindamycin phosphate/adapalene). Efficacy endpoints included treatment success (percentage of participants achieving ≥2-grade reduction from baseline in Evaluator's Global Severity Score and clear/almost clear skin) and reductions from baseline in inflammatory (IL) and noninflammatory lesions (NIL). In a split-face study of adults with acne-prone skin (N=25), participant-application of CAB (0.3 cc) was compared to sequential, layered application of benzoyl peroxide cream, adapalene gel, and clindamycin gel (0.1 cc each). CAB and clindamycin gels were compounded with pyranine, which fluoresces under blue light; photos were taken under blue light to assess evenness of product application.

RESULTS: In all three clinical studies at week 12, half of CAB-treated participants achieved treatment success (range: 49.6%-52.5%), significantly greater than with vehicle (8.1%-24.9%; $P<0.01$, all) or dyads (phase 2 study only; 27.8%-30.5%; $P\leq0.001$, all). Reductions from baseline in both IL and NIL were also significantly greater for CAB vs vehicle (range, IL: 75.7%-80.1% vs 50.4%-59.6%; NIL: 71.0%-73.3% vs 45.8%-49.0%; $P<0.001$, all) and dyads (IL: 64.0%-69.2%; NIL: 58.7%-61.1%; $P<0.01$, all vs CAB). In the split-face study, 100% of Investigator and participant assessments of evenness of application favored CAB over the three layered products. In addition, all participants rated CAB as both easier and faster to apply, and most (96%) preferred CAB for use at home.

CONCLUSIONS: Fixed-dose CAB gel applied more evenly than separate application of its three active ingredients and demonstrated significantly greater efficacy in the treatment of moderate-to-severe acne than dyad gels or vehicle. By addressing three of the main acne pathogenic pathways in a single, easy-to-apply formulation, CAB may improve efficacy of and adherence to acne treatment.

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Abstract AR-03

Follicular Skin Disorders, Inflammatory Bowel Disease, and the Microbiome: A Systematic Review

Lauren Fleshner[1]; Katie Roster[1]; Banu Farabi[1,2]; Rahim Hirani[1,2]; Katharine Tepper[1]; Bijan Safai[1,2]; Shoshana Marmon[1,3]

[1]New York Medical College, Valhalla, NY; [2]Dermatology Department, NYC Health + Hospital/Metropolitan, New York, NY; [3]Dermatology Department, NYC Health + Hospital/Coney Island, Brooklyn, NY

INTRODUCTION: Follicular skin disorders, including Hidradenitis Suppurativa (HS), are commonly comorbid with systemic autoinflammatory diseases, such as Inflammatory Bowel Disease (IBD) and its subtypes, Crohn's disease and ulcerative colitis. Previous literature suggests dysbiosis of the human microbiome as a potential pathogenic link between HS and IBD. However, the role of the microbiome among IBD and all follicular disorders remains understudied.

OBJECTIVE: To systematically review the literature evaluating the microbiome, IBD, and its association with all follicular disorders.

METHODS: Five major databases were searched (PubMed, EMBASE, Web of Science, Cochrane Library, and Google Scholar). Studies were included if they were empirical, peer-reviewed research. Abstracts, poster presentations, case reports, systematic reviews, and meta-analyses were excluded. Pediatric or pregnant populations were excluded. Quality assessments utilizing the Newcastle-Ottawa scale were conducted for all included studies.

RESULTS: Sixteen studies were included for analysis. Four studies evaluated the impact of diet on the microbiome. Ten studies reported on the bacterial colonization of either gut

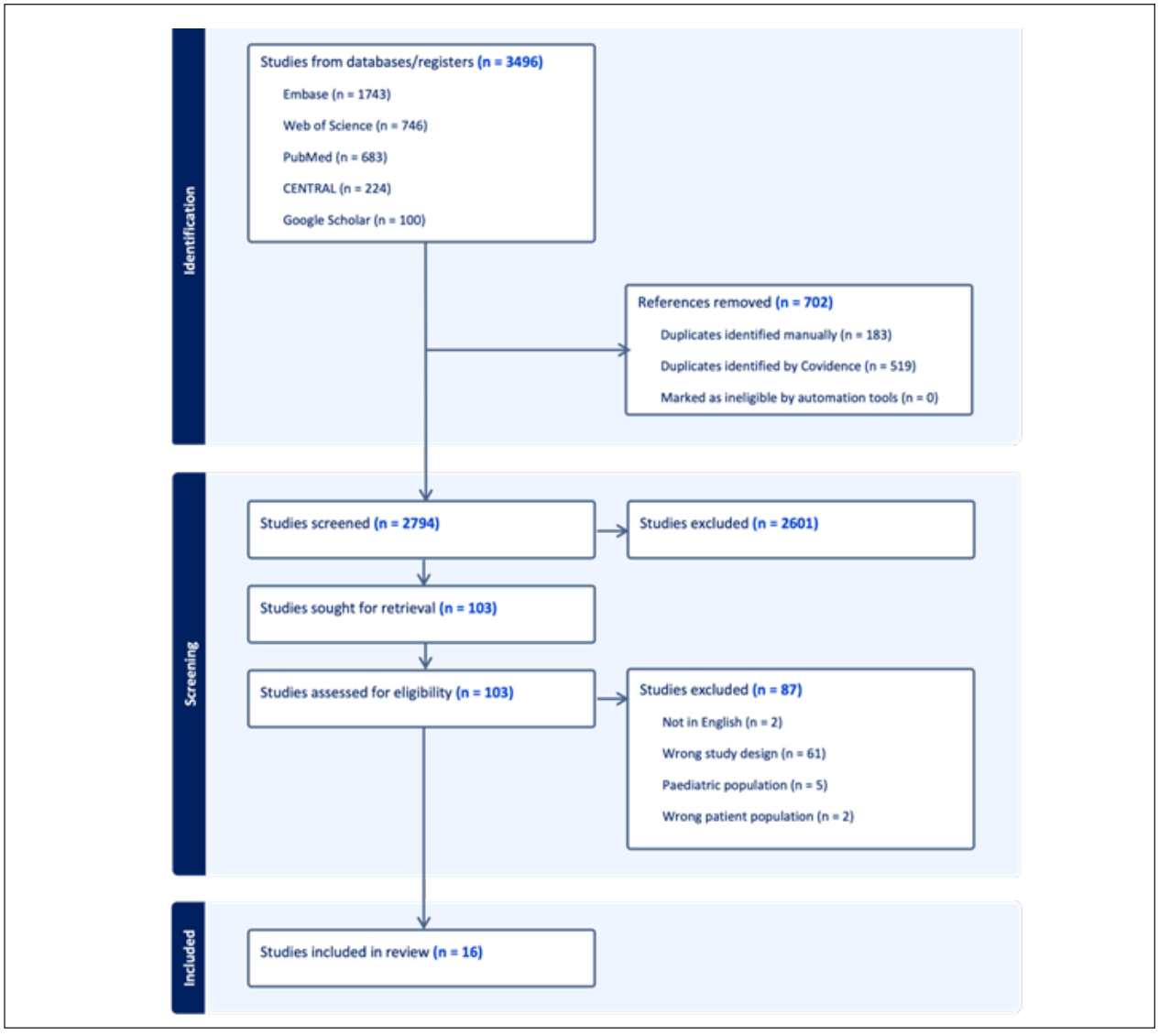

FIGURE 1. PRISMA Diagram Depicting Selection Criteria for Inclusion. Generated by Covidence.

TABLE 1. Studies Included for Analysis and Their Characteristics, Including Patient Population, Sample Size, and the Follicular Disorder Studied

Author	Sample Size	Follicular Disorder	IBD Included?	Gut/Skin Microbiome
Aboud et al	185	HS	Yes	Gut
Cronin et al	252	HS	Yes	Gut
Cannistra et al	12	HS	No	Gut
Colboc et al	20	HS	No	Gut
Assan et al	469	HS	No	Gut
Eppinga et al	123	HS	Yes	Gut
McCarthy et al	59	HS	Yes	Skin and Gut
Nikolakis et al	50	HS	No	Skin
Ogut et al	30	HS	No	Gut
Guenin-Mace et al	66	HS	No	Skin
Matard et al	40	Folliculitis Decalvans	No	Skin
Riverain-Gillet et al	60	HS	No	Skin
Lam et al	37	HS	No	Gut
Hsu et al	34	HS	No	Skin
Giudici et al	3	HS	Yes	NR
Marzano et al	5	HS	Yes	Skin

or skin microbiota. Two reported on immunological or serological biomarkers. Fifteen studies reported on HS, and only one study reported on folliculitis decalvans.

CONCLUSIONS: Our systematic review of the literature highlights the complex interplay between the human microbiome, IBD, and follicular disorders, particularly HS. Dietary interventions are a promising therapeutic intervention to manage the burden of HS and IBD. Routine microbiota analysis and identifying key serological biomarkers are important for solidifying the relationship of dysbiosis in these diseases. Future research should aim to include other follicular disorders in addition to HS, to broaden our understanding of the microbiome's impact.

DISCLOSURES: The authors have nothing to disclose

TABLE 2. Studies Included for Analysis, Stratified by Topic, Evaluating Follicular Skin Disorders and the Microbiome

Category	Author, Year	Quality Assessment
Diet Analysis	Aboud, 2020	Good
	Cannistrà, 2013	Fair
	Colboc, 2016	Good
	Assan, 2020	Good
Colonization of Skin/Gut Microbiome	Eppinga, 2016	Good
	McCarthy, 2022	Good
	Nikolakis, 2017	Good
	Ogut, 2017	Good
	Guenin-Macé, 2020	Good
	Matard, 2020	Good
	Riverain-Gillet, 2020	Good
	Lam, 2021	Good
	Cronin, 2023	Good
	Hsu, 2022	Fair
Immunological/Serological Biomarkers	Giudici, 2015	Poor
	Marzano, 2014	Fair

*Quality assessments were conducted using the Newcastle-Ottawa Scale for Cohort Studies.

Abstract AR-04

Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel for Moderate-to-Severe Acne: Comparison of 4 Clinical Trials

Leon H Kircik, MD[1-3]; Zoe D Draelos, MD[4]; Michael Gold, MD[5]; Neil Sadick, MD[6,7]; Neal Bhatia, MD[8]; Alexis Relampagos, PharmD[9]; Eric Guenin, PharmD, PhD, MPH[9]

[1]Icahn School of Medicine at Mount Sinai, New York, NY; [2]Indiana University School of Medicine, Indianapolis, IN; [3]Physicians Skin Care, PLLC, DermResearch, PLLC, and Skin Sciences, PLLC, Louisville, KY; [4]Dermatology Consulting Services, PLLC, High Point, NC; [5]Tennessee Clinical Research Center, Nashville, TN; [6]Weill Cornell Medical College, New York, NY; [7]Sadick Dermatology, New York, NY; [8]Therapeutics Clinical Research, San Diego, CA; [9]Ortho Dermatologics*, Bridgewater, NJ

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

BACKGROUND: Combination therapies targeting multiple processes of acne pathogenesis are recommended for most acne patients.[1] A three-pronged approach using an antibiotic, retinoid, and antibacterial may also increase treatment efficacy versus monotherapy or dual-combination products.[2] Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (BPO) polymeric mesh gel (CAB) is the first fixed-dose, triple-combination topical approved by the FDA for the treatment of acne.

OBJECTIVE: The objective of this analysis was to compare treatment success and effect size of once-daily CAB with its three constituent dyad gels, branded adapalene 0.3%/BPO 2.5% gel, and vehicle across four clinical studies.

METHODS: Two phase 2 (NCT03170388, NCT04892706) and two phase 3 (NCT04214652, NCT04214639) double-blind, randomized, 12-week studies enrolled participants with moderate-to-severe acne. In all studies, treatment success at week 12 (defined as a ≥2-grade reduction from baseline in Evaluator's Global Severity Score and clear/almost clear skin) was a co-primary endpoint. Other co-primary endpoints (reduction from baseline in inflammatory and noninflammatory lesions) are not shown here.

Treatment-emergent adverse events (TEAEs) and cutaneous safety/tolerability were also assessed. A post hoc analysis of number needed to treat (NNT)—the number of patients who need to be treated with an intervention for one additional patient to achieve success versus vehicle—was performed to provide an additional measure of treatment effect and to indirectly compare data across studies.

RESULTS: Across studies, approximately half of CAB-treated participants achieved treatment success by week 12 (range: 49.6-52.5%) versus less than one-fourth with vehicle (range: 8.1%-24.9%; $P<0.01$, all) and less than one-third with component dyads or branded adapalene 0.3%/BPO 2.5% (range: 27.8%-32.9%; $P\leq0.001$, all). Treatment success rates were significantly greater for all active treatments versus vehicle ($P<0.01$, all). NNT values for CAB (3-5) were lower (better) than for constituent dyads (5-6) or branded adapalene 0.3%/BPO 2.5% (7), further indicative of greater efficacy. TEAEs with CAB were mostly of mild-to-moderate severity. TEAE and discontinuation rates were similar or lower with CAB gel than with adapalene/BPO dyad gels. Mean cutaneous safety/tolerability scores with CAB gel were <1 (mild) at all timepoints.

CONCLUSIONS: CAB gel demonstrated significantly greater efficacy in the treatment of moderate-to-severe acne than dyad gels and branded adapalene 0.3%/BPO 2.5% gel, with approximately half of participants achieving clear/almost clear skin by 12 weeks with CAB. Due to acne pathogenesis, a triple-combination treatment may result in clinical success more often than two-ingredient combination products.

ACKNOWLEDGMENTS AND FUNDING: Funding by Ortho Dermatologics.

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2. Huang C-Y, et al. Comparative efficacy of pharmacological treatments for acne vulgaris: a network meta-analysis of 221 randomized controlled trials. *Ann Fam Med.* 2023;21:358-369.

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ATOPIC DERMATITIS

Abstract AD-01

Interim Results From Admirable, a Phase 3b Open-Label Study Assessing Lebrikizumab in Patients With Skin of Color and Moderate-to-Severe Atopic Dermatitis

A Alexis, MD[1]; A. Moiin, MD[2]; J Waibel, MD[3]; P Wallace, MD[4]; D Cohen, MD[5]; V Laquer, MD[6]; P Kwong, MD, PhD[7]; AR Atwater, MD[8], C Harris, PharmD[8]; J Proper, PhD[8]; M Silk, PhD[8]; E Pierce, PhD[8]; S. Pillai, PhD[8]; MJ Rueda, MD[8]; A Moore, MD[9]

[1]Weill Cornell Medicine, New York, NY, USA; [2]Comprehensive Dermatology Center, Detroit, MI, USA; [3]Miami Dermatology and Laser Institute, Miami, FL, USA; [4]Wallace Skin Research Center, Los Angeles, CA, USA; [5]Skin Care Physicians of Georgia, Macon, GA, USA; [6]First OC Dermatology Research, Fountain Valley, CA, USA; [7]Suncoast Skin Solutions Inc, Jacksonville, FL, USA; [8]Eli Lilly and Company, Indianapolis, IN, USA; [9]Baylor University Medical Center, Dallas, TX, USA; Arlington Research Center, Arlington, TX, USA; Arlington Center for Dermatology, Arlington, TX, USA

BACKGROUND: ADmirable is the first phase 3b, open-label, 24 week(W) study to evaluate the efficacy and safety of Lebrikizumab (LEB) in adult and adolescent patients (pts) with moderate to severe Atopic dermatitis (AD) and skin of color (SOC).

OBJECTIVES: To present the baseline demographics, clinical characteristics, and 16W efficacy from an interim analysis of ADmirable.

METHODS: The analysis included pts who enrolled by June 29, 2023, and completed 16 Ws of LEB treatment/discontinued treatment on/prior to W16. At baseline and W2, pts received a 500mg LEB loading dose followed by 250mg every 2 weeks through W16. Key eligibility criteria: age ≥12 years(yrs) (≥40 kg for adolescents), self-reported race other than White, Fitzpatrick Phototype IV-VI, chronic AD present for ≥1 year, history of inadequate response to topical medications, biologics- naïve, baseline Eczema Area and Severity Index(EASI) ≥16, Investigator's Global Assessment (IGA) ≥3, and ≥10% body surface area(BSA) of AD involvement. Baseline demographics and clinical characteristics were collected during screening. Efficacy endpoints: proportion of pts achieving ≥75%/≥90% reduction in EASI(EASI 75/90); IGA 0,1 with ≥2-point improvement from baseline (IGA 0,1) and ≥3-point and ≥4-point Pruritus Numeric Rating Scale(NRS) improvement from baseline; mean percentage change in EASI and Pruritus NRS; and changes in post-inflammatory hyperpigmented (PIH) lesions as measured by PDCA-Derm™. Innovative objective measures of pigment and erythema were utilized.

RESULTS: Among 50 enrolled pts, 40(80%) were-Black/African-American; 7(14%) Asian; 3(6%) American Indian/Alaska Native; 11(22%) Hispanic/Latino and 39(78%) were not Hispanic/Latino; 8(16%) patients were adolescents and 23(46%) patients were female. The proportions of pts with Fitzpatrick Phototype IV, V, and VI: 42%, 22%, and 36%. At baseline, mean (SD) age- 42.2(19.7) yrs; and disease duration- 19.3(15.8) yrs; BMI- 30.2(7.7) kg/m^2; BSA affected 41.7% (20.8) and 64% pts presented with IGA=3; EASI and Pruritus NRS: 28.1(12.4) and 7.2(2.2) and 27 pts (54%) had at least one PIH lesion. Clinical characteristics included AD with prurigo nodules (16%), follicular/perifollicular accentuation of AD (14%), allergic shiners (12%), pityriasis alba (10%), and AD with nummular features (10%). 40 pts completed the W16 visit. At W16, pts proportions achieving the following outcomes were: EASI 75: 68%; EASI 90: 46%; IGA 0,1: 39%; ≥3-Point Pruritus NRS improvement: 66%; ≥4-point Pruritus NRS improvement: 56%. At W16, the mean percentage change from baseline (improvement):-79.1% for EASI, -53.9% for Pruritus NRS. At W16, 12/21 pts with baseline hyperpigmented lesions had improved PDCA-Derm™; 6 /21 lesions achieved normal skin tone. No serious adverse events were observed.

CONCLUSIONS: This interim analysis of LEB for pts with moderate-to-severe AD and SOC showed that, LEB improved AD signs and symptoms as measured with objective and subjective tools and scales.

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Abstract AD-02

Contemporary Systemic Treatment Patterns in Atopic Dermatitis

Jerry Bagel[1]; Ann P. Quick[2]; Lenka V Hurton[2]; Olga Zolochevska[2]; Aaron S. Farberg[3,4]; Matthew S Goldberg[2]; Jonathan I Silverberg[5]

[1]Schweiger Dermatology Group, East Windsor, NJ; [2]Castle Biosciences, Inc., Friendswood, TX, USA; [3]Baylor Scott & White Health System, Dallas, TX, USA; [4]Bare Dermatology, Dallas, TX, USA; 5Department of Dermatology, The George Washington University School of Medicine and Health Sciences, Washington, DC, USA

INTRODUCTION/BACKGROUND: With newly emerging targeted systemic therapies for atopic dermatitis (AD) there is a need to understand the evolving real-world treatment patterns and implications on AD management. Since the FDA approval of dupilumab for adults in 2017, three additional targeted therapies – the IL-13 inhibitor tralokinumab and 2 JAK inhibitors (abrocitinib and upadacitinib) – were approved for adults with moderate-to-severe AD as of January 2022. Additional treatment options are still awaiting FDA approval, including the IL-31 inhibitor nemolizumab, or undergoing clinical trials (e.g., OX40-OX40L inhibitors). Therefore, an update on real-world contemporary targeted treatment strategies for AD is warranted.

OBJECTIVES: To characterize current systemic treatment patterns in patients with AD.

METHODS: A real-world retrospective observational analysis of US medical and prescription claims data (IQVIA, Durham, NC) was assessed. Individuals with an AD diagnosis were included in analysis if they initiated a modern targeted systemic AD prescription with a dermatology provider at index (patient selection event) for their first line of therapy (LOT) between January 2022 and June 2023, but had no AD systemic treatment 24 months prior to index and were continuously enrolled a minimum of six months for follow-up (n=7000). Treatment patterns, switch rates, comedications, comorbidities, and post-index events were evaluated.

RESULTS: First line targeted systemic therapies for adults included dupilumab (91.2%), upadacitinib (4.2%),

tralokinumab (3.9%), and abrocitinib (0.6%). Over 50% of patients initiating one of these therapies underwent a change in treatment during the follow-up period. Switch rates for monotherapy use of each of these targeted drugs to another targeted systemic therapy were 5%, 10%, 17%, and 16%, respectively. For the second LOT, dupilumab monotherapy decreased to 12% whereas upadacitinib use increased to 50%, tralokinumab to 29%, and abrocitinib to 9% of LOT-2. On average, for patients switching to another systemic therapy, the LOT-1 duration was 5.5 months. Subsequent LOT durations of the LOT-1 switcher decreased, with 5.1 months, 4.7 months, 4.7 months, and 3.5 months for LOTs 2-5, respectively. Of patients only treated with a targeted systemic LOT-1, 47% discontinued the drug within ~5 months and did not switch to another targeted AD therapy. These patients may have switched to other non-targeted systemic treatments, topicals, or ceased any treatment.

In addition to those who switched therapies, some patients who remained on their first LOT had evidence of persisting disease burden. For instance, over half of individuals who maintained their first targeted systemic LOT also used topical therapies. Those who persisted on dupilumab treatment despite continuing pruritus (641/6001, 11%) had 2.6x higher rates of post-index biopsy (5% vs 14%, $p<.0001$) accompanied by increased rates of other cutaneous diagnoses such as mycosis fungoides, contact dermatitis, tinea, and seborrheic dermatitis compared to those who did not. This suggests an unclear diagnosis or multiple pruritic conditions in some of these patients who did not achieve a robust response to targeted treatment.

Post-index pruritus was suggestive of a higher level of overall disease burden and comorbidities as observed by increased proportions of patients receiving topical corticosteroids (61% vs 50%, $p<.0001$) and antianxiety medications (33% vs 20%, $p<.0001$), or who had epidermal thickening (21% vs 5%, $p<.0001$) and other/unspecified dermatitis (36% vs 19%, $p<.0001$) events post index. As new therapies with different mechanisms of action are approved, there will be more options for patients with incomplete response to first-line AD therapy.

CONCLUSIONS: Irrespective of the index treatment for AD, >50% of patients experienced a change in therapy. Some patients who remained on index treatment, had indicators of inadequate disease control, suggesting a need for improvement over empirical selection of therapies to support more proactive management strategies in the context of the emerging treatment landscape for AD.

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Abstract AD-03

Long-Term Dupilumab Treatment is Not Associated with an Increased Overall Risk of Infections in Adults with Moderate-to-Severe Atopic Dermatitis

Lisa A Beck, MD[1]; Krystal Ngo, PharmD[2*]; Eric L Simpson, MD[3]; Diamant Thaçi, MD[4]; Bruin- Marjolein de Weller, MD, PhD[5]; Mette Deleuran, MD[6]; Yoko Kataoka, MD[7]; Adam J. Friedman, MD[8]; Faisal A. Khokhar, MD[9]; Anna Coleman, MS[10]; Guy Gherardi, MD[11]; Zhen Chen, PhD, MPH[9]; Elena Avetisova, MD[9]; Annie Zhang, MD[12]; Tien V Nguyen, MD[9]

[1]University of Rochester Medical Center, Rochester, NY, USA; [2]Sanofi, Irvine, CA, USA; [3]Oregon Health & Science University, Portland, OR, USA; [4]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [5]University Medical Center Utrecht, Utrecht, Netherlands; [6]Aarhus University Hospital, Aarhus, Denmark; [7]Osaka Habikino Medical Center, Osaka, Japan; [8]George Washington University School of Medicine and Health Sciences, Washington, DC, USA; [9]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [10]Regeneron Pharmaceuticals Inc., Dublin, Ireland; [11]Sanofi, Reading, UK; [12]Sanofi, Cambridge, MA, USA

BACKGROUND: Data from LIBERTY atopic dermatitis (AD) open-label extension (OLE) study (NCT01949311) indicates continuous dupilumab treatment for up to 4 years (yrs) in adults with moderate-to-severe AD is not associated with an increased risk of overall systemic or cutaneous infections.[1]

OBJECTIVE: To report exposure-adjusted incidence rates (EAIR) of infections in adults with moderate-to-severe AD treated with dupilumab for up to 5 yrs.

METHODS: This phase 3, multicenter, OLE trial enrolled adults with moderate-to-severe AD from any dupilumab parent study (phase 1–3). Patients (pts) received 300mg dupilumab weekly (qw). 226 pts transitioned to 300mg every 2 weeks from Week 108 to match approved dosage. EAIR (pts with ≥1 event/100 pt-yrs [nP/100PY]) was calculated for treatment-emergent infections and skin infections for overall study population (N=2,677). Because OLE lacked control arm, infection data from 1-yr LIBERTY AD CHRONOS trial (NCT02260986; n=315) are included for comparison.

RESULTS: From 2,677 pts enrolled, 2,207/557/334 completed treatment up to Week 52/148/260. The most common reasons for study withdrawal during OLE were dupilumab approval and commercialization (810/1,380 pts; 58.7% of withdrawals) and pt withdrawal (248/1,380 [18.0%]). Treatment-emergent adverse events led to permanent discontinuation in 101 (3.8%) pts. EAIR of pts with ≥1 treatment-emergent infection was lower in OLE vs placebo (PBO) qw+topical corticosteroids (TCS) arm of 1-yr CHRONOS trial (70.7 vs 107.0 nP/100PY). Over this 5-yr OLE, 50 pts (0.9 nP/100PY) had ≥1 serious infection, 53 (0.9 nP/100PY) had ≥1 severe infection, and 20 (0.3 nP/100PY) had ≥1 infection resulting in permanent treatment discontinuation. Skin infections reported in 535 pts (11.0 nP/100PY), comprising non-herpetic skin infections (249 pts; 4.6 nP/100 PY) and herpes viral infections (343 pts; 6.6 nP/100 PY). EAIR of skin infections decreased throughout OLE (1 yr: 17.2 nP/100 PY; 3 yrs: 11.9 nP/100 PY; 5 yrs: 11.0 nP/100

PY) and was lower than CHRONOS PBO qw+TCS arm (29.5 nP/100 PY). The most common Preferred Terms (PT) (≥5.0 nP/100PY) from System Organ Class infections and infestations were nasopharyngitis (774 pts; 17.6 nP/100PY), upper respiratory tract infection (365 pts; 7.0 nP/100PY), and conjunctivitis (277 pts; 5.2 nP/100PY; unspecified or undetermined etiology, including non-infectious cases). Conjunctivitis was the most common infection PT leading to treatment discontinuation (10 pts; 0.2 nP/100PY). EAIR of serious infections remained stable during OLE (1 yr: 0.8 nP/100PY; 3 yrs: 0.9 nP/100PY; 5 yrs: 0.9 nP/100PY).

CONCLUSIONS: Long-term dupilumab treatment in adults with moderate-to-severe AD does not increase risk of systemic or cutaneous infections. Over 5 yrs, treatment-emergent infection rates in OLE were low compared to PBO+TCS pts in 1-yr study. Serious infection rates remained low and stable over 5-year OLE, confirming dupilumab's safety.

REFERENCES:

1. Blauvelt A, et al. No increased risk of overall infection in adults with moderate-to-severe atopic dermatitis treated for up to 4 years with dupilumab. *Adv Ther*. 2023;40:367-380.

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Abstract AD-04

Real-World Treatment Patterns of Atopic Dermatitis Patients on Tralokinumab by Age: A Claims-Based Analysis

Daniel Butler, MD[1]; Ami J Claxton, MS, PhD[2]; Valerie Ng, MS, PharmD[2]; Shannon Schneider, PhD[2]; Annie Guerin, MS[3]; Marjolaine Gauthier-Loiselle, MS, PhD[3]; Rebecca Burne, MS, PhD[3]; Sanjeev Balu, PhD[2]

[1]University of Arizona, Tucson, AZ, USA; [2]LEO Pharma, Madison, NJ, USA; [3]Analysis Group, Inc., Montreal, QC, Canada; *Current affiliation: Ionis Pharma, Carlsbad, CA, USA

INTRODUCTION: This retrospective study examined characteristics and real-world treatment patterns of US adults with AD initiated on tralokinumab overall and by age.

METHODS: Adults in the Komodo Research Database with ≥1 claim for AD and tralokinumab from approval (12/27/2021) through (9/30/2022) were included. Persistence and proportion of patients with every 4 week dosing (Q4W) were estimated from prescription fill dates. Index date was date of tralokinumab initiation, baseline period was 3 months preceding index date, and study period was index date to end of continuous health plan enrollment or data availability (≥3 months). Persistence was time from initiation until a gap of ≥45 days between last day of supply and next fill or end of the study period. Proportion of patients with Q4W dosing was assessed among patients receiving tralokinumab for ≥6 months and was defined by days between fills for 2 doses as 56 days ± 7 days (Q4W). Kaplan-Meier was used to estimate persistence. Analyses were conducted in all patients and by younger (18-64) and older (≥65 years) age.

RESULTS: Of 647 patients, median age was 50.0 years and 52.4% were females. During baseline period, 54.1% received ≥1 topical corticosteroid and 32.5% were treated with dupilumab. Persistence to tralokinumab at Week 24 was 62.9% (95% confidence interval [CI] 58.6%, 66.8%). Younger patients (n=509) had higher persistence of 65.9% (95% CI 61.1%, 70.3%) while persistence in older patients (n=138) was 51.8% (95% CI 42.7%, 60.2%). Of those treated ≥6 months with tralokinumab (n=176), 26.7% had Q4W dosing at any time, 28.0% and 21.2% in younger and older patients, respectively.

CONCLUSION: This study presents tralokinumab real-world treatment patterns. Overall persistence was 62.9% at Week 24, and 26.7% patients had Q4W dosing based on refill dates. These are lower estimates compared to other published real-world data, highlighting the limitations of using only prescription claims data, which reflects fill dates rather than administration dates. Persistence and Q4W

dosing definitions rely on days between fills, and do not account for a variety of confounders such as patient stockpiling, sampling, etc. Future studies with larger sample size and longer follow-up including outside prescription data claims are needed to investigate persistence to tralokinumab and Q4W dosing.

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Abstract AD-05

Dupilumab Treatment Reduces Signs in Patients with Atopic Hand And Foot Dermatitis: Results From a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial

Eric L Simpson, MD, MCR[1]; Krystal Ngo, PharmD*[2]; Weily Soong, MD[3]; Margitta Worm, MD, PhD[4]; Andreas Pinter, MD[5]; Koji Masuda, MD, PhD[6]; Liyang Shao, PhD[7]; Ariane Dubost-Brama, MD[8]; Ashish Bansal, MD[7]; Andrew Korotzer, PhD[7]; Ana B Rossi, MD[9]

[1]Oregon Health & Science University, Portland, OR, USA; [2]Sanofi, Irvine, USA; [3]Allervie Health/Alabama Allergy & Asthma Center, Birmingham, AL, USA; [4]Charité-Universitätsmedizin Berlin, Berlin, Germany; [5]University Hospital Frankfurt am Main, Frankfurt am Main, Germany; [6]Kyoto Prefectural University of Medicine, Kyoto, Japan; [7]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [8]Sanofi, Chilly-Mazarin, France; [9]Sanofi, Cambridge, MA, USA

BACKGROUND: Dupilumab has previously shown overall efficacy in treating atopic hand and foot dermatitis.

OBJECTIVE: To report the effect of dupilumab treatment on individual signs of atopic hand and foot dermatitis.

METHODS: The phase 3, randomized, double-blind LIBERTY-AD-HAFT (NCT04417894) trial enrolled patients aged ≥12 years with moderate-to-severe (Investigator's Global Assessment [IGA] score of 3/4) atopic hand and foot dermatitis. Patients were randomized to dupilumab monotherapy 300 mg every 2 weeks (q2w) in adults; 200/300 mg q2w in adolescents, or placebo for 16 weeks. This analysis presents the proportion of patients reporting absent, mild, moderate, or severe erythema, scaling/flaking, lichenification, vesiculation/erosion, edema, and fissures, assessed by the modified total lesion sign score (mTLSS) in hands and feet.

RESULTS: At baseline, most patients had scores of moderate or severe signs on their hands. Of the 133 patients enrolled, over 65% of patients treated with dupilumab (n = 67) achieved an absent or mild score by Week 16 in each of the signs/symptoms assessed. Proportion of patients with absent or mild hand scores increased from baseline to Week 16 in erythema (9% vs 71.6%), scaling/flaking (16.4% vs 74.7%), lichenification (4.5% vs 65.6%), vesiculation/erosion (43.3% vs 89.6%), edema (44.7% vs 86.6%), and fissures (23.9% vs 83.5%). Proportion of patients with absent or mild foot scores increased from baseline to Week 16 in erythema (56.7% vs 80.6%), scaling/flaking (56.7% vs 82.1%), lichenification (53.8% vs 82.1%), vesiculation/erosion (76.1% vs 86.6%), edema (76.1% vs 88.1%), and fissures (77.6% vs 86.6%). Safety was consistent with the known dupilumab safety profile in patients with atopic dermatitis.

CONCLUSIONS: Dupilumab treatment in patients improves signs of hand and foot dermatitis, including erythema, scaling/flaking, lichenification, vesiculation/erosion, edema, and fissures.

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Abstract AD-06

Dupilumab Demonstrates Higher Likelihood of Achieving Improvements in Signs, Symptoms, and Quality of Life vs Lebrikizumab: Results From a Placebo-Adjusted Indirect Comparison Analysis

Patricia Guyot, PhD[1]; Krystal Ngo, PharmD[2*]; Yingxin Xu, PhD[3]; Amy Praestgaard, MS[4]; Nick Freemantle, PhD[5]; Ana B Rossi, MD, CMD[4]; Brad Shumel, MD[3]; Gaelle Bego Le Bagousse, MS[2]; Zhixiao Wang, PhD[3]; Kerry Noonan, BA[4]; Mike Bastian, PhD[6]

[1]Sanofi, Gentilly, France; [2]Sanofi, Irvine, CA, USA; [3]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [4]Sanofi, Cambridge, MA, USA; [5]Institute for Clinical Trials and Methodology, University College London, London, UK; [6]Sanofi, Frankfurt, Germany

BACKGROUND: Dupilumab and lebrikizumab are both monoclonal antibodies that have demonstrated efficacy and safety in clinical trials of patients with moderate-to-severe atopic dermatitis (AD). Dupilumab targets both interleukin (IL)-4 and IL-13, and is fully human, whereas lebrikizumab selectively targets IL-13 and is humanized. However, no direct head-to-head clinical trials have been performed to compare efficacy of dupilumab vs lebrikizumab in combination with topical corticosteroids (TCS). Bucher indirect treatment comparisons (ITCs), in which treatment effects are anchored to a common comparator (e.g. placebo), provide a robust and widely accepted method of evaluating the relative efficacy of drugs in the absence of direct comparisons.

OBJECTIVE: To report the results of a placebo-adjusted Bucher ITC of 16-week therapy for moderate-to-severe AD, comparing the efficacy of dupilumab every 2 weeks (q2w) (LIBERTY AD CHRONOS) vs lebrikizumab q2w (ADhere), in combination with TCS.

METHODS: Placebo-adjusted Bucher ITC was conducted using published phase 3 trial data from LIBERTY AD CHRONOS (NCT02260986) and ADhere (NCT04250337). For both studies, data from the 16-week period were used, employing non-responder imputation, with the following doses: 300mg dupilumab + TCS q2w, or placebo + TCS, and 250mg lebrikizumab q2w + TCS, or placebo + TCS. No adjustments were made for baseline characteristics. Outcomes included proportion of patients achieving ≥75% improvement from baseline in Eczema Area and Severity Index (EASI-75), Investigator's Global Assessment score 0/1 (IGA-0/1; clear/almost clear), 4-point improvement from baseline in peak pruritus Numerical Rating Scale score (PP-NRS ≥4), and ≥4-point improvement from baseline in Dermatology Life Quality Index (DLQI ≥4). Odds ratio (OR) with 95% confidence interval (CI) are reported.

RESULTS: Based on EASI and IGA, the patient population enrolled in ADhere presented with lower disease severity compared with the patient population enrolled in LIBERTY AD CHRONOS at baseline; however, PP-NRS and DLQI scores were similar between both trials. This placebo-adjusted Bucher ITC favored dupilumab vs lebrikizumab with TCS combination treatment for all outcomes evaluated. Patients treated with dupilumab + TCS had a significantly higher likelihood of achieving EASI-75 (OR=2.39, 95%CI 1.10–5.19) and PP-NRS ≥4 (OR=2.63, 95%CI 1.17–5.95) at Week 16 vs those treated with lebrikizumab + TCS. OR for the endpoints IGA 0/1 and DLQI ≥4 favored dupilumab, but did not reach statistical significance: IGA 0/1 (OR=1.90, 95%CI 0.81–4.42), DLQI ≥4 (OR=2.35, 95%CI 0.94–5.87).

CONCLUSION: A placebo-anchored Bucher ITC approach showed that the likelihood of achieving improvements in signs, symptoms, and quality of life is higher for patients treated with dupilumab + TCS vs lebrikizumab + TCS.

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Abstract AD-07

Clinically Meaningful Responses in Tralokinumab-Treated Adolescents with Atopic Dermatitis Not Achieving IGA 0/1 at Week-16

Amy Paller, MD[1]; Andrew Blauvelt, MBA, MD[2]; Weily Soong, MD[3]; Chih-ho Hong, MD, FRCPC[4]; Marie LA Schuttelaar, MD, PhD[5]; Shannon Schneider, PhD[6]; Marie Holst Moerch, MS[7]; Eric Simpson, MD, MCR[8]

[1]Feinberg School of Medicine, Northwestern University, USA; [2]Oregon Medical Research Center, USA; [3]Allervie Health-Alabama Allergy & Asthma Center, USA; [4]University of British Columbia, Canada; [5]University Medical Centre Groningen, University of Groningen, The Netherlands; [6]LEO Pharma Inc, USA; [7]LEO Pharma A/S, Denmark; [8]Oregon Health & Science University, USA

BACKGROUND: In the monotherapy phase 3 trial (ECZTRA 6, NCT03526861) in adolescents with moderate-to-severe atopic dermatitis (AD) treated with tralokinumab, IGA of clear/almost clear skin (IGA 0/1) at Week 16 was a primary endpoint. IGA 0/1 can be a high standard to achieve for patients with moderate-to-severe AD and may not fully reflect achievement of other clinically meaningful parameters, such as improvement in signs, symptoms, and/or quality-of-life (QoL).

METHODS: Adolescents (12-17 years) were randomized to subcutaneous tralokinumab 150mg or 300mg, or placebo, every 2 weeks. Patients who did not achieve IGA 0/1 at

Week 16 and/or utilized rescue therapy were included in this post-hoc analysis. Non-responder imputation was used for patients who utilized rescue therapy or had missing data. Clinically meaningful responses were defined as EASI-50, ≥3-point improvement in pruritus NRS, or ≥6-point improvement in CDLQI.

RESULTS: At Week 16, 78.6% and 82.5% of tralokinumab-treated patients (150mg/300mg) versus 95.7% (placebo) exhibited IGA>1 and/or used rescue therapy. 36.4% (150mg) and 52.5% (300mg) of patients with IGA>1 in the tralokinumab arms, compared to 21.1% (placebo), achieved clinically meaningful responses in at least one measure: EASI-50, pruritus NRS, or CDLQI. Greater proportions of tralokinumab-treated patients (150mg/300mg vs. placebo) achieved EASI-50 (31.2%/41.3% vs. 10.0%) and ≥3-point improvement in pruritus NRS (21.6%/22.8% vs. 8.0%). A greater proportion of tralokinumab 300mg patients vs. placebo (35.2% vs. 15.0%) achieved ≥6-point improvement in CDLQI.

CONCLUSION: Many tralokinumab-treated adolescents who did not achieve IGA 0/1 at Week 16 and/or used rescue therapy still achieved clinically meaningful improvements in AD signs, symptoms, and/or QoL.

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Abstract AD-08

Clinical Remission and Therapy-Free Remission in Pediatric Patients With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab: Open-Label Extension Study Preliminary Data

Elaine C Siegfried, MD[1,2]; Krystal Ngo, PharmD[3*]; Thomas Bieber, MD, PhD, MDRA[4]; Amy S Paller, MD[5,6]; Eric L Simpson, MD[7]; Michael J Cork, BSc, MB, PhD, FRCP[8,9]; Stephan Weidinger, MD[10]; Lawrence F Eichenfield, MD[11,12]; Zhen Chen, PhD, MPH[13]; Ashish Bansal, MD[13]; Henry Yu, Pharm D[13]; Ana B Rossi, MD, CMD[14]

[1]Saint Louis University, St. Louis, MO, USA; [2]Cardinal Glennon Children's Hospital, St. Louis, MO, USA; [3]Sanofi, Irvine, CA, USA; [4]Christine Kühne-Center for Allergy Research and Education, Medicine Campus Davos, Switzerland; [5]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [6]Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA; [7]Oregon Health & Science University, Portland, OR, USA; [8]University of Sheffield, Sheffield, UK; [9]Sheffield Children's Hospital, Sheffield, UK; [10]University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany; [11]University of California San Diego, La Jolla, CA, USA; [12]Rady Children's Hospital, San Diego, CA, USA; [13]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [14]Sanofi, Cambridge, MA, USA

BACKGROUND: Pediatric and adolescent patients with moderate-to-severe atopic dermatitis (AD) have a

high burden of disease with higher severity and earlier onset predicting disease persistence. The need for lifelong treatment is a common concern among physicians and caregivers who are considering systemic therapy that must be weighed against the potential benefit of early intervention on disease progression.

OBJECTIVES: To provide preliminary data for pediatric and adolescent patients with moderate-to-severe AD achieving clinical remission with dupilumab and maintaining remission after discontinuing dupilumab.

METHODS: Patients 6 to <18 years old with moderate-to-severe AD (N=356) who were enrolled in the ongoing LIBERTY AD PED open-label extension (OLE; NCT02612454) received weight-tiered dupilumab dosing (5 kg to <15 kg: 200 mg every 4 weeks [q4w]; 15 kg to <30 kg: 300 mg q4w; 30 kg to <60 kg: 200 mg every 2 weeks [q2w]; ≥60 kg: 300 mg q2w) for ≥52 weeks of follow up. Clinical remission was defined as maintaining an Investigators Global Assessment (IGA) score of 0 or 1 (clear or almost clear) for ≥12 weeks after 40 weeks on dupilumab. Patients reaching clinical remission discontinued dupilumab and were monitored for recurrent AD per protocol. Dupilumab was restarted for patients who regressed to IGA score ≥2 (mild or greater) at one visit.

RESULTS: Clinical remission was achieved for 29.4% (30/102) of adolescents and 28.7% (73/254) of children. Clinical remission was maintained in 43.3% (13/30) of adolescents and 60.3% (44/73) of children off dupilumab. Median time from drug withdrawal to last visit off drug was 18.0 and 15.7 weeks, respectively.

CONCLUSION: About one third of pediatric patients experienced sustained remission on dupilumab and about half of these maintained prolonged remission off treatment. The likelihood of therapy-free remission appears to be higher in younger patients. Longer-term observations will elucidate whether these findings are durable, suggesting disease course modification.

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Abstract AD-09

Real-World Effectiveness of Persistent Tralokinumab Use on Clinician and Patient-Reported Outcomes in Patients With Atopic Dermatitis in the CorEvitas Atopic Dermatitis Registry

Jonathan Silverberg, MPH, MD, PhD[1]; Sanjeev Balu, PhD[2]; C Jean Choi, MS[3]; Alvin Li, PhD[3], Oksana Pugach, PhD[3]; Shannon Schneider, PhD[2]; Eric Simpson, MD, MCR[4]

[1]The George Washington School of Medicine and Health Sciences, Washington, DC; [2]LEO Pharma Inc., Madison, NJ; [3]CorEvitas, LLC, Waltham, MA; [4]Department of Dermatology, Oregon Health & Science University, Portland, OR

BACKGROUND: Tralokinumab is a high-affinity monoclonal antibody targeting IL-13, a driver of inflammation in AD. The ECZTRA trials showed tralokinumab is effective and safe, but real-world evidence is limited.

OBJECTIVES: To assess the change from baseline in clinician-assessed and patient-reported outcomes (PROs) among US adults with AD post 6-months of persistent tralokinumab use in the prospective, non-interventional CorEvitas AD registry, which launched in 7/2020.

METHODS: This analysis includes registry patients with baseline data, who started tralokinumab between 2/1/2022 and 5/31/2023 and were persistent on it at 6-month follow-up (FU). Baseline data were summarized using descriptive statistics and stratified by advanced systemic therapy (AST) experience. Outcome measures included: validated Investigator's Global Assessment for AD (vIGA-AD), ≥50%/≥75% improvement in Eczema Area and Severity Index (EASI-50/75), Dermatology Life Quality Index (DLQI), mean weekly pruritis numerical rating scale, and mean change in Work Productivity and Activity Impairment (WPAI).

RESULTS: In the 60 patients, mean age and AD duration were 49.1 and 15.0 years. Most were female (56.7%), White (85.0%), worked full-time (63.3%), and AST-naïve (AST-N, 73.3%). At baseline, most patients had moderate-to-severe AD (EASI≥ 7: 67%; vIGA-AD 3: 83.3%; vIGA-AD 4: 6.7%). Disease severity was lower in AST-experienced (AST-E) patients, all of whom were dupilumab-experienced. A notable proportion of patients experienced improvements from baseline to FU: vIGA-AD ≤1 (6.7% to 55.0%), EASI ≤7 (33.3% to 85.0%), and DLQI ≤5 (38.3% to 66.7%). In patients with baseline EASI ≥7.1, 85.0% and 77.5% achieved EASI-50 (AST-N: 90.9%; AST-E: 57.1%) and EASI-75 (AST-N: 84.8%; AST-E: 42.9%), respectively, at the 6-month FU. In those with baseline vIGA-AD 3 or 4, 79.6% and 66.7% achieved EASI-50 (AST-N: 83.3%; AST-E: 66.7%) and EASI-75 (AST-N: 76.2%; AST-E: 33.3%) at FU. In those with baseline DLQI ≥4, 71.4% achieved ≥4-point improvement at FU (AST-N: 78.1%; AST-E: 50.0%). In patients with baseline mean weekly pruritus NRS ≥3, 69.8% achieved ≥3-point improvement at FU (AST-N: 70.0%; AST-E: 69.2%). Improvements were also reported in WPAI.

CONCLUSIONS: In this real-world study, AD patients experienced improvements in clinician-assessed outcomes and PROs after 6-months of persistent tralokinumab, regardless of prior AST use.

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DISCLOSURES: JS: reports honoraria as a consultant/advisory board member from LEO Pharma and has acted as a consultant for and/or received grants/honoraria from AbbVie, AnaptysBio, Asana Biosciences, Galderma Research and Development, GSK, Glenmark, Kiniksa, LEO Pharma, Lilly, MedImmune, Menlo Therapeutics, Pfizer, PuriCore, Regeneron, and Sanofi. ES: reports grants and/or personal fees from AbbVie, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly, FortéBio, Galderma, Incyte, Kyowa Kirin, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, Novartis, Ortho Dermatologics, Pfizer, Pierre Fabre Dermo Cosmetique, Regeneron, Sanofi, Tioga, and Valeant. AL, OP, JC: Employees of CorEvitas, LLC, which has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, Inc., Arena, Boehringer Ingelheim, Bristol Myers Squibb, Chugai, Eli Lilly and Company, Genentech, GSK, Janssen Pharmaceuticals, Inc., LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Sun Pharmaceutical Industries Ltd., and UCB S.A. SB and SS: Employees of LEO Pharma

Abstract AD-10

Real-World Baseline Characteristics and Persistence in Adult Patients Initiating Tralokinumab in the CorEvitas Atopic Dermatitis Registry

Eric Simpson, MD, MCR[1]; Sanjeev Balu, PhD[2]; C Jean Choi, MS[3]; Alvin Li, PhD[3]; Oksana Pugach, PhD[3]; Shannon Schneider, PhD[2]; Jonathan Silverberg. MPH, MD, PhD[4]

[1]Department of Dermatology, Oregon Health & Science University, Portland, OR, USA; [2]LEO Pharma Inc., Madison, NJ; [3]CorEvitas, LLC, Waltham, MA, USA; [4]The George Washington School of Medicine and Health Sciences, Washington, DC, USA

BACKGROUND: Tralokinumab is a monoclonal antibody that targets IL-13, a key driver of atopic dermatitis (AD). In clinical trials, tralokinumab demonstrated favorable efficacy and safety profiles for moderate-to-severe AD. However, data on real-world patients and treatment persistence is limited.

OBJECTIVES: To describe baseline characteristics and persistence at 6 months in US adults with AD initiating tralokinumab in the CorEvitas AD registry.

METHODS: The CorEvitas AD Registry is prospective and non-interventional, collecting data from adults with AD. Registry patients who initiated tralokinumab between 2/1/2022 and 5/31/2023 with baseline data were analyzed. Baseline demographics and clinical characteristics were summarized using descriptive statistics and stratified by advanced systemic therapy (AST) experience, defined as a history of dupilumab, abrocitinib, or upadacitinib for AD. A 6-month follow-up was defined as a visit 5-9 months following tralokinumab initiation.

RESULTS: Of 259 patients, mean age was 50.8 years, and patients were majority female (60.2%), White (78.0%), worked full-time (55.2%), had private health insurance (77.6%), and concomitantly used topical therapy (78.4%). Most patients had moderate-to-severe disease, with mean Eczema Area and Severity Index (EASI) 14.2. Patients experienced a mean peak pruritus numerical rating scale of 6.2, and mean Dermatology Life Quality Index of 9.8. At tralokinumab initiation, 33.6% of patients were AST-experienced, of whom 95.4% had used dupilumab. Among AST-naïve patients, 80.8% used topical steroids, 36.0% topical calcineurin inhibitors, and 10.5% topical PDE4 inhibitors. AST-naïve patients had higher severity at baseline by mean BSA and mean EASI. Among patients with 6-month follow-up (n=81), 74.1% remained persistent on tralokinumab, 73.3% of whom were AST-naïve. Mean EASI of persistent patients improved from 13.8 to 3.3 at 6 months. Of 21 patients who discontinued tralokinumab, 52.4% were AST-experienced. Reasons for discontinuation included lack of efficacy, safety, and insurance.

CONCLUSIONS: In this US real-world study, adults with AD had a high disease burden, and 74.1% of patients who initiated tralokinumab were persistent at 6 months. Further studies on tralokinumab persistence with longer follow-up are warranted.

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DISCLOSURES: JS: reports honoraria as a consultant/advisory board member from LEO Pharma and has acted as a consultant for and/or received grants/honoraria from AbbVie, AnaptysBio, Asana Biosciences, Galderma Research and Development, GSK, Glenmark, Kiniksa, LEO Pharma, Lilly, MedImmune, Menlo Therapeutics, Pfizer, PuriCore, Regeneron, and Sanofi. ES: reports grants and/or personal fees from AbbVie, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly, FortéBio, Galderma, Incyte, Kyowa Kirin, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, Novartis, Ortho Dermatologics, Pfizer, Pierre Fabre Dermo Cosmetique, Regeneron, Sanofi, Tioga, and Valeant. AL, OP, JC: Employee of CorEvitas, LLC, which has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, Inc., Arena, Boehringer Ingelheim, Bristol Myers Squibb, Chugai, Eli Lilly and Company, Genentech, GSK, Janssen Pharmaceuticals, Inc., LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Sun Pharmaceutical Industries Ltd., and UCB S.A. SB and SS: Employee of LEO Pharma.

Abstract AD-11

Tralokinumab Formulated as a Pre-Filled Pen Was Efficacious and Well-Tolerated in Adults and Adolescents with Moderate-to-Severe Atopic Dermatitis

Jennifer Soung, MD[1]; Vivian Laquer, MD[2]; Matthew Zirwas, MD[3]; Peter van Iperen, PhD[4]; John Stinson, MD[4]; Katrine Lykke Albertsen, MS[4]; Shannon Schneider, PhD[5] Linda Stein Gold, MD[6]

[1]Southern California Dermatology, Santa Ana, CA, USA; [2]First OC Dermatology Research, Fountain Valley, CA, USA, [3]Dermatologists of Southwest Ohio, Bexley, OH, USA, [4]LEO Pharma A/S, Ballerup, Denmark, [5]LEO Pharma, Madison, NJ, USA; [6]Henry Ford Health System, Detroit, MI, USA

INTRODUCTION: Tralokinumab, a high-affinity monoclonal antibody that specifically neutralizes interleukin-13, is approved in multiple countries for adults and adolescents with moderate-to-severe atopic dermatitis (AD)*. Tralokinumab was initially developed as a pre-filled syringe and has recently been developed as a prefilled pen, which offers a more convenient method of administration and reduces the number of injections per dose to 2 injections for the loading dose and 1 injection for subsequent doses. The phase 3 open-label trial INJECZTRA (NCT05194540) assessed the efficacy, safety, and usability of the tralokinumab pre-filled pen in adult and adolescent patients with moderate-to-severe AD.

METHODS: 136 patients (105 adults, 31 adolescents) received tralokinumab administered with the pre-filled pen for 16 weeks. An initial loading dose (600mg tralokinumab, 2 injections) was administered at baseline. At this time patients were trained in correct handling and use of the tralokinumab pre-filled pen. During the rest of the trial, patients self-administered 300 mg tralokinumab (1 injection) every 2 weeks at the trial site or at home. Patients' ability to successfully self-administer tralokinumab with the pre-filled pen was assessed at the site at Week 4 and at home at Week 8. Primary endpoints were IGA 0/1 and EASI-75 at Week 16. Secondary endpoints included a number of adverse events. Topical corticosteroids (TCS) were allowed as rescue medication; patients using TCS were considered non-responders.

RESULTS: At baseline, 33.1% of patients had severe AD (i.e. an IGA score of 4) (adults 32.4%; adolescents 35.5%) and mean EASI score was 25.2 (adults 24.9; adolescents 26.1). At Week 16, 28.7% of patients achieved IGA 0/1 (adults 28.6%; adolescents 29.0%) and 43.5% of patients achieved EASI-75 (adults 44.8%; adolescents 38.7%). 96.2% of patients successfully self-administered tralokinumab at Week 4 (adults 98.0%; adolescents 89.7%) and 97.5% of patients successfully self-administered tralokinumab at Week 8 (adults 96.9%; 100.0% adolescents). 86 adverse events were reported in 50 patients (66 adverse events in 37 adults; 20 adverse events in 13 adolescents). The most common adverse events were injection site reaction (5.9%), atopic dermatitis (4.4%), and conjunctivitis (2.9%).

CONCLUSIONS: Tralokinumab formulated as a pre-filled pen was efficacious and well tolerated. Both adult and adolescent patients were able to self-administer tralokinumab successfully with the pre-filled pen. There were no new, and fewer AEs, compared with the pivotal trials in adults and adolescents. Across all efficacy endpoints, efficacy data were numerically better or comparable to the pivotal adult and adolescent data.

*Approved dose for adults 300 mg every 2 weeks. Approved dose for adolescents 300 mg every 2 weeks in the EU, 150 mg every 2 weeks in the USA.

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Abstract AD-12

Onset and Maintenance of Optimal Itch Response in Adult Patients With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab: Post Hoc Analysis From LIBERTY AD CHRONOS

Sonja Ständer, MD[1]; Krystal Ngo, PharmD[*2]; Gil Yosipovitch, MD[3]; Eric L Simpson, MD, MCR[4]; Brian S Kim, MD[5]; Kenji Kabashima, MD, PhD[6]; Diamant Thaçi, MD[7]; Martin Metz, MD[8,9]; Zhen Chen, MD, PhD[10]; Sandra Hagen, MD, MSc[11]; Mike Bastian, PhD[12]

[1]University Hospital Münster, Münster, Germany; [2]Sanofi, Irvine, USA; [3]University of Miami, Miami, FL, USA; [4]Oregon Health & Science University, Portland, OR, USA; [5]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [6]Kyoto University Graduate School of Medicine, Kyoto, Japan; [7]University of Lübeck, Lübeck, Germany; [8]Charité – Universitätsmedizin Berlin, Berlin, Germany; [9]Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Berlin, Germany; [10]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [11]Regeneron GmbH, Munich, Germany; [12]Sanofi, Frankfurt, Germany

BACKGROUND: Pruritus is one of the essential features of atopic dermatitis (AD). A treat-to-target concept established goals to guide treatment with systemic therapies in AD, including those for itch.

OBJECTIVES: To assess onset and maintenance of optimal itch response according to the treat-to-target concept in adult patients with moderate-to-severe AD treated with dupilumab+concomitant topical corticosteroids (TCS).

METHODS: LIBERTY AD CHRONOS (NCT02260986), a 52-week trial, enrolled patients aged ≥18 years with moderate-to-severe AD. Patients treated with dupilumab every 2 weeks+TCS or placebo+TCS were included in this post hoc analysis. Optimal itch response per the treat-to-target concept was defined as Peak Pruritus Numerical Rating Scale (PP-NRS) score of ≤4, achieved after 6 months of treatment. We assessed time to optimal itch response, percentage of patients achieving optimal itch response, and maintenance of optimal itch response. For maintenance of optimal itch response, the total number and percentage of weeks with PP-NRS ≤4 were calculated for each patient, and maximum duration was assessed as the longest period of consecutive weeks with PP-NRS ≤4 for each patient.

RESULTS: Median (interquartile range) PP-NRS score at baseline was 7.7(6.6–8.5) for patients treated with dupilumab+TCS and 7.6(6.3–8.6) for patients who received placebo+TCS. Median time (95% CI) to achieve optimal itch response was 29(22–43) days for patients treated with dupilumab+TCS and 64(43–105) days for patients who received placebo+TCS (HR [95% CI]=1.668[1.292–2.153]; $P<0.0001$). 61.3% of patients treated with dupilumab+TCS achieved optimal itch response at 6 months, compared with 26.7% of those who received placebo+TCS (P<0.0001). Significantly more patients treated with dupilumab+TCS maintained optimal itch response than patients who received placebo+TCS through 52 weeks.

In the dupilumab group, median (Q1–Q3) maintenance of optimal itch response was 40(11–50) weeks, compared with 3(0–23) weeks in the placebo group ($P<0.0001$), which corresponds to 77.1% of the total study duration (52 weeks) in the dupilumab group, compared with 5.7% in the placebo group. Maximum consecutive duration with optimal itch response was also significantly longer in dupilumab-treated patients than in patients who received placebo (median [Q1–Q3]: 29.2[4–50] weeks for dupilumab vs 2.0[0–13] weeks for placebo; $P<0.0001$).

CONCLUSIONS: Patients treated with dupilumab+TCS achieved optimal itch response rapidly and significantly faster than patients who received placebo+TCS; 29 days in dupilumab-treated patients compared with 64 days in those who received placebo. Significantly more patients treated with dupilumab+TCS achieved and maintained optimal itch response than patients who received placebo+TCS through 52 weeks. Dupilumab+TCS also led to a significantly longer maintenance of optimal itch response (40 weeks) compared with placebo+TCS (3 weeks).

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Abstract AD-13

Dupilumab Improves Patient-Reported Symptom Control Among Adults with Moderate-to-Severe Atopic Dermatitis in Clinical Practice: 4-Year Follow-Up Results From the RELIEVE-AD Study

Zhixiao Wang, PhD[1]; Krystal Ngo, PharmD[*2]; Min Yang, MD, PhD[3]; Jingdong Chao, PhD[1]; Bruno Martins, PhD[3]; Gaelle Bego-Le-Bagousse, MS[4]; Brad Shumel, MD[1]; Debra Sierka, PharmD[5]; Bruce Strober, MD, PhD[6]; Alexandra Boer Kimball, MD, MPH[7]

[1]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [2]Sanofi, Irvine, USA; [3]Analysis Group, Inc., Boston, MA, USA; [4]Sanofi, Chilly-Mazarin, France; [5]Sanofi, Cambridge, MA, USA; [6]Yale University and Central Connecticut Dermatology, Cromwell, CT, USA; [7]Harvard Medical School, Boston, MA, USA

BACKGROUND: Atopic dermatitis (AD) is often perceived to be a childhood disease, but it can also have a highly detrimental impact among adults. Results from the RELIEVE-AD study, which included adults with moderate-to-severe AD who initiated dupilumab in real-world clinical practice showed significant, sustained improvements in disease control, flares, skin symptoms, sleep, quality of life, treatment satisfaction, and concomitant AD medications up to 3 years.[1,2]

OBJECTIVE: The aim of this study is to report 4-year patient-reported symptom control from RELIEVE-AD.

MATERIALS & METHODS: RELIEVE-AD is a single-arm, prospective, longitudinal patient survey study of adults with moderate-to-severe AD who were prescribed dupilumab, enrolled in the US dupilumab patient support program, and agreed to participate in online surveys at baseline and Months 1, 2, 3, 6, 9, 12, 33, and 48. Outcomes presented here are: global change in itch since treatment initiation; absence of flares (increased itching/redness and/or new/spreading lesions) in the previous 4 weeks; skin symptoms (pain, hot/burning, sensitivity) severity in the past week (0 [no symptoms] to 10 [worst symptoms]); and AD-related sleep problems in the past week. Statistical significance was determined using generalized estimating equations to account for correlated data from the same patients. Normal distributions with an identity link function were used for continuous outcomes; binomial distributions with a logit link function were used for categorical outcomes.

RESULTS: Among 698 patients who completed the baseline survey, 353 (50.6%) completed the Month 48 survey. At baseline, the mean age was 46.2 years, 61.7% were female, and common comorbidities included: non-seasonal allergies (36.0%), asthma (32.2%), and hypertension (26.9%). Over 75% of patients reported that their itch was "very much better" at Month 48 in comparison to baseline. Flare-free status over the previous 4 weeks increased from 3.0% at baseline to 33.8% at Month 1 and 43.5%, 45.9%, and 49.0% at Months 12, 33, and 48 (all $p<0.001$). Skin symptoms improved considerably from baseline to Month 1 and then continued to improve to Month 48 (Figure 1). Similarly, AD-related sleep problems in the past week were

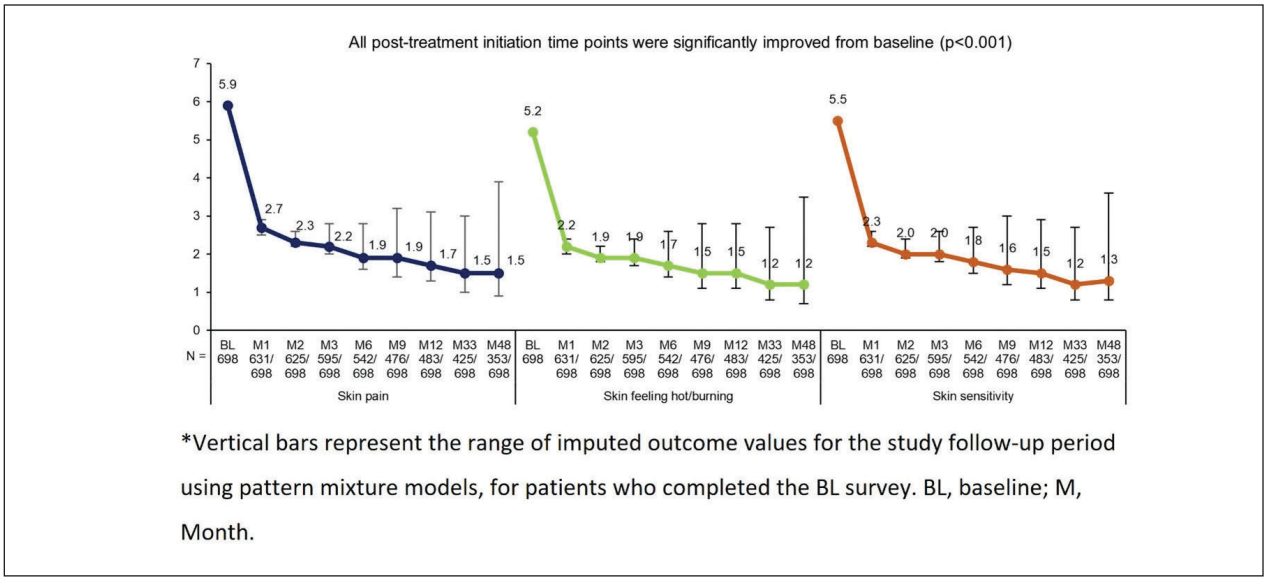

FIGURE 1. Skin pain, feeling hot/burning, and sensitivity scores.*

reported by 77.5% of patients at baseline, falling to 27.1% at Month 1, and 14.1%, 13.4%, and 12.7% at Months 12, 33, and 48, respectively (all $p<0.001$). Only 50.6% of patients were evaluable at Month 48.

CONCLUSION: Dupilumab treatment in real-world clinical practice led to rapid and sustained improvements in multiple patient-reported AD symptoms (itch, flares, skin symptoms, and sleep problems) over 4 years, with similar benefits at 4 years compared to those previously reported at 1 and 3 years.

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Abstract AD-14

Efficacy of Lebrikizumab in Adults and Adolescents With Moderate-to-severe Atopic Dermatitis by Age of Onset: Analysis of Two Phase 3 Clinical Trials

MJ Zirwas, MD[1]; M Boguniewicz, MD[2]; D Rosmarin, MD[3]; ZC Fuxench, MD[4]; RB Warren, PhD[5]; T Torres, MD, PhD[6]; M Bruin-Weller, MD, PhD[7]; Z Dawson, PhD[8]; AR Atwater, MD[8]; H Elmaraghy, MD[8]; E Pierce, PhD[8]; K Huang, PharmD[8]; L Bardolet, PhD[9]; J Zhong, PhD[10]; A Armstrong, MD[11]

[1]Dermatologists of the Central States, Probity Medical Research, and Ohio University, Bexley, OH, USA; [2]National Jewish Health and University of Colorado School of Medicine, Denver, CO, USA; [3]Department of Dermatology, Indiana University School of Medicine Indianapolis, IN, USA; [4]Department of Dermatology, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA, USA; [5]Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; [6]Department of Dermatology, Centro Hospitalar Universitário de Santo António and Instituto de Ciências Biomédicas Abel Salazar, Porto, Portugal; [7]Department of Dermatology and Allergology, National Expertise Center for Atopic Dermatitis, University Medical Center Utrecht, Utrecht, the Netherlands; [8]Eli Lilly and Company; Indianapolis, IN, USA; [9]Almirall S.A., Barcelona, Spain; [10]IQVIA, Durham, NC, USA;[11]Department of Dermatology, University of California Los Angeles, Los Angeles, CA, USA

OBJECTIVES: Efficacy of lebrikizumab (LEB) monotherapy at Week(Wk)-16 was evaluated by age of Atopic Dermatitis(AD) onset in adults and adolescents with moderate-to-severe AD from ADvocate1 and ADvocate2 (identically-designed, randomized, double-blind, placebo-controlled) phase 3 trials.

METHODS: In ADvocate1 and ADvocate2, patients(pts) were randomly allocated 2:1 to receive LEB 250mg or placebo (PBO) every 2 Wk. Pts were stratified by age of AD-onset as ≤2, >2-to-<18, and ≥18 years. Efficacy at Wk 16: Investigator's Global Assessment score of 0 or 1 with ≥2-point improvement (IGA 0,1; the trials' primary endpoint); ≥75% (EASI 75) & ≥90% (EASI 90) improvement in the Eczema Area and Severity Index from baseline; ≥4-point Pruritus Numeric Rating Scale (NRS) improvement from baseline (baseline score ≥4), and % change in total EASI from baseline. Analysis was done on the modified, pooled intent-to-treat population. Treatment-by-age subgroup interaction was assessed with logistic regression. Binary outcomes were analyzed by the Cochran-Mantel-Haenszel method, and continuous outcomes were analyzed with ANCOVA.

RESULTS: At baseline, the numbers of pts treated with LEB and PBO, respectively, were 215 and 117 in the ≤2 years AD-onset subgroup, 178 and 103 in the >2-to-<18 years subgroup, and 171 and 67 in the ≥18 years subgroup. At baseline, the percentages of pts with ≥1 atopic comorbidity were 81% in the ≤2 years subgroup, 74% in the >2-to-<18 years subgroup, and 58% in the ≥18 years subgroup. At Wk 16, treatment-by-age subgroup interactions were not significant at the 0.10 level for IGA 0,1; EASI 75; EASI 90; and Pruritus NRS 4-pt improvement. Within each subgroup, a higher proportion of LEB-treated compared with PBO-treated pts ($p<0.001$) reported IGA 0,1 responses (≤2 years: 41% vs. 12%; >2-to-<18 years: 35% vs. 12%; ≥18 years: 38% vs. 12%), EASI 75 responses (≤2 years: 57% vs. 17%; >2-to-<18 years: 51% vs. 16%; ≥18 years: 58% vs. 20%), and EASI 90 responses (≤2 years: 38% vs. 10%; >2-to-<18 years: 32% vs. 9%; ≥18 years: 33% vs. 8%). Additionally, the least-squares mean percentage change from baseline in total EASI score for LEB and PBO, respectively, was -65% and -26% in the ≤2 years subgroup, -60% and -26% in the >2-to-<18 years subgroup, and -63% and -30% in the ≥18 years subgroup ($p<0.001$ for LEB vs. PBO in all subgroups). The proportion of LEB-treated pts who achieved ≥4-point improvement in the Pruritus NRS from baseline (baseline score ≥4) was greater than PBO-treated pts ([N]; ≤2 years: 43% [201] vs. 11% [108]; >2-to-<18 years: 41% [161] vs. 14% [96]; ≥18 years: 45% [154] vs. 12% [60]; $p<0.001$).

CONCLUSION: Regardless of age of AD onset, LEB was associated with significant improvements in AD signs and symptoms compared with placebo over 16 wks of treatment.

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CUTANEOUS MALIGNANCIES

Abstract CM-01

Evaluating PRAME as a Diagnostic Biomarker in Sebaceous Carcinoma and Sebaceous Neoplasms: A Systematic Review of Immunohistochemical Evidence

Michelle R Anthony, BS[1]; Amritpal Kooner, MA[2]; Natalia Chalupczak, BS[3]; Conor Dolehide, MD[4]

[1]University of Arizona College of Medicine, Tucson, AZ, USA; [2]Chicago College of Osteopathic Medicine, Midwestern University, Downers Grove, IL, USA; [3]Rosalind Franklin University of Medicine and Science, Chicago Medical School, Chicago, IL, USA; [4]Department of Dermatology, Midwestern University, Downers Grove, IL, USA

BACKGROUND: Sebaceous carcinoma is a rare and aggressive type of skin cancer that can be challenging to diagnose because its features are similar to those of other common and rare cutaneous malignancies. Immunohistochemistry can be a viable tool to help dermatopathologists confirm their histological diagnosis. One potential biomarker that can be used is PRAME (Preferentially Expressed Antigen in Melanoma).

OBJECTIVE: This systematic review aims to assess the possible significance of PRAME in the histopathological evaluation of sebaceous carcinoma and other sebaceous neoplasms.

METHODS: Following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, a systematic review was conducted using PubMed, Scopus, and Embase databases to identify studies on PRAME expression in sebaceous carcinoma and other sebaceous neoplasms from the database's inception to July 2024. After screening for eligibility, all full-text articles that met the inclusion criteria were critically appraised, and data was extracted for analysis.

RESULTS: A total of four studies were retrieved from the search for analysis. 31 cases of periocular sebaceous carcinoma (PSC) were examined, along with 20 sebaceous tumors from another study group. In the PSC group, PRAME expression was observed in 26% (5/19) of invasive PSCs, mainly in moderately differentiated tumors, with no expression in situ PSCs. PRAME was less commonly positive than adipophilin (80.6%) but more specific in differentiating sebaceous cells.[1] PRAME showed positive composite scores in all cases in a broader group of sebaceous tumors, indicating more widespread and easily detectable staining in basaloid cells than adipophilin. Among control cases, PRAME was more sensitive and specific than adipophilin, suggesting its potential use as a diagnostic marker for sebaceous carcinoma.[2]

CONCLUSION: PRAME shows promise as a sensitive and specific marker for sebaceous differentiation, particularly in moderately differentiated sebaceous carcinoma. Its more diffuse staining pattern in basaloid cells suggests that PRAME may be more reliable than traditional markers like adipophilin for detecting sebaceous carcinoma in clinical practice. However, the systematic review is limited due to the variability of the study designs and sample size. PRAME may be a promising tool for diagnosing and distinguishing sebaceous carcinoma from other malignancies. Further research in a larger multicenter setting is essential to validate the above findings and explore the therapeutic and prognostic implications of sebaceous carcinoma with PRAME expression.

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Abstract CM-02

Extensive Facial Crusting With Possible Hemophagocytic Lymphohistiocytosis

Amritpal Kooner, MA[1]; Michelle R Anthony, BS[2]; Natalia Chalupczak, BS[3]; Conor Dolehide, MD[4]

[1]Chicago College of Osteopathic Medicine, Midwestern University, Downers Grove, IL, USA; [2]University of Arizona College of Medicine, Tucson, AZ, USA; [3]Rosalind Franklin University of Medicine and Science, Chicago Medical School, Chicago, IL, USA; [4]Department of Dermatology, Midwestern University, Downers Grove, IL, USA

BACKGROUND: A 30-year-old female with a history of marginal zone lymphoma, systemic lupus erythematosus

(SLE), and previous deep vein thrombosis (DVT) presented with extensive facial crusting.

OBJECTIVES: This case highlights the diagnostic challenges with extensive crusted folliculitis and discusses the current treatment options—possible hemophagocytic lymphohistiocytosis (HLH) in this immunosuppressed patient with multiple comorbidities.

METHODS: This patient underwent multiple punch biopsies and deep tissue cultures to identify the causative organism and direct treatment protocols. The patient's condition was managed with antifungals, antibiotics, steroids, and supportive care.

RESULTS: The initial biopsy and culture showed severe suppurative folliculitis with multiple yeast forms, indicating possible Pityrosporum folliculitis. The cultures grew Staphylococcus lugdenensis, Enterobacter cloacae, and other pathogens at lower quantities. The patient was treated with itraconazole and corticosteroids; however, their condition worsened, potentially implicated HLH, indicated by rising ferritin levels and bone marrow findings.

CONCLUSION: The patient's extensive crusted folliculitis and immunosuppressed state require a multifaceted approach to diagnosis and treatment. The clinical findings supported the possibility of HLH and further complicated the management of her dermatological and systemic conditions.

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Abstract CM-03

Looking Beyond UV Exposure: Patient Knowledge About Broader Skin Cancer Risk Factors

Kennedy H Sun BS[1]; Adam Friedman, MD[1]; Vishal A Patel MD[1]

[1]Department of Dermatology, George Washington University School of Medicine and Health Sciences, Washington, DC, USA

BACKGROUND: While the majority of skin cancers are related to UV exposure, many skin cancers and risk factors are independent of UV exposure. However, patient knowledge of this is lacking. Much research has assessed patients' knowledge and beliefs about UV exposure and sunscreen use, as well as noting how these differ across different cultures and identities. It is also important to expand our understanding of patient knowledge holistically and expand future education to all skin cancer risk and protective factors.

OBJECTIVES: We assessed patients' knowledge of less commonly known risk factors for skin cancer such as arsenic, immunosuppression, family history, cigarette use, and potential locations of skin cancer like nails, lips, and hands/feet. We also examined how personal, or family history of skin cancer might influence knowledge of these risk factors. We aimed to evaluate patients perceived and actual knowledge about skin cancer and identify specific topics and demographic groups that require further education focus.

METHODS: 111 patients in a general dermatology clinic (59.5% female) self-identified their skin type and race/ethnicity and self-rated level of knowledge about skin health and skin cancer on a 5-point Likert scale. Participants responded to 21 statements about general concepts, risk and protective factors, and locations/types of skin cancer with True, False, or I don't know. The total number of accurate or 'I don't know' scores were calculated.

RESULTS: Mean self-ratings for skin health and skin cancer knowledge were 2.70 (SD=0.77) and 2.31 (SD=0.81), respectively. The mean number of accurate responses was 13.2/21 (SD=4.92) and 6.15/21 for 'I don't know' (SD=4.82). There were significant differences in mean composite accuracy score based on race, skin type, education level, self-rated knowledge of skin health and skin cancer, and personal, family, or friend history of skin cancer ($p \leq 0.016$). Although 54.1% of the patients had a Master's or Doctorate and did have higher accuracy, the mean accuracy was still only 14.79/21 (SD=4.17). People with a personal, familial, or friend history of skin cancer demonstrated higher accuracy (Independent T-tests $p \leq 0.016$).

CONCLUSIONS: These data provide insight into patient knowledge about skin cancer facts beyond ultraviolet radiation and highlight the importance of broadening patient education efforts in the realm of skin cancer education. Focusing on personal connections to people who have experienced skin cancer may serve as an effective tactic to increase public health knowledge, but it also highlights the heightened importance of educating people before they or their acquaintances are impacted by skin cancer.

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OTHER DERMATOLOGY TOPICS

Abstract OD-1

Exploring Inflammatory Signaling and miRNA Regulatory Mechanisms in Hidradenitis Suppurativa

E Ames, BBA[1]; M Sanders, BS*[1]; M Jacobs, BS*[1]; T Vida, PhD[1]

[1]Kirk Kerkorian School of Medicine at UNLV, Las Vegas, NV, USA

BACKGROUND: Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease marked by recurrent nodules, abscesses, and sinus tracts.[1] The exact initiating factors remain unclear while follicular occlusion is a known trigger. A multifactorial etiology involving genetic predispositions, hormonal imbalances, and environmental factors may disrupt normal follicular keratinization processes.[2] Recent advances highlight microRNA (miRNA) dysregulation as a potential contributor to these inflammatory processes, offering new insights into HS pathogenesis.[3]

OBJECTIVES: This review hypothesizes that miRNA dysregulation triggers aberrant expression in specific inflammatory pathways, contributing to HS's clinical manifestations and progression.

METHODS: A comprehensive literature review was conducted using PubMed and AI tools like Elicit.com, Consensus.app, ResearchRabbit.ai, and GPT-4/4o (OpenAI) to organize themes and identify consistencies and discrepancies in HS understanding. This exploration shed light on how inflammatory pathways contribute to HS's clinical features and progression. In querying GPT-4/4o, we synthesized available evidence to reveal knowledge gaps and formulate our hypothesis focusing on miRNA regulation of inflammatory pathways.

RESULTS: In HS, the dysregulation of specific miRNAs is a novel insight into the disease's pathophysiology. miRNAs such as miR-223, miR-146a-5p, miR-155, and miR-338-5p are key regulators of immune and inflammatory responses.[4,5] Their dysregulation in HS potentially alters inflammatory mediators within the TNF-α, IL-1β, and IL-17/IL-23 pathways.[6] Notable overexpression of miRNA-155-5p, miRNA-223-5p, miRNA-31-5p, miRNA-21-5p, and miRNA-146a-5p in lesional HS skin suggests their involvement in disease pathology.[7]

Biologic therapies targeting specific cytokines are promising treatments for HS. Adalimumab, a monoclonal antibody for TNF-α, and Secukinumab, which targets the IL-17 pathway, are leading examples. Adalimumab is the first FDA-approved biologic for HS, demonstrating up to a 50% reduction in inflammatory nodules and abscesses in moderate to severe cases. Similarly, Secukinumab has shown promise in reducing disease severity and improving

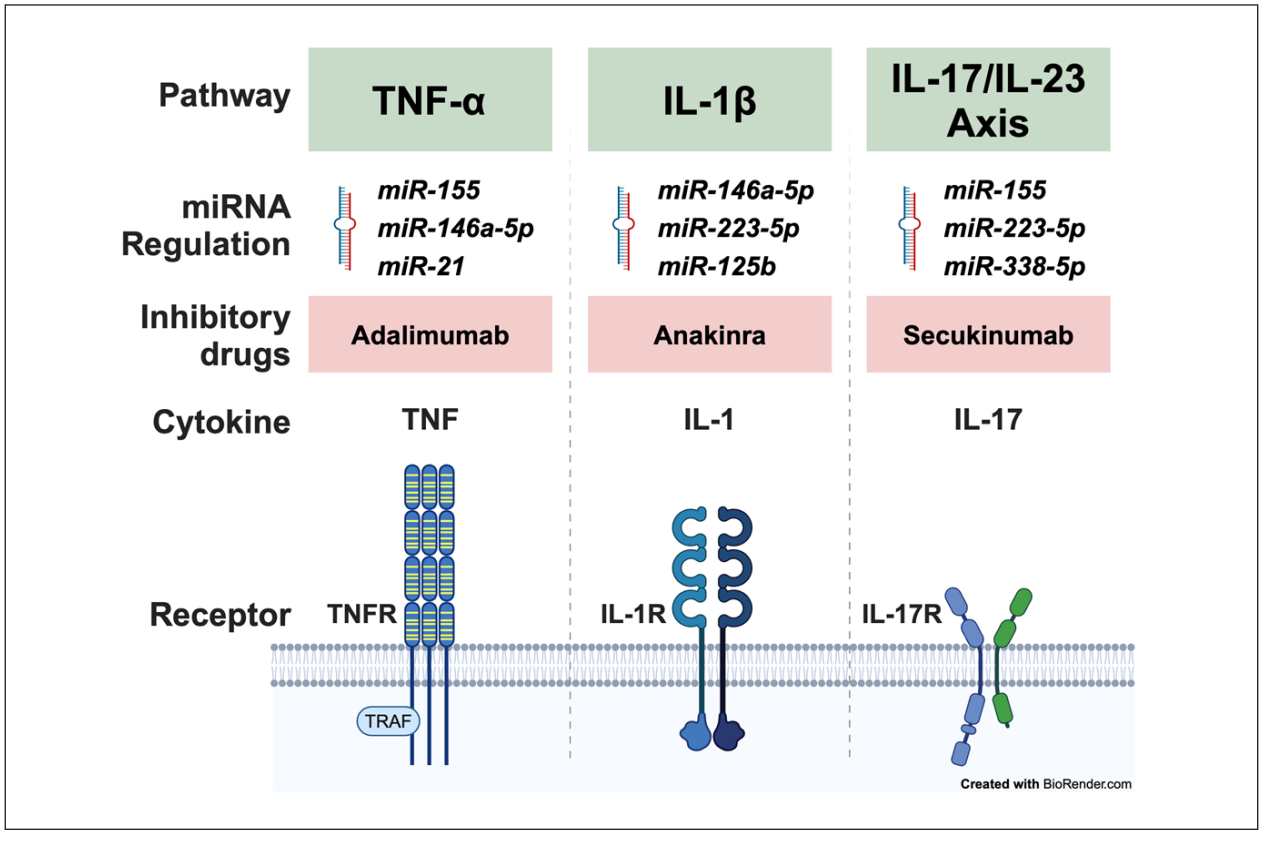

FIGURE 1. Hidradenitis suppurativa inflammatory signaling and miRNA regulatory mechanisms

patient outcomes.[8] However, neither immunotherapy has proven to be curative, highlighting the need for further research on HS pathophysiology.

CONCLUSIONS: HS pathophysiology involves a complex interplay of inflammatory signaling pathways, genetic factors, and environmental influences, which drive this debilitating condition. Key inflammatory mediators such as TNF-α, IL-1β, and the IL-17/IL-23 axis, along miRNA dysregulation, reveal intricate molecular mechanisms underlying HS. Future research into these molecular underpinnings and novel therapies holds promise for improving patient outcomes and quality of life. This review highlights the importance of advancing HS molecular understanding for effective clinical management and therapeutic innovation.

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Abstract OD-02

Comparative Effectiveness of Topical Pumpkin Seed Oil, Other Natural Remedies, and Minoxidil in Treating Alopecia: A Systematic Review

Lisa Anakwenze, MD, MPH, MS[1]; Kelly Scarberry MD[1]

[1]Case Western Reserve University/University Hospitals Cleveland Medical Center, Cleveland, OH, USA

BACKGROUND: Alopecia has various causes, such as genetics or hormonal imbalances. Minoxidil is a first-line treatment for androgenetic alopecia (AGA), but continuous use is necessary for sustained hair retention. Some patients prefer non-pharmaceutical options like hair oils or supplements. Oral pumpkin seed oil (PSO) shows promise for hair growth, with effects comparable to minoxidil. However, topical PSO, compared to minoxidil, has not been systematically reviewed.

OBJECTIVES: This review systematically compares the efficacy of topical PSO with minoxidil and other natural remedies in managing alopecia.

METHODS: A PubMed search up to July 2024 used keywords/MeSH terms including Cucurbita pepo, alopecia, hair loss, pumpkin seed oil, and minoxidil. Emphasis was placed on RCTs, clinical trials, meta-analyses, and systematic reviews. Relevant references from included studies were also screened.

OUTCOMES: Hair regrowth, hair shaft diversity, hair follicle number, and side effects.

RESULTS: PSO vs. Minoxidil: In a mouse RCT, 10% PSO and 2% minoxidil significantly reversed testosterone-induced hair loss after three weeks ($P<0.001$).[1] In a clinical trial with 60 women with AGA, both PSO and minoxidil showed significant improvements in hair shaft diversity and vellus hair reduction after three months ($P<0.001$).[2]

TABLE 1: Pumpkin seed oil, other natural remedies, and minoxidil trials in alopecia

Main Intervention	Comparator	Study Type	Outcome Summary	*P*-Value
Pumpkin Seed oil (PSO) Vs Minoxidil[1]	Testosterone	Mice RCT	Both reversed testosterone's negative effects on hair growth	<0.001
PSO[2]	Minoxidil	Human Experimental	Both decreased shaft diversity. Increased vellus hairs.	<0.001 <0.001/0.02
Sesame oil (SO)[3]	PSO	Human single-blinded experimental	Both hair regrowth. No difference between groups.	<0.001 >0.24
Rosemary oil (RO)[4]	Minoxidil	Human experimental	Both increased hair count. No difference between groups.	<0.05 >0.05
Peppermint oil (PO) Vs Minoxidil[5]	Saline Jojoba oil	Mice RCT	Dermal thickness, hair follicle number, and hair follicle depth for PO and M increased.	<0.001
Lavender oil (LO)[6]	Minoxidil	Mice RCT	Both groups had hair growth.	<0.05

Sesame Oil (SO) vs. PSO: A three-month, single blinded study on alopecia areata found both SO and PSO effective for hair regrowth, with no significant difference between the groups (P=0.24).[3]

Rosemary vs. Minoxidil: In a six-month RCT involving men with AGA, rosemary oil and 2% minoxidil showed similar efficacy in increasing hair count (P<0.05), though minoxidil was associated with more scalp itching (P<0.05).[4]

Peppermint vs. Minoxidil: A four-week RCT on mice showed that 3% peppermint oil resulted in 92% hair regrowth, outperforming 3% minoxidil (55%) (P<0.001).[5]

Lavender vs. Minoxidil: Another four-week RCT on mice found that both 5% lavender oil and 3% minoxidil significantly promoted hair growth (P<0.05).[6]

CONCLUSIONS: Minoxidil was associated with more side effects, including itchiness and increased spleen size compared to lavender oil. Minoxidil, peppermint, rosemary, and lavender oils likely share mechanisms involving vasodilation and prolonging the anagen phase. In contrast, PSO and SO appear to act on 5-alpha-reductase, similar to finasteride, making them viable non-pharmaceutical options for alopecia. Combining essential oils with PSO, SO, or minoxidil may offer added benefits, though further research is needed. The review's limitations include variations in study designs, methods, potencies, and outcomes, complicating direct comparisons.

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Abstract OD-3

Deucravacitinib in Plaque Psoriasis: 4-Year Safety and Efficacy Results From the Phase 3 POETYK PSO-1, PSO-2, and LTE Trials

April W Armstrong[1]; Mark Lebwoh[1,2]; Richard B Warren[3,4]; Howard Sofen[1,5]; Akimchi Morita[6]; Shinichi Imafuku[7]; Mamitaro Ohtsuki[8]; Lynda Spelman[9]; Thierry Passeron[10]; Kim A Papp[11]; Matthew J Colombo[12]; John Vaile[12]; Eleni Vritzali[12]; Kim Hoyt[12]; Carolin Daamen[12]; Subhashis Banerjee[12]; Bruce Strober[13]; Diamant Thaçi[14]; Andrew Blauvelt[15]

[1]University of California Los Angeles, Los Angeles, CA, USA; [2]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, UK; [4]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK; [5]Dermatology Research Associates, Los Angeles, CA, USA; [6]Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; [7]Fukuoka University Hospital Faculty of Medicine, Fukuoka, Japan; [8]Jichi Medical University, Tochigi, Japan; [9]Veracity Clinical Research, Brisbane, QLD, Australia; [10]Université Côte d'Azur, University Hospital of Nice, Nice, France; [11]Alliance Clinical Trials and Probity Medical Research, Waterloo, and the University of Toronto, Toronto, ON, Canada; [12]Bristol Myers Squibb, Princeton, NJ, USA; [13]Yale University School of Medicine, New Haven, and Central Connecticut Dermatology Research, Cromwell, CT, USA; [14]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [15]Oregon Medical Research Center, Portland, OR, USA

BACKGROUND: Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials in moderate to severe plaque psoriasis. Upon completion of these trials, patients could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial. As previously reported, deucravacitinib-treated patients maintained long-term efficacy responses through 3 years with no new safety signals versus Year 2.

OBJECTIVES: To report safety and efficacy of deucravacitinib through 4 years (Week 208; cutoff date, 11/1/2023).

METHODS: PSO-1 and PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast 30 mg twice daily. At Week 52, patients enrolled in the LTE trial received open-label deucravacitinib 6 mg QD. Safety was evaluated in patients receiving ≥1 deucravacitinib dose. Exposure-adjusted incidence rate/100 person-years (EAIR/100 PY) was calculated as 100*(# of patients with an adverse event [AE])/(total exposure time for all patients at risk [time to initial AE occurrence for patients with AE+total exposure time for patients without AE]). Efficacy outcomes included PASI 75, PASI 90, and sPGA 0/1. Efficacy was analyzed using mNRI in patients receiving continuous deucravacitinib treatment from Day 1 of the parent trial and were enrolled and treated in the LTE. As-observed data and results by treatment failure rules imputation were analyzed.

RESULTS: 1519 patients received ≥1 deucravacitinib dose, with cumulative exposure (parent trial) of 4392.8 PY. EAIRs/100 PY were decreased or comparable from the 1- to 4-year cumulative period, respectively, for AEs (229.2, 131.7), serious AEs (5.7, 5.0), deaths (0.2, 0.3), discontinuation due to AEs (4.4, 2.2), herpes zoster (0.8, 0.6), malignancies (1.0, 0.9), major adverse cardiovascular events (0.3, 0.3), and venous thromboembolism (0.2, 0.1). In patients receiving continuous deucravacitinib (n = 513), clinical response rates were maintained from Year 3 (PASI 75, 73.8% [95% CI, 69.6, 78.0]; PASI 90, 49.0% [44.4, 53.7]; sPGA 0/1, 55.2% [50.5, 59.9]) to Year 4 (PASI 75, 71.7% [67.0, 76.3]; PASI 90, 47.5% [42.6, 52.4]; sPGA 0/1, 57.2% [52.1, 62.2]) by mNRI, with similar results regardless of data imputation methodology.

CONCLUSIONS: Deucravacitinib showed a consistent safety profile through 4 years with no emergence of new or long-term safety signals. Efficacy was maintained through 4 years in patients treated continuously with deucravacitinib from Day 1 in the parent trials. These data support the long-term safety and durable efficacy profile through 4 years with deucravacitinib, a first-in-class TYK2 inhibitor treatment for psoriasis.

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Abstract OD-04

Efficacy and Safety of Delgocitinib Cream in Adults With Moderate to Severe Chronic Hand Eczema: Pooled Results of the Phase 3 DELTA-1 and -2 Trials

Robert Bissonnette, MD[1]; Margitta Worm, MD, PhD[2]; Richard B Warren, MBChB PhD[3,4]; Tove Agner, MD[5]; Melinda Gooderham, MD[6,7]; Marie Louise Schuttelaar, PhD[8]; Keith Baranowski, MD[9]; Ursula Plohberger, MSc[9]; Shannon Schneider, PhD[10]; Laura Soerensen, MSc[9]; Sibylle Schliemann, MD[11]

[1]Innovaderm Research, Montreal, Quebec, CA; [2]Division of Allergy and Immunology, Department of Dermatology, Venerology and Allergy, Charité Universitätsmedizin Berlin, DE; [3]Dermatology Centre, Northern Care Alliance NHS Foundation Trust; [4]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, UK; [5]Department of Dermatology, Bispebjerg Hospital, University of Copenhagen, Copenhagen, DK; [6]Department of Dermatology, Queens University, Peterborough, Ontario, CA; [7]SKiN Centre for Dermatology and Probity Medical Research, Peterborough, Ontario, CA; [8]University Medical Centre Groningen, University of Groningen, NL; [9]LEO Pharma A/S, Ballerup, DK; [10]LEO Pharma Inc, Madison, NJ, USA; [11]Department of Dermatology, University Hospital Jena, Jena, Germany

INTRODUCTION: Chronic Hand Eczema (CHE) is a frequent inflammatory skin disease associated with pain, pruritus, and significant occupational, functional, social, and psychological burden. Delgocitinib is a topical pan-JAK inhibitor which showed a dose-dependent efficacy in adults with CHE in a Phase 2b trial.

OBJECTIVES: The objectives of this analysis were to study (1) the efficacy of twice-daily applications of delgocitinib cream 20 mg/g, as assessed by Investigator's Global Assessment for CHE treatment success (primary outcome), and the secondary outcomes ≥75%/≥90% improvement in Hand Eczema Severity Index and ≥4-point improvement in the Dermatology Life Quality Index, and (2) the safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle in the treatment of adults with moderate to severe CHE in a pooled analysis of the DELTA-1 and DELTA-2 trials.

METHODS: In the Phase 3 DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) trials, adults with moderate to severe CHE were randomized 2:1 to twice-daily delgocitinib cream 20 mg/g or cream vehicle for 16 weeks. The primary endpoint was the Investigator's Global Assessment for CHE (IGA-CHE) treatment success at Week 16, defined as IGA-CHE score of 0/1 (clear/almost clear, i.e., no/barely perceptible erythema and no other signs), with a ≥2-step improvement from baseline. Key secondary endpoints included ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) and ≥4-point improvement in the Dermatology Life Quality Index (DLQI). This DELTA-1 and -2 pooled analysis included 639 patients treated with delgocitinib cream and 321 with cream vehicle.

RESULTS: At Week 16, a significantly greater proportion of delgocitinib-treated patients, versus cream vehicle, achieved IGA-CHE treatment success (24.3% vs. 8.4%; $P<0.001$),

HECSI-75 (49.4% vs. 20.9%; P<0.001), HECSI-90 (30.3% vs. 10.6%; *P*<0.001), and DLQI ≥4-point improvement (73.3% vs. 47.8%; *P*<0.001). Most frequent adverse events (occurring in ≥5% of patients) were COVID-19, nasopharyngitis, and headache with similar rates in both treatment groups.

CONCLUSION: In the DELTA-1 and -2 pooled analysis, delgocitinib cream twice-daily confirmed its clinical efficacy in patient- and clinician-reported efficacy outcomes versus cream vehicle in adult CHE patients and suggests an innovative treatment option in this often difficult-to-treat patient population.

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DISCLOSURES: RB: is an Advisory Board Member, Consultant, Speaker and/or Investigator for and receives honoraria and/or grant from AbbVie, Arcutis, Arena Pharma, Asana BioSciences, Bellus Health, Boehringer-Ingelheim, CARA, Dermavant, Eli Lilly, EMD Serono, Galderma, Incyte, Kiniksa, Kyowa Kirin, LEO Pharma, Novan, Pfizer, Ralexar, RAPT, Regeneron, Sanofi Genzyme, and Sienna. He is also an employee and shareholder of Innovaderm Research. MW: reports grants and personal fees from Stallergens, HAL Allergie, Bencard Allergie, Allergopharma, ALK-Abello, Mylan Germany, Actelion Pharmaceuticals Deutschland, Biotest, AbbVie Deutschland, Lilly Deutschland Aimmune, DBV Technologies, Regeneron Pharmaceuticals, Sanofi Aventis, Leo Pharma, Novartis and Viatris, outside the submitted work and is past WAO co-chair of the anaphylaxis committee. TA: has been a speaker/investigator/advisor for AbbVie, Eli Lilly, LEO Pharma, Pfizer, Regeneron and Sanofi-Genzyme. MG: has been an investigator, speaker and/or advisor for: AbbVie, Amgen, Akros, Arcutis, Aristea, AnaptysBio, Apogee, Bausch Health, BMS, Boehringer Ingelheim, Celgene, Dermira, Dermavant, Eli Lilly, Galderma, GSK, Incyte, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, Moonlake, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Tarsus, Takeda, UCB, Union and Ventyx. RW: has received research grants or consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DiCE, GSK, Janssen, Lilly, Leo, Novartis, Pfizer, Sanofi, Sun Pharma, UCB and UNION. MLS: has been a consultant, advisory board member, investigator, and/or speaker for Sanofi Genzyme, Regeneron Pharmaceuticals, Inc., Pfizer, LEO Pharma, Eli Lilly, Galderma, AbbVie, Novartis and Amgen. KB, UP and LS: are employees of LEO Pharma A/S. SS: is an employee of LEO Pharma Inc. SS: is a consultant, advisory board member, investigator, and/or speaker for LEO Pharma, Sanofi-Aventis, Novartis Pharma, Lilly Pharma and AbbVie.

Abstract OD-05

A Phase 2b, Long-Term Extension, Dose-Ranging Study of Oral JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis: FRONTIER-2

Laura K Ferris, MD, PhD[1]; Jerry Bagel, MD, MS[2]; Yu-Huei Huang, MD[3]; Andrew Pink, PhD[4]; Stephen K Tyring, MD, PhD[5]; Georgios Kokolakis, MD[6]; Amy M DeLozier, PhD[7]; Shu Li, PhD[8]; Yaung-Kaung Shen, PhD[8]; Santiago Munoz, PharmD[8]; Takayuki Ota, MD[7] Robert Bissonnette, MD[9]

[1]University of Pittsburgh, Pittsburgh, PA, USA; [2]Psoriasis Treatment Center of Central NJ, East Windsor, NJ, USA; [3]Department of Dermatology at Chang Gung Memorial Hospital and the School of Medicine at Chang Gung University, Taoyuan City, Taiwan; [4]NHS Foundation Trust Great Maze Pond, London, England; [5]Center for Clinical Studies, Webster, TX, USA; [6]Psoriasis Research and Treatment Center, Department of Dermatology, Venereology and Allergology, Charité – Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [7]Janssen Research & Development, LLC, San Diego, CA, USA; [8]Janssen Research & Development, LLC, Spring House, PA, USA; [9]Innovaderm Research, Montreal, QC, Canada

BACKGROUND: JNJ-77242113, a targeted oral peptide, inhibits interleukin (IL)-23 signaling by binding the IL-23 receptor. JNJ-77242113 showed superior efficacy versus placebo in moderate-to-severe psoriasis in the FRONTIER-1 study (Bissonnette R, et al. 25th World Congress of Dermatology 2023).

OBJECTIVES: To study the efficacy and safety of oral JNJ-77242113 for the treatment of moderate-to-severe plaque psoriasis in the FRONTIER-2 study.

METHODS: FRONTIER-1 randomized patients 1:1:1:1:1:1 to JNJ-77242113 25 mg once daily (QD), 25 mg twice daily (BID), 50 mg QD, 100 mg QD, 100 mg BID, or placebo through Week (W) 16. FRONTIER-2 was a long-term extension, phase 2b study in which patients completing FRONTIER-1 (W16) continued the assigned dose through W52; those randomized to placebo crossed over to 100 mg QD (placebo–100 mg). The primary endpoint was the proportion of patients achieving Psoriasis Area and Severity Index (PASI)75 at W52. Response rates were estimated using non-responder imputation and FRONTIER-1 baseline data.

RESULTS: At W52, proportions of patients achieving PASI75 were JNJ-77242113: 25 mg QD 48.8%, 25 mg BID 58.5%, 50 mg QD 69.8%, 100 mg QD 65.1%, 100 mg BID 76.2%, and placebo–100 mg 65.7%; corresponding rates for PASI90/PASI100 were 27.9%/14.0%, 36.6%/17.1%, 41.9%/20.9%, 51.2%/25.6%, 64.3%/40.5%, 57.1%/34.3%, respectively. Proportions of patients achieving Investigator's Global Assessment (IGA) 0/1 and IGA 0 were JNJ-77242113: 25 mg QD 37.2%/14.0%, 25 mg BID 46.3%/19.5%, 50 mg QD 60.5%/23.3%, 100 mg QD 60.5%/30.2%, 100 mg BID 73.8%/42.9%, placebo–100 mg 65.7%/31.4%. Across treatment groups, 58.6% of patients experienced adverse events (AEs), with no evidence of dose-dependent increase in AEs, including gastrointestinal disorders. Serious AEs were considered unrelated to the study treatment.

CONCLUSIONS: In patients with psoriasis receiving JNJ-77242113, the first targeted oral peptide to selectively block IL-23 pathway signaling, rates of near-complete/complete skin clearance from FRONTIER-1 (Bissonnette R, et al. 25th World Congress of Dermatology 2023) were maintained through W52; 100 mg BID yielded the highest response rates. Consistent with prior studies, no safety signals were identified.

DISCLOSURES: LF: served as an investigator for AbbVie, Acelyrin, Amgen, Apogee, Arcutis, Aristea, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, DermTech, Eli Lilly, Galderma, GRAIL, Incyte, Janssen, Leo Pharma, Moberg, Mobius, Novartis, Regeneron, SkinAnalytics, Takeda, and UCB; consultant for AbbVie, Amgen, Apogee, Arcutis, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Dermavant, DermTech, Janssen, Leo Pharma, Novartis, Pfizer, Regeneron, and Takeda; speaker for AbbVie Arcutis, Boehringer-Ingelheim, Bristol-Myers Squibb, and Regeneron.

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Y-HH has conducted clinical trials for or received honoraria as a consultant for AbbVie, Bristol Myers Squibb, Celgene, Janssen-Cilag Pharmaceuticals, Novartis, and Pfizer Pharmaceuticals.

AP: served as an advisory board member, consultant, and/or speaker and received honoraria from AbbVie, Almirall, BI, BMS, Galderma, Janssen, Leo, Lilly, Novartis, Pfizer, Sanofi, UCB; served as an investigator for AbbVie, BI, BMS, Galderma, Leo, Pfizer, and Sanofi.

SKT: has received grants, consultant/speaker honoraria (paid to institution) from AbbVie, Agenus, AiCuris GmbH, Almirall, Amgen, Bayer, BMS, Demira, Dr Reddy's Laboratory, Eli Lilly, Foamix Pharma, Galderma, Genocea Biosciences, GlaxoSmithKline Immunology, Glenmark Pharma, IQVIA, Janssen Research & Development, Kiniksa Pharma, LEO Laboratories, Menlo Therapeutics, Merck, Novartis, Nycomed Amersham, Parexel, Quintiles Pharma, Regeneron Pharma, Sanofi, Trevi Therapeutics, UCB, and Vical.

GK: is or has acted as a speaker and/or advisory board member for honoraria from AbbVie, Abbott, Actelion Pharmaceuticals, Amgen, Basilea Pharmaceutica, Bayer, Biogen IDEC, Boehringer, Bristol-Myers Squibb, Celgene, Hexal, Janssen-Cilag, LEO Pharma, Lilly, MSD, Mylan, Novartis, Parexel, Pfizer, Sanofi-Aventis, Sharpe and Dohme, Takeda, and UCB.

AMD, SL, Y-KS, SM, and TO: are employees of Janssen Research and Development, LLC; employees may own stock/stock options in Johnson & Johnson.

RB is an Advisory Board Member, Consultant, Speaker and/or Investigator for and received honoraria and/or grants from AbbVie, Alumis, Amgen, AnaptysBio, Bausch Health, Boston, BMS/Celgene, Dermavant, Eli Lilly, Janssen, LEO Pharma, Nimbus, Novartis, Pfizer, Regeneron, UCB, VentyxBio, and Xencor; also an employee and shareholder of Innovaderm Research.

Abstract OD-06

Long-Term Safety and Efficacy of Delgocitinib Cream for up to 36 Weeks in Adults With Chronic Hand Eczema: Results of the Phase 3 Open-Label Extension DELTA-3 Trial

Melinda Gooderham, MD[1,2]; Sonja Molin, MD[3]; Robert Bissonnette, MD[4]; Margitta Worm, MD, PhD[5]; Marie-Noëlle Crépy, PhD[6,7]; Luca Stingeni, MD[8]; Richard B Warren, MBChB PhD[9,10]; Sibylle Schliemann, MD[11]; Cherry Lou Balita-Crisostomo, MD[12]; Marie Louise Oesterdal, MSc[12]; Shannon Schneider, PhD[13]; Tove Agner, MD[14]

[1]Queens University, Kingston, Ontario, CA; [2]SKiN Centre for Dermatology and Probity Medical Research, Peterborough, Ontario, CA; [3]Queen's University, Kingston, Canada; [4]Innovaderm Research, Montreal, Quebec, CA; [5]Charité Universitätsmedizin Berlin, DE; [6]University Hospital of Centre of Paris, Cochin Hospital, AP-HP, Paris, FR; [7]University Hospital of Centre of Paris, Hôtel-Dieu Hospital, AP-HP, Paris, FR; [8]University of Perugia, Perugia, IT; [9]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, UK; [10]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK; [11]University Hospital Jena, Jena, DE; [12]LEO Pharma A/S, Ballerup, DK; [13]LEO Pharma Inc, Madison, NJ, USA; [14]Bispebjerg Hospital, University of Copenhagen, Copenhagen, DK

INTRODUCTION: In patients with moderate to severe Chronic Hand Eczema (CHE), delgocitinib cream, a topical pan-Janus kinase inhibitor, was well tolerated and demonstrated significant improvement in all efficacy endpoints in DELTA-1 and -2.

OBJECTIVES: The objectives of this study were to evaluate the long-term safety and efficacy of twice-daily applications of delgocitinib cream 20 mg/g as needed for up to 36 weeks in adults with CHE in the Phase 3 open-label DELTA-3 trial (NCT04949841), an extension trial of the 16-week DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) trials.

METHODS: In DELTA-3, subjects who completed the 16-week (W) treatment period in DELTA-1 and DELTA-2 were treated on an as-needed basis with twice-daily delgocitinib cream 20 mg/g for 36 weeks (n=801). Subjects with Investigator's Global Assessment for CHE (IGA-CHE) ≥2 received delgocitinib cream until symptoms resolved (i.e., IGA-CHE 0/1 [clear/almost clear]). Primary endpoint was number of treatment-emergent adverse events (TEAEs). Key secondary endpoints were IGA-CHE 0/1 and ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) scores; Hand Eczema Symptom eDiary captured patient-reported worst severity of itch/pain over the past 24 hours.

RESULTS: No safety concerns were identified during delgocitinib cream treatment in DELTA-1 (n=325; R=305.4; PYO=100.9), DELTA-2 (n=313; R=280.6; PYO=95.9) and DELTA-3 (n=801; R=231.1; PYO=535.7). In DELTA-3, the most frequent TEAEs were COVID-19 and nasopharyngitis. In DELTA-3, IGA-CHE 0/1, HECSI-75, HECSI-90 and ≥4-point itch/pain reduction were maintained from baseline (24.6%, 51.8%, 31.8%, and 50.6%/51.9%, respectively) to W36 (30.0%, 58.6%, 36.6%, and 52.4%/55.4%, respectively)

among delgocitinib cream-treated subjects in the parent trials. Among those treated with cream vehicle in parent trials, response rates improved from baseline (9.1%, 23.7%, 12.0%, and 26.3%/32.3%, respectively) to W36 (29.5%, 51.5%, 35.7%, and 41.3%/43.3%, respectively).

CONCLUSION: Overall, with delgocitinib cream 20 mg/g treatment no safety concerns were identified and efficacy further improved, supporting the benefit of long-term as-needed use of delgocitinib cream in patients with moderate to severe CHE.

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DISCLOSURES: MG: has been an investigator, speaker and/or advisor for: AbbVie, Acelyrin, Amgen, Akros, Arcutis, Aristea, AnaptysBio, Apogee, Bausch Health, Bristol Myer Squibb, Boehringer Ingelheim, Celgene, Dermira, Dermavant, Eli Lilly, Galderma, GSK, Incyte, InMagene, Janssen Pharmaceuticals, Kyowa Kirin, LEO Pharma A/S, MedImmune, Meiji, Merck, Moonlake, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Tarsus, Takeda, UCB, UNION Therapeutics and Ventyx. SM: has received honoraria as consultant/advisor or speaker and/ or grants from AbbVie, Almirall, Aralez, Arcutis, Basilea, Bausch Health and Lomb, Bristol Myer Squibb, Boehringer Ingelheim, Evidera, Galderma, GSK, Incyte, LEO Pharma A/S, Eli Lilly, Novartis, Pfizer, Sanofi, Sun Pharma and UCB. She is currently investigator for Novartis and LEO Pharma A/S. RB: is an Advisory Board Member, Consultant, Speaker and/or Investigator for and receives honoraria and/or grant from AbbVie, Arcutis, Arena Pharma, Asana BioSciences, Bellus Health, Boehringer Ingelheim, CARA, Dermavant, Eli Lilly, EMD Serono, Galderma, Incyte, Kiniksa, Kyowa Kirin, LEO Pharma A/S, Novan, Pfizer, Ralexar, RAPT, Regeneron, Sanofi Genzyme, and Sienna. He is also an employee and shareholder of Innovaderm Research. MW: reports grants and personal fees from Stallergens, HAL Allergie, Bencard Allergie, Allergopharma, ALK-Abello, Mylan Germany, Actelion Pharmaceuticals Deutschland, Biotest, AbbVie Deutschland, Eli Lilly Deutschland Aimmune, DBV Technologies, Regeneron Pharmaceuticals, Sanofi Aventis, LEO Pharma A/S, Novartis and Viatris, outside the submitted work and is past WAO co-chair of the anaphylaxis committee. MNC: is a consultant, advisory board member, investigator, and/or speaker for AbbVie, Eli Lilly, LEO Pharma A/S, Novartis, Pfizer, and Sanofi Genzyme. LS: has been principal investigator in clinical trials sponsored by and/or and has received personal fees for participation in advisory board from AbbVie, Amgen, LEO Pharma A/S, Eli Lilly, Novartis, and Sanofi, outside the submitted work. RW: has received research grants or consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DiCE, GSK, Janssen Pharmaceuticals, Eli Lilly, LEO Pharma A/S, Novartis, Pfizer, Sanofi, Sun Pharma, UCB & UNION Therapeutics. SS: is a consultant, advisory board member, investigator, and/or speaker for AbbVie, LEO Pharma A/S, Eli Lilly, Sanofi-Aventis, Novartis. CLBC and MLO: are employees of LEO Pharma A/S. SS: is an employee of LEO Pharma Inc. TA: has given lectures, participated in clinical studies, or been on advisory boards for Allmiral, Sanofi, LEO Pharma A/S, Pfizer, Eli Lilly, Galderma, and AbbVie.

Abstract OD-7

Systemic Exposure and Safety Profile of Delgocitinib Cream in Adults With Moderate to Severe Chronic Hand Eczema in the Phase 3 DELTA-2 Trial

Melinda Gooderham, MD[1,2]; Diamant Thaçi, MD[3]; Tina Damgaard, MSc[4]; Daniel Madsen, PhD[4]; Shannon Schneider, PhD[5]; Anders Soehoel, PhD[4]; Robert Bissonnette, MD[6]

[1]Department of Dermatology, Queens University, Peterborough, Ontario, Canada; [2]SKiN Centre for Dermatology and Probity Medical Research, Peterborough, Ontario, Canada; [3]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [4]LEO Pharma A/S, Ballerup, Denmark; [5]LEO Pharma Inc, Madison, NJ, USA; [6]Innovaderm Research, Montreal, Quebec, Canada

INTRODUCTION: In the DELTA-2 (NCT04872101) Phase 3 trial, delgocitinib cream 20 mg/g, a topical pan-Janus kinase inhibitor, was well-tolerated and demonstrated significant improvement in all efficacy endpoints versus cream vehicle in adults with moderate to severe chronic hand eczema (CHE).

OBJECTIVES: The objectives of this analysis were (1) to examine systemic exposure of delgocitinib cream 20 mg/g in adults with moderate to severe CHE in the randomized, double-blind, vehicle-controlled DELTA-2 trial (2) to compare the DELTA-2 systemic exposure with corresponding data following oral administration of delgocitinib in a Phase 1 trial, (3) to present a summary of safety related to delgocitinib cream from the randomized, double-blind, vehicle-controlled DELTA-2 trial.

METHODS: Pharmacokinetic blood sampling in DELTA-2 was performed 2-6 hours after delgocitinib application at Weeks 1, 4, and 16 using a liquid chromatography/mass spectrometry-based method (lower limit of quantitation: 5 pg/ml). In the Phase 1 trial (NCT05050279), single oral doses of delgocitinib were tested in healthy volunteers with sampling performed for up to 24-hours post-administration.

RESULTS: In DELTA-2, minimal systemic exposure was recorded in 313 delgocitinib-treated patients, with the highest geometric mean plasma concentration being 0.21 ng/ml at Week 1 (n=286). In the Phase 1 trial, the lowest oral delgocitinib dose tested (1.5 mg; n=8) is regarded as subtherapeutic and showed a peak systemic exposure (geometric mean Cmax) of 7.2 ng/ml. In DELTA-2, adverse events (AEs) were reported by 45.7% (n=143/313; delgocitinib cream) and 44.7% (n=71/159; cream vehicle) of patients, with COVID-19 being most common (11.5% vs 12.6%, respectively). The rate of possibly or probably related AEs was low and similar between delgocitinib cream and cream vehicle. No deaths were reported. Few serious AEs were reported with none assessed as related to the study drug.

CONCLUSION: The DELTA-2 trial demonstrated minimal systemic exposure in association with a favorable safety profile, supporting a lack of meaningful systemic effect from twice-daily applications of delgocitinib cream in patients with moderate to severe CHE.

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DISCLOSURES: MG: has been an investigator, speaker and/or advisor for: AbbVie, Amgen, Akros, Arcutis, Aristea, AnaptysBio, Apogee, Bausch Health, BMS, Boehringer Ingelheim, Celgene, Dermira, Dermavant, Eli Lilly, Galderma, GSK, Incyte, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, Moonlake, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Tarsus, Takeda, UCB, Union and Ventyx. DT: has received honoraria or fees for serving on advisory boards, as a speaker, as a consultant from AbbVie, Amgen, Almirall, Beiersdorf, Bristol-Meiers-Squibb, Boehringer Ingelheim, Galapagos, LEO Pharma, Merck Sharp & Dohme, Morphosys, Lilly, Novartis, Janssen-Cilag, Pfizer, Regeneron, Sanofi, Hexal, Sun Pharmaceuticals, and UCB and grants from LEO Pharma and Novartis. TD: was an employee of LEO Pharma A/S.
DM: and AS: are employees of LEO Pharma A/S. SS: is an employee of LEO Pharma Inc. RB: is an Advisory Board Member, Consultant, Speaker and/or Investigator for and receives honoraria and/or grant from AbbVie, Arcutis, Arena Pharma, Asana BioSciences, Bellus Health, Boehringer-Ingelheim, CARA, Dermavant, Eli Lilly, EMD Serono, Galderma, Incyte, Kiniksa, Kyowa Kirin, LEO Pharma, Novan, Pfizer, Ralexar, RAPT, Regeneron, Sanofi Genzyme, and Sienna. He is also an employee and shareholder of Innovaderm Research.

Abstract OD-08

Factors Associated With Worsening Hidradenitis Suppurativa Disease Activity in Transgender Patients Receiving Gender Affirming Hormone Therapy With Testosterone

Reese L Imhof, MD[1]; Caroline J Davidge-Pitts, MB, BCh[2]; Afsaneh Alavi, MD[1]

[1]Department of Dermatology, Mayo Clinic, Rochester, MN; [2]Division of Endocrinology, Diabetes and Metabolism, Mayo Clinic, Rochester, MN.

BACKGROUND: Hidradenitis suppurativa (HS) is a chronic, inflammatory disease with multiple contributing factors. Research indicates that hormones contribute to the onset and worsening of HS.[1,2] Prior research suggests that testosterone therapy might increase the risk of HS development or aggravation in transgender men.[3,4] In a previous study, patients who received gender affirming hormone therapy (GAHT) with testosterone were more likely to experience worsening of HS.[5] However, specific factors related to the worsening of HS activity, such as testosterone levels and testosterone formulations, have not been previously studied.

TABLE 1. Hidradenitis suppurativa (HS) disease history and course

	Results (n, %)
Age at HS diagnosis	
Mean	25 years
Median	23 years
Range	18-42 years
HS diagnosis before or after initiation of hormone therapy	
Before	7, 53.8%
After	6, 46.2%
Hurley Stage initial visit	
I	9, 69.2%
II	3, 23.1%
III	1, 7.7%
Hurley Stage most recent visit	
I	6, 46.2%
II	5, 38.5%
III	2, 15.4%
HS sites of involvement	
Axillary	9, 69.2%
Chest	3, 23.1%
Abdomen	1, 7.7%
Groin/genitals	10, 76.9%
Thighs	3, 23.1%
Buttocks	2, 15.4%
HS course post testosterone therapy initiation	
Improving	0, 0%
No change	4, 30.8%
Worsening	9, 69.2%

TABLE 2. Patient baseline characteristics, medical comorbidities, and gender affirming care received, including testosterone levels

	Results (n, %)
Gender identity	
Man/male	11, 84.6%
Non-binary/other	2, 15.4%
Sex assigned at birth	
Female	13, 100.0%
Race	
Asian	1, 7.7%
White	10, 76.9%
Other	2, 15.4%
BMI	
Mean	42.6
Median	43
Range	27-54
Smoking Status	
Current/Active Smoker	6, 46.1%
Former Smoker	3, 23.1%
Never Smoker	4, 30.8%
Comorbidities	
Depression	10, 76.9%
Metabolic syndrome	5, 38.5%
Anxiety	4, 30.8%
Acne	3, 23.1%
Polycystic ovary syndrome (PCOS)	2, 15.4%
Psoriatic arthritis	1, 7.7%
Gender affirming hormone therapy received	
Testosterone	13, 100.0%
Age of initiation of testosterone	
Mean	26 years
Median	23 years
Range	18-41 years
Gender affirming surgical interventions received	
Hysterectomy	1, 7.7%
Masculinizing chest surgery	3, 23.1%
Phalloplasty	1, 7.7%
Testosterone formulation received	
Intramuscular (IM) injections	9, 69.2%
Subcutaneous (SQ) injections	2, 15.4%
Topical gel	2, 15.4%
Testosterone bioavailable, serum (ng/dL)	
Mean (worsened patients)	198.5 ng/dL
Median (worsened patients)	210 ng/dL
Range (worsened patients)	37-353 ng/dL
Mean (non-worsened/stable patients)	101 ng/dL
Median (non-worsened/stable patients)	76 ng/dL
Range (non-worsened/stable patients)	56-170 ng/dL
Testosterone total by mass spectrometry, serum (ng/dL)	
Mean (worsened patients)	562.9 ng/dL
Median (worsened patients)	490.5 ng/dL
Range (worsened patients)	155-1320 ng/dL
Mean (non-worsened/stable patients)	279.2 ng/dL
Median (non-worsened/stable patients)	305.5 ng/dL
Range (non-worsened/stable patients)	111-395 ng/dL
Duration of follow up (days)	
Mean	965.9
Median	616
Range	58-3296

continued

OBJECTIVES: Investigate HS disease activity in transgender and gender diverse (TGD) patients receiving testosterone.
METHODS: This retrospective case series was approved by our Institutional Review Board. A search was performed using our electronic medical records to identify adult patients between 01/01/1990 and 12/31/2022 with gender dysphoria/incongruence and a diagnosis of HS using ICD codes and a text-based search. Adult patients were included if they consented to research, identified as TGD, and met diagnostic criteria for HS. Patients were then stratified further for this study to include adult patients with HS who were prescribed testosterone GAHT.
RESULTS: A total of 13 patients with HS who identified as TGD and initiated testosterone GAHT were included. Complete baseline and disease characteristics are outlined in Tables 1 and 2. Most patients experienced worsening of their HS (9, 69.2%). Of the patients whose HS worsened (n = 9), most were prescribed intramuscular (IM) injections (8, 88.9%). None of the patients who received topical testosterone gel experienced worsening of their HS. Testosterone bioavailable and testosterone total by mass spectrometry serum levels and ranges were evaluated. Mean, median, and ranges for serum total and bioavailable testosterone levels in TGD patients whose HS worsened were compared with those whose HS did not worsen (Table 2).
CONCLUSIONS: In this case series of TGD adult patients on testosterone, we found that patients who experienced worsening of HS were typically receiving IM testosterone injections and had overall higher mean and median total and bioavailable testosterone levels. Our findings suggest that patients receiving testosterone GAHT with worsening HS may consider switching to topical testosterone formulations and/or a discussion with their hormone provider regarding reducing serum total and bioavailable testosterone levels. This must be balanced with each individual patient's gender-affirming goals.

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DISCLOSURES: AA: is a consultant for Almiral, BI, Leo, Incyte, InflarX, Novartis and UCB. Investigator for BI and Processa. Serves on the Board of Directors for the Hidradenitis Suppurativa Foundation.

Abstract OD-09

VISIBLE Cohort B: Guselkumab Improves Patient Reported Impact of Skin Discoloration at Week 16 in Participants With Moderate-to-Severe Scalp Psoriasis Across All Skin Tones

Jensen Yeung, MD[1-3]; Neelam Vashi, MD[4]; Mona Shahriari, MD[5]; Adrian Rodriguez, MD[6]; Maxwell Sauder, MD[3,7]; Theodore Alkousakis, MD[8]; Olivia Choi, MD, PhD[8]; Katelyn Rowland, MS, ARNP[8]; Daphne Chan, PhD[8]; Jenny Jeyarajah, PhD[9]; Phoebe Lewis, PhD[8]; Grimes Pearl, MD10; Taylor Susan, MD[11]

[1]Women's College Hospital, Toronto, ON, Canada; [2]Sunnybrook Health Sciences Centre, Toronto, ON, Canada; [3]Probity Medical Research, Waterloo, ON, Canada; [4]Boston University School of Medicine, Boston, MA, USA; [5]Yale University School of Medicine, New Haven, and Central Connecticut Dermatology, Cromwell, CT, USA; [6]Nashville Skin Comprehensive Dermatology Center, Nashville, TN, USA; [7]University of Toronto, Toronto, ON, Canada; [8]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [9]Janssen Research & Development, LLC, Spring House, PA, USA; [10]The Grimes Center for Medical and Aesthetic Dermatology; Vitiligo and Pigmentation Institute of Southern California, Los Angeles, CA, USA; [11]University of Pennsylvania, Philadelphia, PA, USA

BACKGROUND AND OBJECTIVE: VISIBLE is an ongoing, first-of-its-kind, large-scale, prospective, Phase 3b, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of guselkumab in patients of color across all skin tones, with a cohort specifically dedicated to moderate-to-severe scalp psoriasis. Scalp psoriasis can extend beyond the hairline onto the face (eg, forehead), neck, etc., and can negatively affect quality of life (QoL) due to its visibility. Psoriasis, like other inflammatory skin diseases, is commonly associated with post-inflammatory pigment alteration (PIPA). While PIPA can affect all skin tones, it can have a significant impact on QoL, in particular for those with melanin-enriched skin types (Fitzpatrick Skin Type [FST] IV-VI). Here we report the effect of pigmentation on VISIBLE participants' QoL and the impact of guselkumab treatment on psoriasis-associated PIPA.
METHODS: In VISIBLE Cohort B, 108 participants were randomized 3:1 to receive guselkumab 100 mg or placebo at Weeks 0, 4, then every 8 weeks. The impact of guselkumab treatment on psoriasis-associated PIPA was assessed using the Skin Discoloration Impact Evaluation Questionnaire (SDIEQ), a five-question patient-reported outcome measure that examines the effect of pigmentation on QoL. SDIEQ scores range from 0 to 15 and are categorized as follows: mild effect (0-6), moderate effect (7-11), and severe effect (12-15). Results at Week 16 are reported for all participants and also as stratified by baseline FST I-III and IV-VI. The efficacy analysis population included all participants who were correctly randomized to Cohort B (n=102); safety was evaluated for all randomized participants (n=108).
RESULTS: At baseline, 37% of participants were categorized as having FST I-III and 63% as having FST IV-VI. Mean SDIEQ scores were generally comparable between the guselkumab and placebo groups at baseline (overall, guselkumab 8.0 and placebo 10.0; FST I-III, guselkumab 9.4

and placebo 10.7; FST IV-VI, guselkumab 7.2 and placebo 9.5), with participants experiencing at least a moderate impact from skin discoloration on their QoL. At Week 16, a significantly greater mean change from baseline in SDIEQ score (ie, improvement) was observed in the guselkumab group compared to the placebo group (-5.4 vs -0.8, respectively; $p<0.001$). Similar significant improvements for guselkumab vs placebo were observed by FST strata (FST I-III: guselkumab -6.2 vs placebo -2.0, $p<0.05$; FST IV-VI: guselkumab -4.9 vs placebo 0.1, $p<0.001$).

CONCLUSION: After just 3 doses of guselkumab, significant improvements in SDIEQ scores, a measure of the impact of skin discoloration on quality of life, were observed in participants with moderate-to-severe scalp psoriasis across all skin tones.

DISCLOSURES: JY: is a speaker/consultant/honoraria recipient/trialist for: AbbVie, Amgen, Anacor, Arcutis, Astella, Bausch, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Coherus, Dermira, Eli Lilly, Forward, Galderma, Janssen, Leo, Medimmune, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun, Takeda, UCB, Xenon. NV: has served as a consultant for Janssen, L'Oreal, Canfield, Pfizer. MS: has served as an advisor/consultant and/or speaker for AbbVie, Arcutis, Bristol Myers Squibb, Dermavant, Janssen, Leo Pharma, Lilly USA, Novartis, Ortho Dermatologics, Sanofi-Genzyme, Regeneron, UCB, Pfizer. AR: has served as an advisor and/orspeaker for Arcutis, Dermavant, EPI Health, Janssen, Leo Pharma, Lilly, Novartis, Sciton, Sun, and UCB; owns stock in Strathspey Crown. MS: has served as an investigator/advisor and/or speaker for AbbVie, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Janssen, LEO Pharmaceuticals, Novartis, Pfizer, Sun Pharmaceuticals, UCB, Viatris. TA, OC, KR, DC: are employees of Janssen Scientific Affairs, LLC; JJ and PL: is an employee of Janssen Research & Development, LLC; employees may own stock/stock options in Johnson & Johnson. PG: has served as a clinical investigator and/or consultant for Galderma, Clinuvel, L'Oreal, Johnson & Johnson, LaserOptek, Mother Science, VYNE Therapeutics, RAPT Therapeutics, Incyte, Pfizer, AbbVie/Allergan, SkinBetterScience, and Medscape. ST: has received honoraria/stock options serving as an advisor/consultant and/or speaker for AbbVie, Arcutis Biotherapeutics, Inc., Armis Scientific, Avita Medical, Beiersdorf, Inc., Biorez, Inc., Bristol-Myers-Squibb, Cara Therapeutics, Dior, Eli Lilly, EPI Health, Evolus, Inc., Galderma Laboratories, L.P., GloGetter, Hugel America, Inc., Janssen, Johnson & Johnson Consumer Products Company, L'Oreal USA, Medscape/WebMD, MJH LifeSciences, Piction Health, Regeneron/Sanofi, Scientis US, UCB, Vichy Laboratories, Mercer Strategies (honoraria/Board of Directors), McGraw-Hill (author/royalties), editorial board: Practical Dermatology, Cutis, Archives in Dermatologic Research, British Journal of Dermatology (peer reviewer); investigator: Concert Pharmaceuticals, Croma-Pharma, Eli Lilly, and Pfizer.

Abstract OD-10

Deucravacitinib in Plaque Psoriasis: Laboratory Parameters Through 4 Years of Treatment in the Phase 3 POETYK PSO-1, PSO-2, and LTE Trials

Neil J Korman[1]; Thierry Passeron[2]; Yukari Okubo[3]; Jerry Bagel[4]; Richard B Warren[5,6]; Lynda Spelman[7]; Kevin Winthrop[8]; Kim Hoyt[9]; Thomas Scharnitz[9]; Subhashis Banerjee[9]; Diamant Thaçi[10]; Mona Shahriari[11]; Linda Stein Gold[12]

[1]Case Western Reserve University, University Hospitals of Cleveland, Cleveland, OH, USA; [2]Université Côte d'Azur, University Hospital of Nice, Nice, France; [3]Tokyo Medical University, Tokyo, Japan; [4]Psoriasis Treatment Center of New Jersey, East Windsor, NJ, USA; [5]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, UK; [6]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK; [7]Veracity Clinical Research, Brisbane, QLD, Australia; [8]Oregon Health & Science University, Portland, OR, USA; [9]Bristol Myers Squibb, Princeton, NJ, USA; [10]University of Lübeck, Lübeck, Germany; [11]Yale University School of Medicine, New Haven, and Central Connecticut Dermatology, Cromwell, CT, USA; [12]Henry Ford Health System, West Bloomfield, MI, USA

BACKGROUND: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in multiple countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious versus placebo and apremilast and was well tolerated in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials. At Week 52, patients could enroll in the ongoing POETYK long-term extension (LTE; NCT04036435) trial and receive open-label deucravacitinib.

OBJECTIVES: Changes in laboratory parameters in the blood known to be associated with Janus kinase (JAK) 1,2,3 inhibitors were evaluated through 4 years of deucravacitinib treatment.

METHODS: Changes from baseline in lipid (cholesterol, triglycerides), chemistry (alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine, creatine phosphokinase [CPK]), and hematology (hemoglobin, lymphocytes, neutrophils, platelets) parameters in the blood known to be affected by JAK1,2,3 inhibitors in clinical trials were evaluated through Week 208 (4 years; data cutoff, November 1, 2023). Treatment discontinuations due to laboratory abnormalities were assessed.

RESULTS: A total of 1519 patients received ≥1 deucravacitinib dose (total exposure, 4392.8 person-years); 1203 (79.2%) had ≥52 weeks and 542 (35.7%) had ≥208 weeks of continuous deucravacitinib exposure (median, 185 weeks). No trends or clinically meaningful mean changes from baseline were observed in any of the above laboratory parameters. A total of 3 patients discontinued treatment due to increased CPK, and 1 patient each discontinued due to abnormal hepatic function, increased ALT, increased AST, and lymphopenia. Discontinuations due to triglyceride elevations were not observed.

CONCLUSION: In PSO-1/PSO-2/LTE, no trends or clinically meaningful mean changes from baseline were observed in lipid, chemistry, or hematology parameters, in contrast to signature changes (eg, increased cholesterol, creatinine, serum transaminases, CPK, cytopenias) that have been observed with JAK1,2,3 inhibitors. Discontinuations due to the laboratory abnormalities noted above were rare (n=7 events) through 4 years of deucravacitinib treatment. Results suggest deucravacitinib treatment does not warrant routine laboratory testing for all patients, in contrast with the requirements for JAK1,2,3 inhibitors, reflecting its selectivity for TYK2.

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Abstract OD-11

DRESS and Drug-Induced Necrolysis/ Stevens-Johnson Treated With a Combination of Steroids and Etanercept

Xochitl Longstaff, BS[1,2]; Angelina Labib, MD[1,3]; Reid Oldenberg, MD-PhD[1,3]; Grace S Ahn, MD[1,3]; Lawrence Eichenfield, MD[1,4]; Dawn Eichenfield, MD-PhD[1,4]

[1]Division of Pediatric and Adolescent Dermatology, Rady Children's Hospital San Diego, San Diego, CA; [2]UCLA David Geffen School of Medicine, Los Angeles, CA; [3]University of Miami Miller School of Medicine, Miami, FL; [4]Department of Dermatology, University of California San Diego School of Medicine, La Jolla, CA

BACKGROUND: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Drug-induced Necrolysis (DIN)/Stevens-Johnson Syndrome (SJS) are Severe Cutaneous Adverse Reactions (SCAR). There is no consistent standard of care treatment for DIN, however, typical treatment involves supportive care, withdrawal of culprit drugs, and immunosuppression, often with systemic corticosteroids. Systemic corticosteroid monotherapy is associated with serious side effects, such as gastrointestinal bleeds.1 Recent retrospective studies and a number of case reports have shown favorable outcomes with regard to morbidity and mortality using a combination of corticosteroids and etanercept, a tumor necrosis factor (TNF)-α inhibitor, to treat other SCAR, such as SJS/TEN and DRESS.[1,2] This combination may similarly convey favorable results for patients presenting with other types of SCAR, such as DRESS and DIN.

OBJECTIVE: To evaluate the safety and efficacy of a combination regimen of corticosteroids and etanercept in treating overlap DRESS and DIN/SJS.

METHODS: We present a case of an 18-year-old transgender male with DRESS and DIN/SJS successfully treated with a combination regimen of etanercept and oral prednisone.

CASE: An 18-year-old transgender male on testosterone therapy had undergone gender-affirming mastectomy. During the postoperative course, a methicillin-sensitive Staphylococcus aureus (MSSA) abscess developed, which was treated with incision and drainage, and a course of trimethoprim-sulfamethoxazole (TMP-SMX). On day six of therapy, he was admitted for fever, rash, and hypotension. Over four days in the hospital the patient developed diffuse oral erosions, worsening rash, and facial swelling. The rash began on the knees and chest, spread to the trunk, extremities, face and neck, and was accompanied by severe skin pain, facial and lip swelling, blurry vision, and watery eyes. The rash progression, combined with elevated liver function tests (LFTs: AST/ALT 86/111 U/L, later rising to 198/235 U/L), eosinophilia (absolute eosinophils rising to 0.5 from a baseline of 0.1 TH/μL) and elevated C-reactive protein (CRP) of 12.6 mg/dL, prompted a dermatology consultation to evaluate the patient for DRESS versus SJS/TEN.

Physical exam showed diffuse erythema that progressed into linear vesicular plaques, and shallow erosions on various body parts. A RegiSCAR score of 4 indicated probable DRESS, while a SCORTEN of 2 was noted. Biopsy of the right leg revealed a brisk vacuolar interface reaction with epithelial necrosis, suggestive of a SCAR. Given the clinical findings and biopsy results, the patient was diagnosed with overlap DRESS/DIN (SJS) likely secondary to TMP-SMX. Treatment commenced with oral prednisone 60 mg daily and three doses of etanercept 50 mg administered on hospital days 4, 6, and 9. The patient showed significant improvement and was discharged on hospital day 13 with plans for outpatient lab monitoring and prednisone tapering.

CONCLUSIONS: This case illustrates the successful treatment of overlap DRESS/DIN(SJS) with a combination of corticosteroids and etanercept. The patient's positive response supports emerging evidence favoring this combination therapy over corticosteroid monotherapy for SCAR. Recent studies, including a 2021 systematic review by Sachdeva et al., and a 2022 study by Ao et al., demonstrated improved outcomes, such as reduced hospital stay times and shorter acute phase duration with combination therapies for SJS/TEN compared to corticosteroid monotherapy.[3,4] Additionally, Zhang et al.'s retrospective study of 242 patients showed lower mortality rates and lower risk of severe complications with combination therapy.[1] These findings highlight the potential of combining corticosteroids with a TNF–α inhibitor as a more effective treatment regimen for overlap DRESS with SJS/TEN. However, more retrospective and prospective studies are necessary to thoroughly evaluate this approach's efficacy and safety.

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Abstract OD-12

Dupilumab Improves Itch in Chronic Spontaneous Urticaria: LIBERTY-CSU CUPID Study A

Maurer Marcus, MD[1,2]; Krystal Ngo, PharmD[*3]; Thomas B Casale, MD[4]; Sarbjit S Saini, MD[5]; Moshe Ben-Shoshan, MD[6]; Philip Sugerman, MD[7]; Allen Radin, MD[8]; Jennifer Maloney, MD[8], Raolat Abdulai, MD[7], Eric Mortensen, PhD[8]; Deborah Bauer, MS[7]; Elizabeth Laws, PhD[7]

[1]Institute of Allergology, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [2]Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Allergology and Immunology, Berlin, Germany; [3]Sanofi, Irvine, USA; [4]University of South Florida, Tampa, FL, USA; [5]Johns Hopkins Asthma and Allergy Center, Baltimore, MD, USA; [6]McGill University Health Centre, Montréal, QC, Canada; [7]Sanofi, Bridgewater, NJ, USA; [8]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA

BACKGROUND: Chronic spontaneous urticaria (CSU) is a chronic inflammatory disease characterized by wheals and/or angioedema that recur for >6 weeks. The burden of disease for patients with CSU often remains high despite antihistamine treatment, with deleterious effects on quality of life.

OBJECTIVE: To evaluate the effect of dupilumab on itch in the randomized, double-blind, placebo-controlled, 24-week, phase 3 trial LIBERTY-CSU CUPID Study A.

METHODS: Patients were aged ≥6 years with diagnosed CSU >6 months, itch and hives for >6 consecutive weeks despite H1-antihistamine use, and omalizumab-naïve; Urticaria Activity Score over 7 days (UAS7; range 0–42) ≥16 and Itch Severity Score over 7 days (ISS7; range 0–21) ≥8. Endpoints included itch-free days, ISS7 change from baseline through Week 24, and proportion of patients with a minimum important difference (MID) improvement in ISS7 of ≥5 points. For continuous endpoints, missing data after discontinuation for lack of efficacy were imputed by worst observation carried forward; other missing data were imputed by multiple imputation. *P*-values were calculated via ANCOVA. Safety endpoints included treatment-emergent adverse events and serious adverse events.

RESULTS: Baseline characteristics were well balanced between groups. The least squares mean changes in the number of itch-free days during Week 24 compared to baseline were (dupilumab [N=70] vs placebo [n=68], standard error [SE]) 3.2 (0.41) vs 2.01 (0.41; nominal $P<0.05$). Dupilumab treatment led to a reduction over time in mean ISS7 through the 24-week treatment period (dupilumab vs placebo, SE) −10.24 (0.91) vs −6.01 (0.94; $P=0.0005$) at Week 24. ISS7 improvement by ≥5 points was attained by significantly more dupilumab-treated patients (72.9%) than placebo (42.6%; $P<0.005$).

CONCLUSION: Dupilumab treatment resulted in significantly increased itch-free days and a higher proportion of patients reporting an MID improvement in itch at Week 24 compared with placebo. Dupilumab safety was consistent with the known safety profile.

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Abstract OD-13

Upadacitinib in the Treatment of Hailey-Hailey Disease: a Clinical Case Study

Maggie Sanders, BS[1]; George Alhwayek, BS[1]; Victoria Farley, MD[2]

[1]Kirk Kerkorian School of Medicine at UNLV. Las Vegas, NV; [2]Vivida Dermatology. Las Vegas, NV

INTRODUCTION: Hailey-Hailey disease (HHD), or familial benign chronic pemphigus, is a skin disorder characterized by erythematous blisters and chronic inflammation.[1,2] Current treatment of HHD typically focuses on directly addressing lesions using topical steroids and/or antiseptics.[1] Small studies have shown symptom improvement with medications aimed at treating the underlying inflammatory process behind HHD.[3-6] Upadacitinib, a Janus kinase (JAK) inhibitor, was shown to be effective at treating refractory HHD in one prior case study.[10] The following case report exemplifies an additional patient with refractory HHD who was successfully treated with Upadacitinib.

CASE PRESENTATION: A 63 year old male presented to our clinic with a case of Hailey-Hailey disease refractory to treatments including various topical steroid creams, oral glucocorticoids, oral antibiotics, and systemic immunosuppressants such as methotrexate (Figure 1). The

patient was started on upadacitinib 15 mg by mouth daily. Initially, the patient was tolerating the treatment well, however without significant relief of symptoms. After 2 months, the dosage of upadacitinib was increased to 30 mg daily. Within one month, the patient reported significant improvement of the lesions on his bilateral axilla. After 4 months of treatment, the patient reported clearance of the lesions on his groin and buttocks, as well as substantial improvement of his axilla. After 11 months of adhering to treatment, this patient had fewer, milder break outs with some areas remaining nearly clear (Figure 2).

DISCUSSION: Hailey-Hailey disease (HHD) is a chronic inflammatory condition which causes painful, erythematous blisters on intertriginous areas that significantly affect the quality of life of patients. There are currently various topical treatments accepted for use in HHD, and emerging research is investigating the possibility of systemic treatments. One drug class of interest in the treatment of inflammatory skin conditions is JAK inhibitors and other immune modulators. Systemic JAK inhibitors have recently been showing promise in treating inflammatory and bullous skin conditions, suggesting possible usage in the treatment of other autoimmune skin conditions such as HHD.[7-9] Along with one previous case report, our study provides further evidence for the utility of upadacitinib in HHD.[10] Additional, larger studies are necessary to further evaluate the true efficacy of upadacitinib as a treatment for HHD.

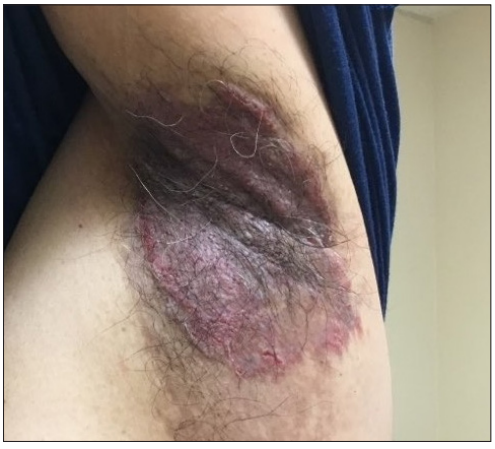

FIGURE 1. Hailey-Hailey disease lesion in axilla before treatment

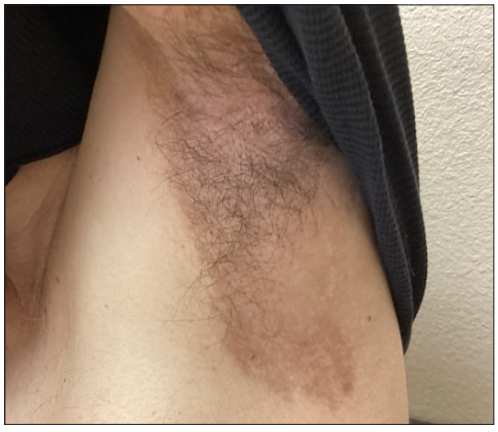

FIGURE 2. Hailey-Hailey disease lesion in axilla after 11 months of treatment with upadacitinib

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Abstract OD-14

Onset and Maintenance of Optimal Itch Response in Adult Patients With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab: Post Hoc Analysis From LIBERTY AD CHRONOS

Sonja Ständer, MD[1]; Krystal Ngo, PharmD[*2]; Gil Yosipovitch, MD[3]; Eric L Simpson, MD, MCR[4]; Brian S Kim, MD[5]; Kenji Kabashima, MD, PhD[6]; Diamant Thaçi, MD[7], Martin Metz, MD[8,9]; Zhen Chen, MD, PhD[10]; Sandra Hagen, MD, MSc[11]; Mike Bastian, PhD[12]

[1]University Hospital Münster, Münster, Germany; [2]Sanofi, Irvine, USA; [3]University of Miami, Miami, FL, USA; [4]Oregon Health & Science University, Portland, OR, USA; [5]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [6]Kyoto University Graduate School of Medicine, Kyoto, Japan; [7]University of Lübeck, Lübeck, Germany; [8]Charité – Universitätsmedizin Berlin, Berlin, Germany; [9]Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Berlin, Germany; [10]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [11]Regeneron GmbH, Munich, Germany; [12]Sanofi, Frankfurt, Germany

BACKGROUND: Pruritus is one of the essential features of atopic dermatitis (AD). A treat-to-target concept established

goals to guide treatment with systemic therapies in AD, including those for itch.

OBJECTIVES: To assess onset and maintenance of optimal itch response according to the treat-to-target concept in adult patients with moderate-to-severe AD treated with dupilumab+concomitant topical corticosteroids (TCS).

METHODS: LIBERTY AD CHRONOS (NCT02260986), a 52-week trial, enrolled patients aged ≥18 years with moderate-to-severe AD. Patients treated with dupilumab every 2 weeks+TCS or placebo+TCS were included in this post hoc analysis. Optimal itch response per the treat-to-target concept was defined as Peak Pruritus Numerical Rating Scale (PP-NRS) score of ≤4, achieved after 6 months of treatment. We assessed time to optimal itch response, percentage of patients achieving optimal itch response, and maintenance of optimal itch response. For maintenance of optimal itch response, the total number and percentage of weeks with PP-NRS ≤4 were calculated for each patient, and maximum duration was assessed as the longest period of consecutive weeks with PP-NRS ≤4 for each patient.

RESULTS: Median (interquartile range) PP-NRS score at baseline was 7.7(6.6–8.5) for patients treated with dupilumab+TCS and 7.6(6.3–8.6) for patients who received placebo+TCS. Median time (95% CI) to achieve optimal itch response was 29(22–43) days for patients treated with dupilumab+TCS and 64(43–105) days for patients who received placebo+TCS (HR [95% CI]=1.668[1.292–2.153]; $P<0.0001$). 61.3% of patients treated with dupilumab+TCS achieved optimal itch response at 6 months, compared with 26.7% of those who received placebo+TCS ($P<0.0001$). Significantly more patients treated with dupilumab+TCS maintained optimal itch response than patients who received placebo+TCS through 52 weeks.

In the dupilumab group, median (Q1–Q3) maintenance of optimal itch response was 40(11–50) weeks, compared with 3(0–23) weeks in the placebo group ($P<0.0001$), which corresponds to 77.1% of the total study duration (52 weeks) in the dupilumab group, compared with 5.7% in the placebo group. Maximum consecutive duration with optimal itch response was also significantly longer in dupilumab-treated patients than in patients who received placebo (median [Q1–Q3]: 29.2[4–50] weeks for dupilumab vs 2.0[0–13] weeks for placebo; $P<0.0001$).

CONCLUSIONS: Patients treated with dupilumab+TCS achieved optimal itch response rapidly and significantly faster than patients who received placebo+TCS; 29 days in dupilumab-treated patients compared with 64 days in those who received placebo. Significantly more patients treated with dupilumab+TCS achieved and maintained optimal itch response than patients who received placebo+TCS through 52 weeks. Dupilumab+TCS also led to a significantly longer maintenance of optimal itch response (40 weeks) compared with placebo+TCS (3 weeks).

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Abstract OD-15

VISIBLE: Clearance and Symptom Improvement With Guselkumab at Week 16 in Skin of Color Participants With Moderate to Severe Plaque Psoriasis

Linda Stein Gold, MD[1]; Jensen Yeung, MD[2-4]; Adrian Rodriguez, MD[5]; Jessica Vasquez, MD[6]; Olivia Choi, MD, PhD[6]; Katelyn Rowland, MS[6]; Theodore Alkousakis, MD[6]; Lewis, Phoebe, PhD[6]; Jenny Jeyarajah, PhD[7]; Javier Alonso-Llamazares, MD[8]; Stephen Tyring, MD, PhD[9]; April Armstrong, MD, MPH[10]

[1]Henry Ford Health System, West Bloomfield, MI, USA; [2]Women's College Hospital, Toronto, ON, Canada; [3]Sunnybrook Health Sciences Centre, Toronto, ON, Canada; [4]Probity Medical Research, Waterloo, ON, Canada; [5]Nashville Skin Comprehensive Dermatology Center, Nashville, TN, USA; [6]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [7]Janssen Research & Development, LLC, Spring House, PA, USA; [8]Driven Research, Coral Gables, FL, USA; [9]Center for Clinical Studies, Webster, TX, USA; [10]University of California Los Angeles, Los Angeles, CA, USA

BACKGROUND AND OBJECTIVE: VISIBLE (NCT05272150) is an ongoing, first of its kind, large-scale, prospective, phase 3b, randomized, double-blind, placebo-controlled study to examine the efficacy and safety of guselkumab in skin of color (SoC) participants with moderate to severe plaque psoriasis.

METHODS: VISIBLE Cohort A comprised 103 participants with moderate to severe plaque psoriasis who self-identified as non-white, across all skin tones. Participants were randomized (3:1) to receive guselkumab 100 mg or placebo at Weeks 0, 4, and then every 8 weeks. Psoriasis Area and Severity Index (PASI), Investigator Global Assessment (IGA), and body surface area (BSA) results, along with participant health-related quality of life improvements as assessed by the Psoriasis Symptoms and Signs Diary (PSSD), were collected at Week 16.

RESULTS: At Week 16, co-primary endpoints of IGA 0 (clear) /1 (almost clear) and ≥90% improvement from baseline on PASI score (PASI90) were achieved by significantly higher proportions of participants treated with guselkumab versus (vs) placebo (IGA 0/1, 74.0% vs 0%; PASI90, 57.1% vs 3.8%; both $p<0.001$), as were IGA 0 (32.5% vs 0%; $p<0.001$) and PASI100 (29.9% vs 0%; $p<0.01$). The proportions of guselkumab-treated participants achieving improvements in each PASI component (erythema, induration, scaling) were similar over time. In the guselkumab and placebo groups, respectively, mean percent improvements from baseline were: BSA, 77.9% vs 0.9%; PASI, 84.5% vs 8.3% (both $p<0.001$). Mean changes from baseline in PSSD symptom score were: guselkumab –49.4 vs placebo –8.2 ($p<0.001$), with a change of ≥40 considered clinically meaningful. Mean changes from baseline in individual PSSD symptom scores for guselkumab vs placebo were: redness, –6.2 vs –1.4; dryness, –4.9 vs –0.9; scaling, –6.2 vs –1.2 (all $p<0.001$). Overall safety was consistent with the established safety profile of guselkumab, and no new safety signals were identified.

CONCLUSIONS: After 3 doses of guselkumab, the majority of VISIBLE participants with moderate to severe plaque psoriasis achieved significantly clearer skin and reported clinically meaningful improvement in psoriasis symptoms.

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Abstract OD-16

Utility of Artificial Intelligence in Patient Education: an Appraisal of Mohs Surgery Information Generated by ChatGPT-3.5 and ChatGPT-4

Kennedy H Sun, BS[1]; William Liakos, MD[2]; Vishal A Patel, MD[1]

[1]Department of Dermatology, George Washington University School of Medicine and Health Sciences, Washington, DC, USA; [2]Department of Dermatology, Kansas University Medical Center, Kansas City, KS, USA

INTRODUCTION: Patients utilize the internet to pursue health knowledge and better serve as advocates for their own care. This frequently involves online searches, where information can often differ from guidelines, and increasingly, artificial intelligence (AI) systems such as ChatGPT.[1] ChatGPT has demonstrated the ability potentially reduce dermatologist workload and communicate well with patients regarding common medical questions.[2,3] However, AI systems have not been evaluated for accuracy of their dermatology-related information. We investigated the utility of ChatGPT-3.5 (free) and ChatGPT-4 (paid premium version), in providing information on Mohs surgery.

METHODS: We input 12 common patient questions about Mohs surgery into GPT-3.5 and GPT-4.

Answers were evaluated by five dermatologists, including four board-certified Mohs surgeons, for accuracy from 1 (completely inaccurate) to 5 (completely accurate) and sufficiency for patient education from 1 (inaccurate and missing lots of critical information) to 5 (complete and accurate, no additional information needed from clinician). Dermatologists were blinded to whether responses were generated by GPT-3.5 or GPT-4.

TABLE. Selection of Sample Patient Questions and ChatGPT-3.5 and ChatGPT-4

Question	ChatGPT-3.5 Response	ChatGPT-4 Response
4. How do I know if I need Mohs surgery over other skin cancer removal surgeries?	The decision of whether you need Mohs surgery or another skin cancer removal procedure depends on several factors, including the type size, location, and aggressiveness of the skin cancer, as well as your medical history and overall health. Mohs surgery is often recommended in the following scenarios: 1) Skin cancers with poorly defined borders, 2) Large or aggressive tumors, 3) Skin cancers in areas where preserving healthy tissue and cosmetic appearance are critical (e.g., face, ears, nose), 4) Skin cancers that have recurred after previous treatments and 5) Skin cancers in areas where there is a higher risk of cancer spreading or where preserving function is vital. Your dermatologist or skin cancer specialist will assess these factors and recommend the most appropriate treatment option for your specific case, ensuring the best chance of successful cancer removal while minimizing the impact on surrounding healthy tissue.	Whether you need Mohs surgery over other skin cancer removal methods depends on several factors. Mohs surgery is often recommended for skin cancers located in cosmetically sensitive or functionally crucial areas, like the face, hands, or feet, because it conserves the maximum amount of healthy tissue. It's also favored for aggressive, large, or ill-defined tumors, recurrent cancers, or cancers growing in scarred areas. The tumor's type, size, location, and growth pattern, as well as any previous treatments, play a role in this decision. A dermatologist or surgical oncologist will evaluate your specific case and recommend the most suitable treatment. While Mohs has distinct advantages, it's essential to have a personalized consultation to determine the best surgical approach for your situation.
11. What is postoperative recovery like after getting Mohs surgery?	Postoperative recovery after Mohs surgery typically involves minimal discomfort and a relatively short healing period. The wound will be dressed, and you may experience some soreness or swelling in the treated area. Most patients can resume normal activities the day after the procedure, but it's advised to avoid strenuous exercises and heavy lifting for a few days. The wound will gradually heal over the next weeks to months, and any stitches used will be removed during a follow-up visit. Proper wound care and sun protection are essential during this time to optimize healing and minimize scarring. Regular follow-up appointments with your surgeon will monitor your progress and address any concerns for a successful recovery.	Postoperative recovery after Mohs surgery varies depending on the surgery's size and location but generally involves a few common experiences. Patients may experience mild to moderate pain, swelling, and bruising around the surgical site, which usually subsides within a few days to a week. Proper wound care, as instructed by the surgeon, is crucial: this often involves keeping the area clean, dry, and covered, and applying antibiotic ointment if recommended. Stitches, if used, are typically removed within a week or two. Activities that might strain the surgical area should be avoided for the initial days post-surgery. It's essential to protect the wound from direct sunlight to reduce scar darkening.

RESULTS: The ChatGPT systems delivered responses of varying accuracy, readability (using FKGL), and technical detail (Table). On average, reviewers rated the accuracy of GPT-3.5 responses as 4.15 and sufficiency for patient education as 3.72, although there was low agreement. For GPT-4, the accuracy and sufficiency were 4.17 and 3.97, respectively. However, there was no significant difference observed in average ratings for GPT-3.5 versus GPT-4 for accuracy nor sufficiency. Most responses (70.8%) included a referral for patients to speak with a physician for further details or advice which suggests that AI cannot generate the same level of individualized answers as physicians. It is noteworthy that GPT outputs are dynamic and a singular comparison is insufficient to fully understand significant differences in responses.

DISCUSSION: ChatGPT will likely be utilized by individuals interested in obtaining medical information, particularly for specialized treatments such as Mohs surgery. Fortunately, ChatGPT appears to be a tentatively acceptable option to answer common questions about Mohs surgery, although there are differing opinions about response adequacy. It is encouraging that answers did not differ significantly between the free and premium versions, which suggests that AI systems might not exacerbate inequities in access to health information. Patients benefit from access to multiple modalities of education regarding Mohs, and AI systems can potentially help patients to better conceptualize Mohs surgery.[4] It is critical that Mohs surgeons are aware of patient's potential use and how it can best be incorporated into practice.

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