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INNOVATIONS IN DERMATOLOGY

FALL ABSTRACT COMPENDIUM

INNOVATIONS IN DERMATOLOGY FALL ABSTRACT COMPENDIUM

ABSTRACT 01

A CME Virtual Patient Simulation Improves Management of Adult and Pediatric Patients with Moderate to Severe Atopic Dermatitis

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INTRODUCTION: Atopic dermatitis (AD) is an inflammatory skin disease that affects children and adults. This study examined whether continuing medical education (CME) with online virtual patient simulation (VPS) experiences improved dermatologists' performance in the management of AD.
METHODS: CME case-based interventions in an online VPS platform allowed learners to interact and interview patients via video, order lab tests, make diagnoses, and order treatments supported by an extensive database of diagnostic and treatment possibilities matching the scope and depth of actual practice. Clinical decisions were analyzed, and learners received clinical guidance (CG) based on current evidence and expert recommendations. Learners were permitted to modify their decisions post-CG. Pre- (baseline) to post-CG decisions were compared using a McNemar's test. The interventions launched on Nov. 22, 2019, and Dec. 10, 2019, and data were collected through July 7, 2020.
RESULTS: Significant improvements were made as a result of education. This included increased ordering of skin exams in adult and pediatric patients (84% vs 92% and 82% vs 87% pre/post-CG; $P<.001$, respectively) and in diagnosing moderate to severe AD in 2 adult cases (51% vs 69% and 60% vs 75% pre/post-CG; $P<.001$) and in an adolescent case (47% vs 63% pre/post-CG; $P<.001$). Selection of an approved biologic for moderate to severe AD also improved following guidance in 2 adult cases (31% vs 64% and 45% vs 68% pre/post-CG; $P<.001$) and in an adolescent case (39% vs 67% pre/post-CG; $P<.001$).
DISCUSSION: Dermatologists who participated in a VPS educational initiative that replicates an authentic patient encounter significantly improved their management of patients with moderate to severe AD.

References

Silverberg JI and Spergel J. 2019 Nov 22. https://www.medscape.org/viewarticle/915948.
Lio P and Mancini AJ. 2019 Dec 10. https://www.medscape.org/viewarticle/920065.

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ABSTRACT 02

Achievement of Body Surface Area Treatment Targets in Clinical Trials of Brodalumab

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BACKGROUND: The National Psoriasis Foundation (NPF) expert consensus study identified achievement of body surface area (BSA) involvement of 1% or less as the ideal treatment target 12 weeks after initiation of plaque psoriasis treatment. Additionally, achievement of BSA involvement of 3% or less or BSA improvement from baseline of 75% or more at 12 weeks are considered acceptable treatment responses (Armstrong AW et al. J Am Acad Dermatol. 2017). Although the NPF established treatment targets, additional data are needed to develop guidelines on how to accomplish these goals.
OBJECTIVE: To contextualize the efficacy of brodalumab in terms of the NPF recommendations and offer insights into the role of brodalumab in achieving treatment targets, we conducted a post hoc analysis of data from phase 3 trials of brodalumab, an interleukin-17 receptor A antagonist efficacious for treatment of moderate to severe plaque psoriasis.
METHODS: Pooled data from three phase 3, double-blind, placebo- or active-comparator–controlled trials were analyzed (Lebwohl M et al. N Engl J Med. 2015; Papp KA et al. Br J Dermatol. 2016). Data herein include patients treated with brodalumab 210 mg every 2 weeks (Q2W) vs. placebo for 12 weeks (AMAGINE-1/-2/-3) or brodalumab 210 mg Q2W vs. ustekinumab for 12 weeks (AMAGINE-2/-3). The NPF targets for BSA outcomes, both ideal (BSA involvement of 1% or less) and acceptable (BSA involvement of 3% or less or BSA improvement from baseline of 75% or more), were used to assess treatment success at 12 weeks.
RESULTS: In all 3 trials, a significantly greater proportion of patients receiving brodalumab 210 mg Q2W vs. placebo achieved BSA involvement of 1% or less at week 12 (53.5% vs. 0.9%; P less than 0.0001). A significantly greater proportion of patients also achieved BSA involvement of 3% or less or BSA improvement from baseline of 75% or more

at week 12 in the brodalumab vs. placebo group (64.3% vs. 2.8% and 74.7% vs. 5.1%, respectively; *P* less than 0.0001 for both). In AMAGINE-2/-3, a significantly greater proportion of patients achieved BSA involvement of 1% or less with continuous brodalumab 210 mg Q2W vs. ustekinumab at week 12 (53.4% vs. 34.2%; *P* less than 0.0001).

CONCLUSIONS: In phase 3 trials, patients treated with brodalumab were more likely to meet the NPF definitions of ideal and acceptable treatment targets compared with those treated with placebo or ustekinumab. At week 12, approximately half of patients treated with brodalumab across studies achieved the ideal treatment target. These results can inform both clinician approaches when treating patients and clinician expectations for achievement of recommended targets.

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ABSTRACT 03

Assessing and Optimizing Readability of Dermatology Patient Education Materials

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INTRODUCTION: Inadequate health literacy is a well-established barrier to optimal health outcomes (Prabhu AV et al. JAMA Dermatol 2016 Aug 1;152(8):946-7). Patient education materials (PEMs) are a powerful tool to improve patient comprehension and disease self-management. The average American reads at an eighth-grade level; however, the National Institutes of Health (NIH) recommend is the sixth-grade level for PEMs (Agarwal et al. JAMA Intern Med. 2013 Jul 8;173(13):1257-9). It is plausible that higher reading levels of PEMs may result in confusion and suboptimal outcomes (Tracey E et al. Cutis. 2019 Feb;103(2):E27-8). This poses a challenge in pediatrics, as caring for a child's skin needs is contingent on physician-parent communication. The purpose of this study is to assess and optimize pediatric dermatology PEMs to identify changes that are most effective at lowering reading level without diluting educational content.

METHODS: This study assessed the readability of 39 PEMs provided by the Society for Pediatric Dermatology. Reading levels were determined using www.readabilityformulas.com. Numerical data collected included number of words, average words per sentence, average syllables per word, percentage of words that are 3 syllables or more, and number of words with 3 syllables or more. The educational content of PEMs often contains medical terminology. This is frequently necessary for the purpose of the PEM (that is, use of "melanoma" in a PEM concerning moles) but increases reading level. For each of the 39 PEMs, reading level and numerical data were collected twice. Once for the original PEMs and a second time for the PEMs without medical terminology (names of diseases, medications, microbes, and so on). PEMs were identified as having potential for improving readability if the reading level remained high without medical terminology. Of the 39 PEMs, seven had high reading levels that were unchanged by exclusion of medical terminology. The original versions of these seven PEMs were subjected to evidence-based revisions until reading level reached the sixth grade. Numerical data for the seven revised PEMs was then collected a third time.

RESULTS: A Paired Samples t Test was conducted to see if there was a relationship between reading levels of the original PEMs and reading level of the PEMs without medical terminology. The reading levels differed significantly between the 39 original PEMs (M = 9.05, SD = 1.12) and PEMs without medical terminology (M = 7.82, SD = 1.14), *P* less than 0.005. All numerical data compared between the seven original PEMs and revised sixth-grade level PEMs were statistically significant. For number of words and average words per sentence, *P* less than 0.05. Average syllables per word, percent of words that are 3 syllables or more, and number of words with 3 syllables or more were significant to a level of P less than 0.005.

CONCLUSION: Decreasing average syllables per word, percent of words that are 3 syllables or more, and number of words with 3 syllables or more may be the most effective method for improving readability without decreasing educational content.

Acknowledgement: This project was made possible by a nationwide collaborative effort of dermatologists who took the time to write these patient education materials and make them easily accessible through the Society for Pediatric Dermatology.

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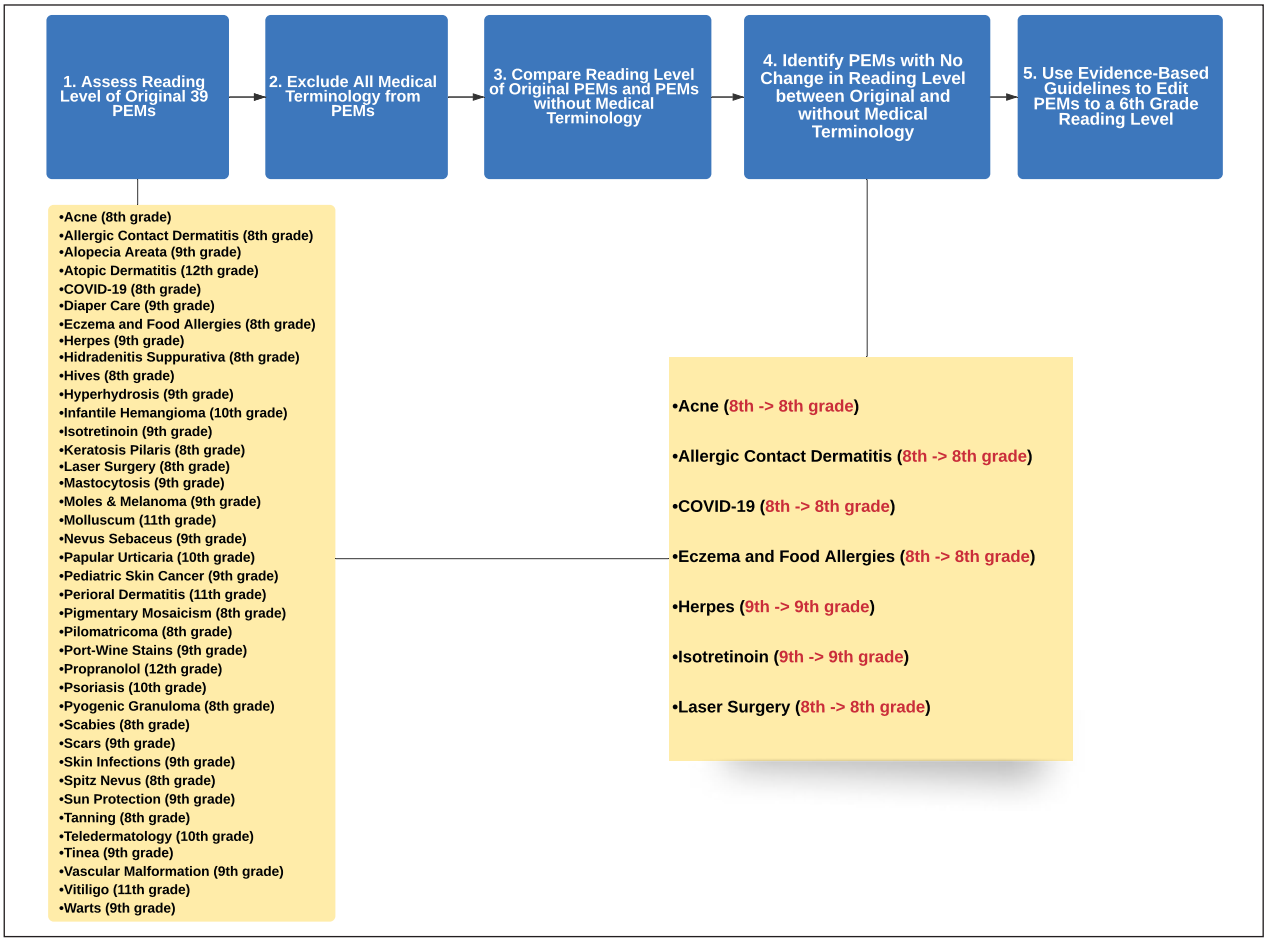

FIGURE 1. Stepwise process in identifying patient education materials (PEMs) with potential for improving readability. Reading levels for each of the original 39 PEMs are provided along with the seven PEMs identified as having high potential for improving readability. The original versions of these seven PEMs were subjected to evidence-based revisions.

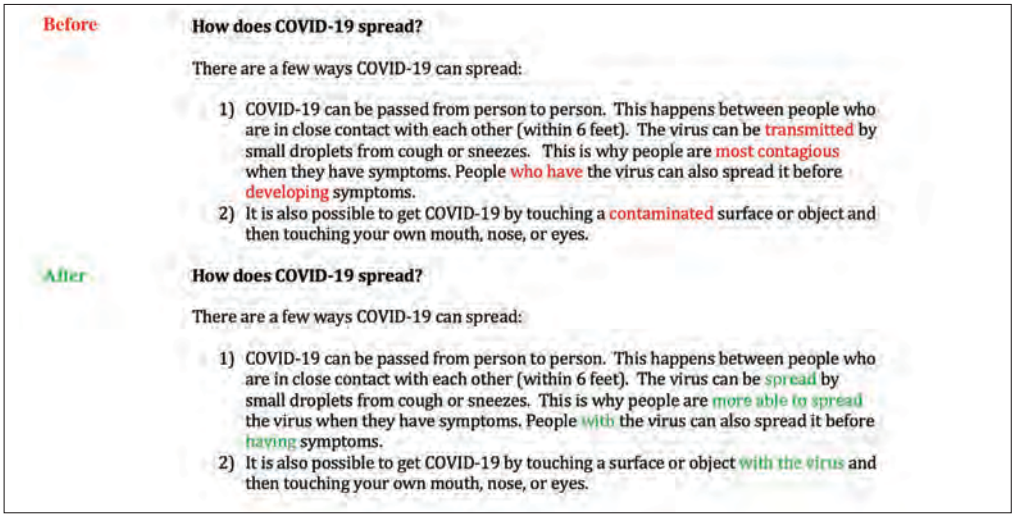

FIGURE 2. Before and after evidence-based revisions according to "Creating and Using Patient-Friendly Written Materials" by the American Medical Association Foundation, "Simply Put: A Guide for Creating Easy-to-Understand Materials" by the Centers for Disease Control and Prevention, and "How to Write Easy-to-Read Health Materials" by the National Institutes of Health. The following revisions were to the original COVID-19 patient education material (PEM) to reduce reading level to sixth grade.

ABSTRACT 04

Assessing Public Interest in Sunscreen Safety During Pregnancy

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BACKGROUND: The systemic absorptive properties of chemical sunscreen ingredients above federally recommended limits have raised concern about the long-term effects of chemical sunscreen use, especially in pregnant women and nursing mothers where chemical sunscreen byproducts have been detected (Matta et al. JAMA 2019). Despite these concerns, there have been no known studies analyzing patient attitudes on type of sunscreen use during pregnancy to assist dermatologists in anticipating patient questions on this evolving topic.

OBJECTIVES: In this study, we aimed to identify public interest in sunscreen safety during pregnancy and complete an internet analysis related to dermatologist and patient recommendations for sunscreens.

METHODS: We used Google Trends to measure changes in the search terms "sunscreen safe pregnancy," "pregnancy sunscreen," and "sunscreen for pregnancy" in the United States, comparing 2011-2014 and 2018-2021, assessing for significantly different changes using a student's t-test. Google, YouTube, and Reddit searches were conducted using the term "pregnancy safe sunscreen" on August 18, 2021. Results were assessed for recommendations from a dermatologist and, separately, any recommendations about sunscreen use and type during pregnancy. The first 30 results were analyzed from Google, YouTube, and Reddit in accordance with previous studies indicating that 90% of viewers do not continue their search after this point (iProspect, 2006).

RESULTS: We found significantly higher average Google searches for the terms "sunscreen safe pregnancy," "pregnancy sunscreen," and "sunscreen for pregnancy" (*P* less than 0.0001) between 2018 and 2021 compared with 2011-2014. Searches were higher in summer, when sunscreen is more commonly used. Google search analysis revealed 23% (7/30) of articles included dermatologist suggestions specifying type of sunscreen to use during pregnancy; all seven recommended physical sunscreens. Of the remaining 23 articles, 96% (22/23) recommended physical sunscreens and 4% (1/23) recommended chemical sunscreen. The Reddit search returned 17 posts; no posts included a self-identified dermatologist in the dialogue. Of the 56 sunscreens Reddit commenters recommended, 11% (6/56) were chemical sunscreens and 89% (50/56) were physical sunscreens. Last, of the 30 videos analyzed on YouTube, 19 discussed safe sunscreen use during pregnancy, whereas 11 did not discuss pregnancy. Of the 19 videos, 7 included dermatologists' recommendations. Of the seven dermatologists, 29% (2/7) recommended chemical and 71% (5/7) recommended physical sunscreens.

CONCLUSION: Google Trends analysis indicating higher average search interest suggest possible increased concern over chemical sunscreen use during pregnancy. There is heterogeneity among recommendations among dermatologists surrounding recommendations for type of sunscreen during pregnancy. Limitations to this study include small sample size and possibility of content not representing overall patient attitudes.

References:

Matta MK et al. JAMA. 2019;321(21):2082-91.

iProspect Search Engine User Behaviour Study. 2006:17. Available at: www.iprospect.com

ABSTRACT 05

Bimekizumab Response Maintenance Through Two Years of Treatment in Patients With Moderate to Severe Plaque Psoriasis Who Responded After 16 Weeks: Interim Results From the BE BRIGHT Open-Label Extension Trial

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BACKGROUND: Plaque psoriasis is a chronic disease; it is important to understand long-term treatment efficacy.

OBJECTIVE: To evaluate maintenance of response rates among patients with moderate to severe plaque psoriasis receiving bimekizumab who had an initial response (Investigator's Global Assessment [IGA] 0/1, body surface area [BSA] 1% or less, Psoriasis Area and Severity Index [PASI] 100) at week 16 of the three phase 3 feeder studies and received bimekizumab 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) maintenance dosing over 2 years.

METHODS: Patients who completed one of three phase 3 studies could enroll in the BE BRIGHT (NCT03598790) 2-year open-label extension (OLE) (Reich K et al. Lancet 2021; Gordon KB et al. Lancet 2021; Warren RB et al. N Eng J Med 2021). These analyses include patients randomized to bimekizumab 320 mg Q4W who responded at week 16 of the feeder study, received bimekizumab 320 mg Q4W or Q8W maintenance dosing from week 16, and enrolled in BE BRIGHT.

We report maintenance of IGA 0/1, BSA 1% or less and PASI 100 (complete skin clearance) through 2 years of treatment (OLE week 48) among week 16 responders who received

continuous bimekizumab maintenance dosing in the OLE (Q4W/Q4W/Q4W or Q4W/Q8W/Q8W). Missing data were imputed using modified nonresponder imputation (mNRI): patients with missing data following treatment discontinuation due to lack of efficacy were considered nonresponders; multiple imputation methodology was used for other missing data. Week 16 responder rates are included for context (NRI).

RESULTS: A total of 989 patients were initially randomized to bimekizumab Q4W; at week 16, 87.5% achieved IGA 0/1; 74.9% achieved BSA 1% or less; 62.7% achieved PASI 100 (NRI).

Among week 16 IGA 0/1 responders, 93.9% (Q4W/Q4W/Q4W; N=384) and 97.8% (Q4W/Q8W/Q8W; n = 185) maintained IGA 0/1 to OLE week 48. Among week 16 BSA ≤1% responders, 90.7% (Q4W/Q4W/Q4W; n = 330) and 92.5% (Q4W/Q8W/Q8W; n = 172) maintained BSA 1% or less to OLE week 48. Among week 16 PASI 100 responders, 83.7% (Q4W/Q4W/Q4W; n = 275) and 86.3% (Q4W/Q8W/Q8W; n = 147) maintained PASI 100 to OLE week 48.

CONCLUSIONS: A high proportion of patients who achieved complete or near complete skin clearance after 16 weeks' bimekizumab treatment maintained responses through to 2 years with continuous Q4W or Q8W maintenance dosing.

References:

1. Reich K et al. Lancet. 2021;397:487-98; **2.** Gordon KB et al. Lancet. 2021;397:475-86; **3.** Warren RB et al. N Engl J Med. 2021;385:130-141.

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ABSTRACT 06

CME Improves Dermatologists' Knowledge and Competence Related to Therapies for Minimizing Acne Scarring

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INTRODUCTION: Although acne is commonplace in dermatology practice, treating truncal acne and minimizing scar formation can be challenging. The goal of this study

was to evaluate the effect of continuing medical education (CME) on increasing knowledge, competence, and confidence in managing facial and truncal acne.

METHODS: Dermatologists (N=140) participated in an online multi-segment activity comprised of video and synchronized slides. Effectiveness was analyzed using 3 multiple-choice and 1 self-efficacy question, presented as pre-/post-CME repeated pairs. The activity posted on June 23, 2019 and data were collected through July 29, 2019. Chi-square test assessed changes in responses to questions from pre- to post-CME.

RESULTS: Education resulted in significant increases in knowledge, competence, and confidence. Post-CME there was a 22% absolute improvement in knowledge regarding clinical data for trifarotene in truncal acne (69% to 91% pre/post; P <.0001) and in knowledge regarding topical minocycline in moderate to severe acne (64% to 86% pre/post; P <.0001). Dermatologists had a 9% absolute increase in competence regarding the role of adapalene/benzoyl peroxide in scar prevention (79% to 88% pre/post; P <.05). Education also resulted in 44% and 55% of learners with increased and reinforced confidence in their ability to individualize therapy to prevent acne scarring.

DISCUSSION: Online CME consisting of video-based discussions with synchronized slides improved dermatologists' knowledge, competence, and confidence in managing difficult to treat acne.

Reference: Tan J, Alexis, A, Jackson JM, Stein Gold, L, Tanghetti E. Management and Minimizing Acne Scars: What Does the Data Tell Us? https://www.medscape.org/viewarticle/914631. June 23, 2019.

ABSTRACT 07

Cutaneous Disease in Hospitalized Patients Receiving Chimeric Antigen Receptor T-Cell Therapy: Data from the National Inpatient Sample

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BACKGROUND: Chimeric antigen receptor (CAR) T-cell therapy is an emerging form of oncologic immunotherapy involving ex vivo expansion of autologous T-cells genetically modified to express tumor antigen-–specific receptors. This treatment is currently used for relapsed/refractory hematologic malignancies (multiple myeloma, acute lymphoblastic leukemia, B-cell lymphoma) and is being investigated in other oncologic settings. Frequent complications of CAR T-cell administration include cytokine release syndrome, neurologic toxicity, and cytopenias.

OBJECTIVES: To measure the incidence of dermatologic illness/toxicities in patients receiving CAR T-cells and explore associations between cutaneous disease and patient epidemiologic and clinical factors.

METHODS: This retrospective observational study used the Healthcare Cost and Utilization Project Nationwide Inpatient Sample 2018. A cohort of adult inpatients treated with CAR T-cells was identified using an ICD-10-PCS procedure code. ICD-10 diagnosis codes were used to identify cohort patients with cutaneous illness. Associations between patient factors and the incidence of dermatologic illness were measured by logistic regression with calculations of odds ratios with 95% confidence intervals using STATA software.

RESULTS: A cohort of 205 adult inpatients receiving CAR T-cell therapy was identified. These patients were predominantly male (58%) and White (66% versus 4% African American, 12% Hispanic, 5% Asian/Pacific Islander, 7% other) with a median age of 58 years (range 18-84 years). Malignancies treated in this cohort included diffuse large B-cell lymphoma (60.5% of patients), multiple myeloma (14.6%), acute lymphoblastic leukemia (8.3%), follicular lymphoma (6.3%), mantle cell lymphoma (3.9%), and other B-cell lymphomas (3%). The incidence of comorbid skin disease in this cohort was 14.6% (versus 10.2% in the overall adult inpatient population). The most common dermatologic issues identified among CAR T-cell recipients included cellulitis, drug-induced dermatitis, and psoriatic disorders; less commonly detected skin disorders included nonpressure extremity ulceration, seborrheic dermatitis, rosacea, miliaria rubra, sycosis, lupus erythematosus, and erythema multiforme. No statistically significant associations between the incidence or type of dermatologic illness and patient gender, race, age, underlying malignancy, or presumed CAR T-cell target (CD19 versus BCMA) were identified.

CONCLUSION: A specific CAR T-cell therapy ICD-10-PCS procedure code first available in late 2017 permits retrospective observational research by query of large medical databases. The current study suggests that, as with other forms of oncologic immunotherapy, CAR T-cell administration is associated with increased comorbid skin disease. An anticipated increased number of CAR T-cell patients in future inpatient databases will likely facilitate further definition of specific risk factors for the development of dermatologic toxicity with this therapy.

ABSTRACT 08

Cutaneous Reactions due to Pfizer's BNT162b2 mRNA and Moderna's mRNA-1273 Vaccines

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BACKGROUND: The clinical trials for both the Moderna and the Pfizer COVID-19 vaccines reported local injection site cutaneous reactionss;[1,6] however, varied cutaneous reactions have been noted including a delayed large local cutaneous called "Covid arm" and rashes characterized based on their dermatologic morphological equivalents such as urticarial, morbilliform, pernio/chilblains-like, and pityriasis rosea-like reactions.[2]

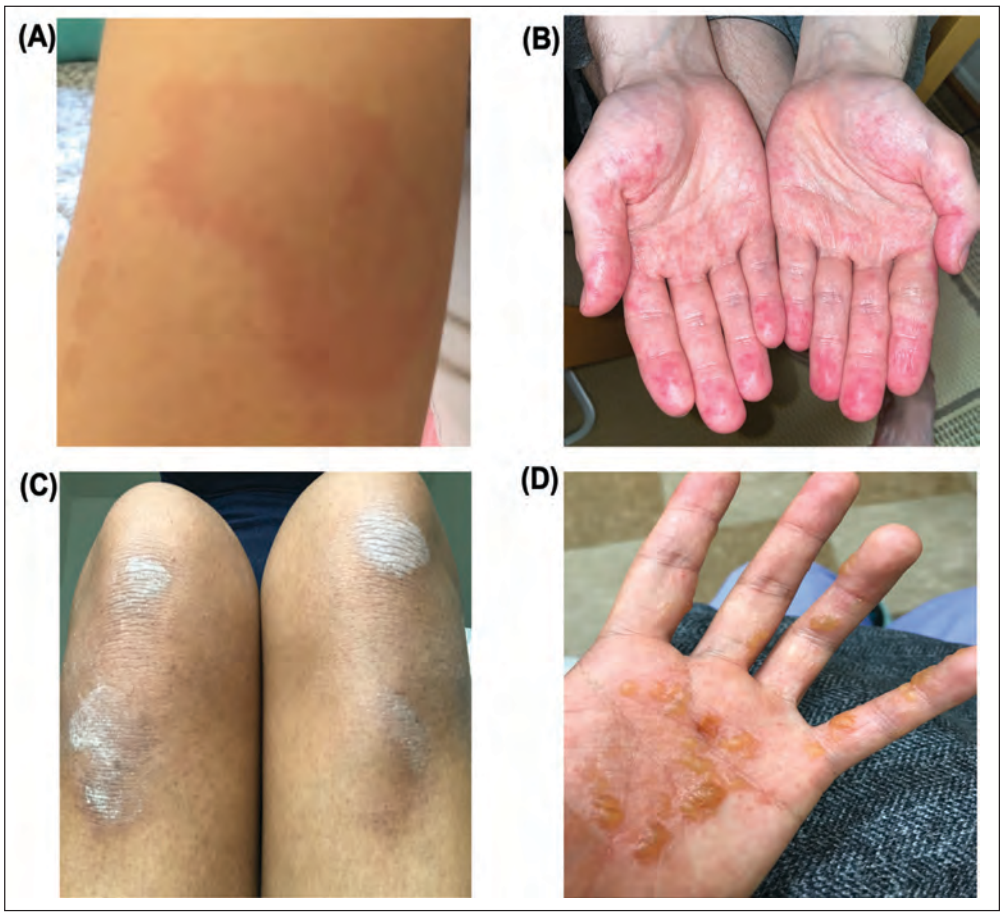

FIGURE 1. Cutaneous manifestations after COVID mRNA vaccination. (A) A 23-year-old White/Korean female health care worker presenting with an injection site reaction within 48 hours of receiving the first dose of the Moderna vaccine (B) A 23-year-old male health care worker presenting with a pernio-like/chilblains-like rash after receiving his first dose of the Moderna mRNA vaccine (C) A 33-year-old African American female health care worker presenting with psoriasiform lesions after receiving her first dose of the Pfizer mRNA vaccine (D) A 30-year-old White/Filipino female health care worker presenting with a dyshidrotic eczema flare after receiving her second dose of the Pfizer mRNA vaccine

OBJECTIVE: Our objective was to characterize dermatologic reactions to both Moderna and Pfizer COVID-19 vaccines.

METHODS: An anonymous Qualtrics survey was distributed to medical students, residents, fellows, and attending physicians at Loma Linda (Calif.) University Medical Center to capture participants' cutaneous reactions after receiving the Moderna or Pfizer vaccine. Survey submissions were elicited from March 29, 2021, to May 29, 2021.

RESULTS: Of the 137 responses, 24 cutaneous reactions to mRNA COVID-19 vaccines were noted. Most cutaneous reactions were local to the injection site and characterized as red, raised, and pruritic. Less-common reactions included dyshidrotic eczema, pernio/chilblains, and psoriasis-like lesions (**Figure 1**). Twenty of these reactions were noted in females and four were noted in males ($P = 0.007$). A total of 58.3% of the participants who developed a reaction had a pre-existing dermatologic condition. Interestingly, 70.83% of the cutaneous reactions were noted after vaccination with Moderna's COVID-19 vaccine while 29.17% were noted with Pfizer's COVID-19 vaccine.

CONCLUSION: Females were more likely to develop a cutaneous reaction to vaccination with the Moderna and Pfizer COVID-19 vaccines. This finding is supported by studies demonstrating that women mount stronger immune responses and produce higher antibody responses to vaccination.[3]

Most participants who developed a cutaneous reaction to vaccination had a pre-existing dermatologic condition. This finding could be related to a Th1 inflammatory response induced by vaccination contributing to flares of existing dermatologic conditions and/or novel reactions.[4]

Cutaneous reactions following COVID-19 vaccination were more frequently reported by individuals who received the Moderna vaccine as opposed to the Pfizer vaccine. Although this trend did not reach statistical significance, it is consistent with other literature reports.[2,5] The mechanism contributing to the higher reactogenicity has yet to be elucidated.

Most important, most reported cutaneous reactions were mild and self-limited. Therefore, reactions that are exclusively cutaneous noted after the first vaccine dose

should not dissuade completion of the vaccine course, particularly for those with similar demographics to the health care workers surveyed in this study.

References:

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TABLE. Demographics of all survey participants as well as characterization of cutaneous reactions to the Moderna and Pfizer COVID-19 mRNA Vaccines.

Cutaneous reactions were reported by 24 (17.5%) participants – four reported a cutaneous reaction after both vaccine doses, eight reported a cutaneous reaction only after the first vaccine dose, and eight reported a cutaneous reaction only after the second vaccine dose. 7 of the 62 (11.3%) participants who received the Pfizer BNT162b2 mRNA vaccine reported a cutaneous reaction compared to 17 of the 75 (22.3%) participants who received the Moderna mRNA-1273.

Characteristics	Moderna	Pfizer	Total
Sex - no. of subjects (%)			
Male	36 (48)	26 (41.9)	62 (45.3)
Female	39 (52)	36 (58.1)	75 (54.7)
Cutaneous reaction with pre-existing dermatologic conditions (%)			
Hives and rash when exposed to specific allergens and Skin Dermatographia	1 (5.9)	0 (0)	1 (4.2)
Hives	3 (17.7)	0 (0)	3 (12.5)
Rash when exposed to specific allergens	4 (23.5)	1 (14.3)	5 (20.8)
Eczema	0 (0)	3 (42.9)	3 (12.5)
Eczema and hives	1 (5.9)	0 (0)	1 (4.2)
Psoriasis	0 (0)	1 (14.3)	1 (4.2)
None	8 (47.1)	2 (28.6)	10 (41.7)
Cutaneous reaction to vaccine after 1st dose - average age (number of subjects)			
Arm at injection site	10 (90.9)	4 (80)	14 (87.5)
Arm away from injection site, legs, and feet	0 (0)	1 (20)	1 (6.25)
Hands	1 (9.1)	0 (0)	1 (6.25)
Recurrent cutaneous reaction to 2nd dose - no. of subjects (%)			
Arm at injection site	3 (100)	1 (100)	4 (100)
New cutaneous reactions to 2nd dose - no. of subjects (%)			
Arm at injection site	4 (66.7)	1 (50)	5 (62.5)
Arm away from injection site	1 (16.7)	0 (0)	1 (12.5)
Hands	0 (0)	1 (50)	1 (12.5)
Legs and trunks	1 (16.7)	0 (0)	1 (12.5)
Time taken to resolve cutaneous reaction to mRNA vaccine - no. of subjects (%)			
1-2 days	4 (23.5)	0 (0)	4 (16.7)
3-7 days	10 (58.8)	5 (71.4)	15 (62.5)
8-14 days	3 (17.6)	1 (14.3)	4 (16.7)
30+ days	0 (0)	1 (14.3)	1 (4.2)

ABSTRACT 09

Fixed-Combination Halobetasol Propionate and Tazarotene Lotion Reduces Signs and Symptoms of Psoriasis in Patients With Body Surface Area Involvement of 3% to 5%

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BACKGROUND: Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is approved for topical treatment of plaque psoriasis in adults. Joint AAD-NPF guidelines recommend combined use of TAZ with topical steroids for mild to moderate psoriasis (Elmets CA et al. J Am Acad Dermatol. 2021). Patients with body surface area (BSA) involvement of 3%-5% and Dermatology Life Quality Index (DLQI) less than 5 may be good candidates for combined topical therapy.

METHODS: Two phase 3, multicenter, double-blind trials (NCT02462070 and NCT02462122) enrolled 418 adults with BSA involvement of 3%-12% and investigator's global assessment (IGA) of 3 (moderate) or 4 (severe) at baseline. Participants were randomized 2:1 to receive HP/TAZ or vehicle lotion once daily for 8 weeks, with a 4-week post-treatment follow-up. Pooled post hoc analyses were conducted in participants with BSA involvement of 3%-5% at baseline and participants with BSA involvement of 3%-5% and DLQI less than 5 at baseline. Efficacy measures were treatment success (defined as 2-grade or more reduction in IGA and score of 0 [clear] or 1 [almost clear]) and success rates in reductions of plaque elevation and scaling (defined as 2-grade or more improvements from baseline). Treatment-emergent adverse events (TEAEs) were also evaluated.

RESULTS: Of 418 participants at baseline, 232 had BSA involvement of 3%-5% and 84 had BSA involvement of 3%-5% and DLQI less than 5. Participants with BSA involvement of 3%-5% who received HP/TAZ had significantly higher rates of treatment success at week 8 versus those who received vehicle (42.7% versus 11.4%; *P* less than 0.001). Treatment success rates at week 8 for those with BSA involvement of 3%-5% and DLQI less than 5 were numerically higher but not statistically significant with HP/TAZ versus vehicle (41.6% versus 14.7%; *P* = 0.068). At week 8, HP/TAZ versus vehicle was associated with significantly higher success rates in reductions of plaque elevation (56.0% versus 19.4%; *P* less than 0.001) and scaling (62.7% versus 25.6%; *P* less than 0.001) in participants with BSA involvement of 3%-5%. Comparable results were observed at week 8 in those with BSA involvement of 3%-5% and DLQI less than 5 (plaque elevation: 59.6% versus 28.4%; *P* = 0.016; scaling: 63.2% versus 26.0%; *P* = 0.016). Overall, TEAEs occurred more frequently in participants who received HP/TAZ versus vehicle through week 8 in both subgroups; rates of serious TEAEs and discontinuations were low (up to 5%).

CONCLUSIONS: HP/TAZ was associated with higher efficacy rates versus vehicle and was generally well tolerated in participants with lower BSA involvement who are candidates for topical psoriasis therapy.

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ABSTRACT 10

Hijab Etiquettes: Recommendations to Improve Care in Dermatology Clinics and Teledermatology Visits

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PURPOSE: The purpose of this submission is to provide recommendations on how to deliver culturally sensitive health care and ultimately improve physician relationships with patients who wear the hijab in dermatology clinics and teledermatology visits.

METHODS: Multiple dermatologists who routinely provide care to this patient population provided recommendations based on their clinical experiences and feedback received from patients.

FINDINGS: These recommendations emphasize patient privacy and comfort during the dermatology visit. Use proper terminology when discussing the hijab, which includes "headscarf" and "veil." If such is desired by the patient, provide options for them to see a female provider if possible and limit the number of male providers during the physical exam. Assess the patient's comfort level when removing her hijab during the visit and provide notes in the patient's chart and room about these preferences. Conduct teledermatology visits in private areas to avoid exposure to individuals not involved in the patient's care. Patients should also be encouraged to take representative photographs of their skin condition and send to providers ahead of time via secure email or patient portal, which is accessed only by authorized individuals. This option empowers patients with the ability to control how much information is shared and to exclude any identifiers. Although it is important to be respectful

of patient preferences, we must offer the standard of care at all times.

CONCLUSIONS: We have provided some recommendations that may assist dermatologists to provide culturally sensitive yet quality health care to patients who wear the hijab to ensure strong physician relationships. We hope that utilizing the aforementioned recommendations will alleviate anxieties patients may have and ultimately foster high quality health care for this group of patients.

ABSTRACT 11

Impact of an Educational Pilot Outreach on Hydrochlorothiazide Skin Cancer Risk in Patients With History of Squamous Cell Carcinoma Taking Hydrochlorothiazide

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BACKGROUND: Numerous population studies show increased risk of squamous cell carcinoma (SCC) with hydrochlorothiazide (HCTZ) use (Pedersen S et al. JAAD. 2018; Adalsteinsson J et al. JAAD. 2021; Eworuke E et al. JNCI Cancer Spectr. 2021). The Food and Drug Administration recently updated HCTZ labeling to include increased SCC risk, though the communication notes that HCTZ cardiovascular benefits outweigh SCC risks for most patients (FDA. 2020). History of SCC increases risk for subsequent lesions, and the potential for additional SCC risk associated with HCTZ use in this population is unknown (Adalsteinsson J et al. JAAD. 2021). Individuals with SCC history on HCTZ may be unaware of this risk or conversely may be prone to discontinuing HCTZ prematurely because of updated labeling.

OBJECTIVE: To identify the short-term impact in terms of medication adherence and provider follow-up volume of an HCTZ skin cancer risk educational communication sent to patients with a documented history of SCC and HCTZ prescription in chart, as part of a pilot study in a single dermatology clinic within a closed health care system.

METHODS: Individuals with a history of SCC and HCTZ prescriptions in chart were administratively identified and sent an informational communication through email about HCTZ skin cancer risk. The email focused on reminders to practice skin protective measures and to continue skin cancer screenings. The communication advised HCTZ continuation and to follow-up with providers with questions. Patients who were deceased, no longer active members of our health care system, or not actively enrolled in secured email communication were excluded. Communication for this pilot study was sent March 2021, and electronic medical records were reviewed 4 months after outreach.

RESULTS: A total of 76 individuals met inclusion criteria. Median age was 76.5 years (range 52-88 years). Email communication was read by 84% (n = 64) of patients. Percentage of patients who followed up with providers regarding concerns with HCTZ use and SCC was 12% (n = 9) and 3% (n = 2) in primary care and dermatology departments, respectively. At the time of chart review, 70% (n = 53) of those notified continued to have active HCTZ refills. Of the 30% with no active HCTZ refills at time of chart review (n = 23), the majority were noted to have discontinued therapy prior to the pilot (17 of 23). Of the six patients who discontinued HCTZ post pilot, four had discontinued therapy as a direct result of the email communication and because of concerns about SCC risk.

CONCLUSIONS: Education about HCTZ and SCC risk in a pilot population with SCC history resulted in moderate frequency of follow-up inquiries with providers, but overall low incidence of HCTZ discontinuation acutely after communication distribution. More studies on a larger scale with longer follow-up and additional endpoints would be needed to determine if similar educational efforts might impact long-term medication adherence or if education might improve adequate skin-protective measures and regular skin cancer screenings in this at-risk population.

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ABSTRACT 12

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

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BACKGROUND: Excessive sebum production is a factor in facial acne development (Tuchayi SM et al. Nat Rev Dis Primers. 2015 Sep 17;1:15029) and oily skin is a frequent complaint of dermatology patients with or without acne (Endly D et al. J Clin Aesthet Dermatol. 2017 Aug;10(8):49-55). Larger pore size is associated with higher rates of sebum production

(Roh M et al. Br J Dermatol. 2006 Nov;155(5):890-4). The topical retinoid tazarotene has been shown to reduce apparent facial pore size (0.1% cream; Kang S et al. J Am Acad Dermatol. 2005 Feb;52(2):268-74). A lower-dose 0.045% tazarotene lotion has also demonstrated efficacy in reducing acne lesions and acne-induced sequalae such as hyperpigmentation (Tanghetti E et al. J Drugs Dermatol. 2020 Mar 1;19(3):272-9).

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

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

RESULTS: In patients with oily skin, tazarotene 0.045% lotion provided significantly greater least-squares mean percent reductions from baseline to week 12 in inflammatory/noninflammatory lesions versus vehicle (–57.0% versus –48.4%; –55.9% versus –42.1%; *P* less than 0.001, both). Treatment success rates were significantly higher for tazarotene-treated participants versus vehicle (29.8% versus 19.2%; *P* less than 0.01). Most participants reported an improvement in skin oiliness to "moderately" or "low/not" oily with tazarotene 0.045% and vehicle (71.4% and 71.1%); more participants, however, reported an improvement to "low/not" oily skin with tazarotene than vehicle (35.0% versus 28.6%). TEAE rates with tazarotene in oily-skin patients were similar to the overall population. While there were transient increases in the severity of cutaneous safety and tolerability assessments with tazarotene, the percentage of participants reporting "none" was generally similar to baseline values for most assessments by week 12.

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

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ABSTRACT 13

Ligelizumab Achieves Fast Control of Symptoms In Patients With Chronic Spontaneous Urticaria: A Rolling UAS7 Analysis

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BACKGROUND: In a phase 2b clinical trial, ligelizumab, a next generation anti-IgE antibody, demonstrated substantial symptom control in patients with moderate-to-severe chronic spontaneous urticaria (CSU) inadequately controlled with antihistamines (Maurer M et al. N Engl J Med. 2019;381(14):1321-32). Here, we analyzed how fast patients respond with ligelizumab 72mg and 240mg vs. omalizumab 300mg.

METHODS: Patients captured their daily urticaria signs and symptoms (Urticaria Activity Score [UAS]) in an e-diary. The UAS7 is a 7-day cumulative score of daily wheal numbers and itch severity (range: 0-42). To investigate how fast patients responded, we analyzed urticaria activity via a novel rolling weekly UAS7 (rUAS7) analysis. The median time to complete control of urticaria signs and symptoms (rUAS7 = 0; that is, the first 7 consecutive days with UAS = 0) was evaluated (nominal *P*-values were evaluated with no multiplicity adjustments). The percentage of urticaria-free days during the treatment period was also calculated for each treatment arm.

RESULTS: The median time to achieve rUAS7 = 0 with ligelizumab 72mg and 240mg was 48 days (95% CI: 23-91) and 71 days (95% CI: 21-not estimatable [NE]), respectively, as compared with 101 days with omalizumab (95% CI: 62-NE). In the placebo group, only 25.1% patients achieved rUAS7 = 0, and median time could not be estimated. Nominal *P*-values were 0.025 (ligelizumab 72mg vs. omalizumab), 0.275 (ligelizumab 240mg vs. omalizumab), and less than 0.001 (ligelizumab 72 or 240mg vs. placebo). The proportion of patients who achieved rUAS7 = 0 within the first 4 weeks (after the first injection) was 40.5%, 39.6%, 26.2%, and 4.7% with ligelizumab 72mg, 240mg, omalizumab, and placebo, respectively. In the treatment period of the core study (20 weeks), the mean plus or minus SD percentage of urticaria-free days with ligelizumab 72mg, 240mg, omalizumab, and placebo was 39.2±38.9, 36.0±40.0, 25.1±34.3, and 3.0±7.2, respectively. During the

treatment-free follow-up period (weeks 20-32) the mean plus or minus SD proportion of urticaria-free days with ligelizumab 72mg, 240mg, omalizumab, and placebo was 26.5±36.2, 36.2±41.3, 17.0±27.9, and 4.6±15.4, respectively.

CONCLUSION: In the phase 2b study, patients achieved rUAS7 = 0 numerically faster with ligelizumab than with omalizumab and placebo. Treatment with ligelizumab was linked to numerically higher numbers of urticaria-free days than with omalizumab even after treatment was withdrawn.

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ABSTRACT 14

Long-Term Efficacy of Dupilumab in Adults With Moderate to Severe Atopic Dermatitis: Results From an Open-Label Extension Trial up to 172 Weeks

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BACKGROUND: Moderate to severe atopic dermatitis (AD) is often poorly controlled by topical therapies, and long-term use of systemic immunosuppressants can be limited because of safety concerns or side-effects. Dupilumab is a fully human monoclonal antibody that blocks the shared receptor component for interleukin (IL)-4 and IL-13, key and central drivers of type 2 inflammation in multiple diseases. Data from this open-label extension (OLE) study (NCT01949311) previously demonstrated acceptable safety and sustained efficacy in adult patients for up to 148 weeks. Here, we present long-term efficacy and safety of dupilumab in adult patients with moderate to severe AD up to 172 weeks.

METHODS: Adult patients with moderate to severe AD who had previously participated in any dupilumab parent study (phase 1 to 3) were enrolled in this long-term, multicenter, open-label extension (OLE) study (LIBERTY AD OLE, NCT01949311), with an initial duration of 3 years. Protocol amendments extended the trial to a maximum treatment duration of 5 years. Following protocol amendments in June 2017 and January 2018, 113 and 272 patients re-entered the trial with 102 and 207 patients having a treatment interruption of more than 8 weeks between weeks 148 and 164, respectively. Participants entering this OLE study were treated with 300 mg dupilumab every week. Concomitant treatments for AD, including topical corticosteroids and topical calcineurin inhibitors, were permitted. Data shown are for the overall study population.

RESULTS: A total of 2,677 patients were enrolled in this OLE study; 2,207 (82%) patients completed up to week 52, 1,064 (40%) to week 100, 534 (20%) to week 148, 253 (10%) to week 172, and 215 (8%) had treatment duration longer than 172 weeks. Most patient withdrawals (60%) were due to the regulatory approval and commercialization of dupilumab. At week 172, 94.6%/82.6% of patients achieved 75%/90% reductions from parent study baseline in Eczema Area and Severity Index (EASI) score, respectively. Mean (standard deviation [SD]) EASI at week 172 was 1.82 (3.21), with an absolute change from parent study baseline of −30.97 (14.18). In the Peak Pruritus Numerical Rating Scale

(PP-NRS) score, 64.5% of patients achieved a point reduction of 4 or greater from parent study baseline to week 172. Mean (SD) PP-NRS score at week 172 was 2.20 (1.70), with an absolute change from parent study baseline of −4.60 (2.23). Treatment-emergent adverse events (TEAEs) were reported in 2,268 (84.7%) patients, with 96 (3.6%) having TEAEs resulting in permanent study drug discontinuation.

CONCLUSIONS: In this long-term, open-label study, dupilumab, given on a weekly basis, showed robust and sustained efficacy substantiated by incremental improvement of AD signs and symptoms in patients with moderate to severe AD. Safety data were consistent with the known dupilumab safety profile.

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ABSTRACT 15

Long-term Management of Plaque Psoriasis: Maintenance of Treatment Success After Cessation of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion

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BACKGROUND: Psoriasis is a chronic relapsing-remitting disease that can have a substantial effect on quality of life because of both physical symptoms, such as itch and pain, and psychological burden from the stigma of visible lesions. To effectively address these issues, there is a need for therapies that provide a rapid onset of response, long-term therapeutic effect, and continued safety and efficacy should longer durations of treatment or retreatment be needed. Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is approved for treatment of plaque psoriasis in adults. Because this topical combination may mitigate adverse effects of chronic steroid use and tazarotene-related irritation, it is promising as a long-term treatment. Here, we examined the maintenance of treatment effect after HP/TAZ treatment cessation.

METHODS: In a 52-week open-label study (NCT02462083), participants with plaque psoriasis were treated with once-daily HP/TAZ for 8 weeks. Participants with treatment success (defined as investigator's global assessment [IGA] score of clear [0] or almost clear [1]) discontinued treatment for 4 weeks. At week 12, all participants were reevaluated for 1-grade or better improvement in IGA from baseline; those without improvement were discontinued from the study, whereas those with improvement continued the study and were managed in 4-week cycles (that is, those who did not achieve treatment success continued receiving once-daily HP/TAZ, whereas those who achieved treatment success did not receive treatment until the next evaluation). Maximum continuous exposure was 24 weeks. In this post hoc analysis, maintenance of treatment success was evaluated after HP/TAZ cessation in participants who were enrolled for 8 weeks or more and achieved an IGA of clear at 1 visit or later.

RESULTS: Of 550 participants, 318 (57.8%) achieved treatment success at some point during the study; 54.4% of participants achieved treatment success by week 8. Fifty-six participants were enrolled for 8 weeks or longer and achieved an IGA of clear at the first visit or later. Among these participants, after achieving the first IGA of clear, 28.6% did not require any HP/TAZ retreatment; 53.6%, 62.5%, and 83.9% did not require retreatment for 85 or more, 57 or more, and 29 or more days, respectively. After retreatment, 9 of 37 participants who relapsed (24.3%) achieved an IGA of clear (mean time to reachieve clear, 11.6 weeks). The most common treatment-related adverse events among the 56 participants who achieved an IGA of clear at first visit or later were application site reactions. At week 52, most participants had no burning (89.3%), itching (66.1%), or dryness (69.6%).

CONCLUSIONS: Over 52 weeks, 53.6% of participants who achieved clear skin with HP/TAZ did not require retreatment for more than 12 weeks. HP/TAZ was well tolerated, and most participants were symptom free at the end of the study period.

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ABSTRACT 16

Maintenance of Response After Guselkumab Withdrawal in Patizents With Moderate to Severe Psoriasis: A Post Hoc Analysis of the VOYAGE 2 Trial

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BACKGROUND AND OBJECTIVES: This post hoc analysis of VOYAGE 2 data evaluated maintenance of response in patients presenting with Psoriasis Area and Severity Index (PASI) of 0/less than 1, or Investigator's Global Assessment (IGA) of 0/less than or equal to 1 at the time of guselkumab withdrawal.

METHODS: Kaplan-Meier analyses of time to loss of response were undertaken in four subgroups of guselkumab-treated PASI 90 responders with the following PASI/IGA scores at week 28: (1) PASI = 0; (2) PASI less than 1; (3) IGA = 0; (4) IGA less than or equal to 1. Patients were evaluated at week 72, at study discontinuation, or at guselkumab reinitiation.

RESULTS: Baseline mean (standard deviation [SD]) characteristics for the PASI = 0 subgroup (n = 106) were age, 41.9 (11.6) years; body mass index, 28.6 (6.4) kg/m2; psoriasis disease duration, 17.0 (11.4) years; PASI score, 22.3 (8.1). Baseline data for the PASI less than 1 subgroup (n = 140) were 41.8 (11.4) years; 28.8 (6.8) kg/m2; 17.1 (11.3) years; 22.4 (8.8). In the PASI = 0 subgroup, estimated median time to loss of response was 86 days; and median time to PASI up to1/up to 3/up to 5 was 119/159/192 days, respectively. In the PASI less than 1 subgroup, median time to PASI up to 1/up to 3/up to 5 was 112/147/182 days. Median time to loss of response in the IGA = 0 (n = 120) and IGA up to 1 (n = 177) subgroups was 85 and 137 days, respectively.

CONCLUSIONS: Median time to loss of clear skin (IGA = 0/PASI = 0) after guselkumab withdrawal was 85/86 days, respectively. PASI up to 1/up to 3/up to 5 and IGA 0/up to 1, which are considered clinically meaningful cutoffs, provide a granular assessment of the characteristics of psoriasis relapse, following elective discontinuation of guselkumab therapy.

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ABSTRACT 17

Nalbuphine in the Attenuation of Substance P–Induced Itch in Mice

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ABSTRACT: Nalbuphine is a dual-acting ƙ-agonist/μ-antagonist opioid that is thought to exert an antipruritic effect by regulating imbalances that can exacerbate itch. The purpose of this study was to evaluate the effect of nalbuphine for attenuating itch using an established preclinical animal model. The substance P (subP)–induced mouse itch model has been previously used to simulate antihistamine-resistant pruritus observed in patients with various dermatoses. Nalbuphine was tested using a vehicle control and nalfurafine as a positive comparative control (PCC). Nalbuphine was tested at doses that were shown in initial phases of this study to have no effect on spontaneous motor function, to ensure that the potential effect on scratching behavior would not be confounded by overall sedation. Mice were pretreated with vehicle, PCC (0.01 or 0.02 mg/kg), or nalbuphine (10 mg/kg or 30 mg/kg) and video recorded in individually housed plexiglass cages for 30 min to establish baseline scratching. The mice were then challenged with vehicle or subP (250 ng/0.05 mL) and recorded for an additional 30–60 min. Scratching scores were calculated using 2 independent raters trained prior to the study and blinded to the dosing scheme. Scratches to the injection site (upper right shoulder) with hind paws were counted; continuous scratching over 1 second was counted as 1 scratch. Nalbuphine pretreatment resulted in a significant reduction in scratching at both tested doses: 10 mg/kg: 43% reduction (107 to 61 scratches; $P < 0.001$); 30 mg/kg: 51% reduction (107 to 52; $P < 0.001$). Although there was an apparent dose-response effect, there was no statistical difference between the tested nalbuphine doses. An equivalent suppression in scratching activity was observed between nalbuphine and the PCC, supporting the hypothesis that nalbuphine may be capable of reducing the sensation of itch in humans. In conclusion, the effects of nalbuphine on this subP–induced mouse itch model suggest that nalbuphine may be a potential therapy for pruritic conditions.

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Abstract 18

Periungual Squamous Cell Carcinoma in Childhood

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BACKGROUND: Bowen's disease (BD) is the second most common form of skin cancer worldwide,[1] associated with sun exposure, arsenic, radiotherapy, trauma, immunocompromise, and actinic keratosis.[1] In pediatrics, it is rare but seems to be the third most common pediatric skin cancer,[3] normally associated with albinism, epidermolysis bullosa, xeroderma pigmentosum, or immunosuppression.[4] There has been an increase in the incidence of squamous cell carcinoma (SCC) cases in recent years in the pediatric population, probably associated with immunosuppression, and human papilloma virus (HPV),[4-6] being the subtype 16, the most found in BD.[7] Reports of subungual SCC in children are based on isolated cases.[6,7]

CASE REPORT: We report the case of an 11-year-old girl, native from Mexico City, with no significant family or personal history. She was seen for a 5-year history of a dark brown plaque, asymptomatic, slow-growing on the periungual region of the second finger of the right hand (**Figure 1**). Dermoscopic exam with polarized light (Fotofinder, 20x, HD Medicam 800) revealed a brown pigment network with focal scattered brown-gray dots (**Figure 2**). An incisional biopsy was performed, and histopathologic examination revealed hyperplastic epidermis with hyperkeratosis with foci of confluent parakeratosis. There was acanthosis with elongated and widened epidermal rete ridges, which showed full thickness keratinocytic atypia. Keratinocytes were large with abundant eosinophilic cytoplasm, and exhibited pleomorphic and hyperchromatic nuclei with hyperchromatic chromatin and prominent nucleoli. There was evidence of suprabasal mitoses, as well as individual cell necrosis. Some of the atypical keratinocytes showed melanin granules within their cytoplasm. Hypergranulosis with large keratohyalin granules and few vacuolated keratinocytes with irregular contours were seen in some areas. Histological diagnosis of pigmented squamous cell carcinoma *in situ* of acral skin was rendered. Peripheral skin margins were excised in two instances, the nail apparatus was removed, and 5% imiquimod cream was used as adjuvant. Tissue defect was covered with skin graft placement. There has been no recurrence of the lesion in 2-year follow-up.

DISCUSSION: This is an unusual case of SCC because of its subtle clinical appearance of an asymptomatic brownish plaque, without a pre-existing dermatosis, the early age of onset, and the absence of risk predisposing factors, which made it difficult to reach this diagnosis. The clinician should take a biopsy, when faced to a rapidly enlarging lesions, considering malignancy as a differential diagnosis even in pediatric patients. Acral anatomical sites, like nail apparatus or periungual region, can increase the diagnostic challenge. Pigmented SCC can also be confused with other lesions like melanocytic nevi, melanoma, seborrheic keratoses, or warts; therefore, diagnostic tools such as dermoscopy are very useful to find clues to make an adequate and prompt diagnosis.

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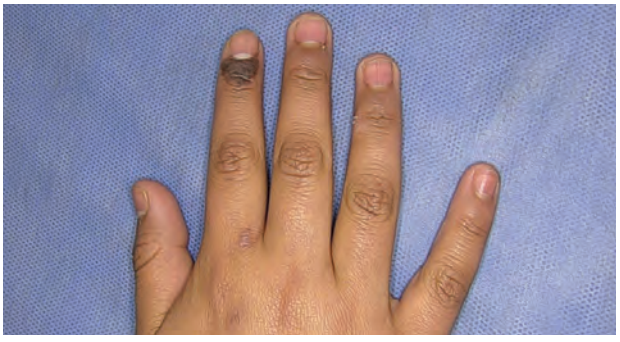

FIGURE 1.

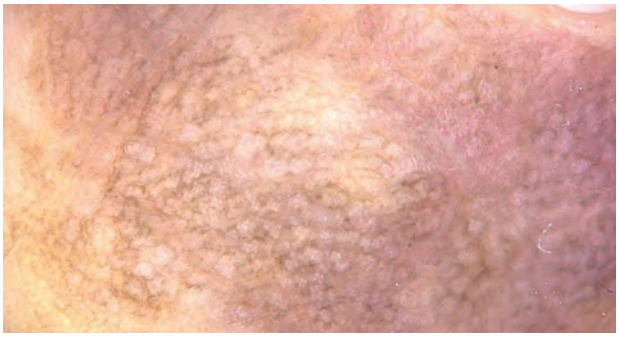

FIGURE 2.

ABSTRACT 19

Psoriasis Symptoms and Impacts Measure (P-SIM) responses from the BE SURE bimekizumab in moderate to severe plaque psoriasis phase 3 trial

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BACKGROUND: Psoriasis Symptoms and Impacts Measure (P-SIM) is a novel, 14-item patient-reported outcome validated tool developed to capture key signs, symptoms, and life impacts of plaque psoriasis.

OBJECTIVES: To evaluate patient experiences of the signs, symptoms, and impacts of moderate to severe plaque psoriasis using P-SIM in BE SURE (NCT03412747). Additionally, to compare patient experiences of moderate to severe plaque psoriasis for those receiving bimekizumab versus adalimumab.

METHODS: Patients were randomized to: bimekizumab 320 mg every 4 weeks (Q4W); bimekizumab Q4W to Week 16, then every 8 (Q8W) to Week 56; or adalimumab per label to Week 24, then bimekizumab Q4W to Week 56. P-SIM items were scored daily (0–10: no–very severe sign/symptom/impact) and averaged weekly through Week 24. Proportions of patients achieving marked clinically meaningful improvements (≥4-point reduction from baseline) for pain, itch, and scaling items are reported. Comparisons versus adalimumab were based on the stratified Cochran-Mantel-Haenszel test for the general association. Missing data were imputed as non-response (NRI).

RESULTS: Of patients randomized to bimekizumab Q4W (N=158), bimekizumab Q4W/Q8W (N=161), and adalimumab (N=159), the proportions with baseline scores ≥4 were: 67.7%, 71.4%, 57.9% for pain; 75.9%, 79.5%, 67.3% for itch; 77.2%, 80.1%, 68.6% for scaling. At Week 4, the proportions of patients randomized to bimekizumab Q4W, bimekizumab Q4W/Q8W, and adalimumab achieving ≥4-point reduction from baseline were: 51.4%, 58.3%, 20.7% for pain; 49.2%, 50.0%, 20.6% for itch; 56.6%, 58.9%, 18.3% for scaling (all comparisons versus adalimumab: nominal $P < 0.001$). Week 24 proportions were: 70.1%, 67.8%, 46.7% for pain; 66.7%, 65.6%, 45.8% for itch; 69.7%, 65.9%, 47.7% for scaling (all comparisons versus adalimumab: nominal $P \leq 0.004$).

CONCLUSIONS: Greater proportions of bimekizumab-treated patients reported rapid and marked clinically meaningful improvements in pain, itch, and scaling compared with adalimumab.

Reference:

BE SURE: https://www.clinicaltrials.gov/ct2/show/NCT03412747.

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RBW: Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, UCB Pharma; honoraria from Astellas, DiCE, GSK, Union; has received research grants to his institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, UCB Pharma.

MA: Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, and Xenoport.

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VC: Employee of UCB Pharma.

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ABSTRACT 20

Psoriasis Symptoms and Impacts Measure Responses From a Phase 3b Trial With Bimekizumab (BE RADIANT)

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BACKGROUND: The Psoriasis Symptoms and Impacts Measure (P-SIM) is a novel, reliable, fit for purpose, patient-reported outcome tool capturing signs, symptoms, and impacts of plaque psoriasis in the bimekizumab (BKZ) clinical program (Gottlieb AB et al. Dermatol Ther [Heidelb]. 2020). BE RADIANT (NCT03536884) is the first phase 3 trial to directly compare dual inhibition of interleukin (IL)-17A and IL-17F with BKZ, with inhibition of IL-17A alone with secukinumab (SEC).

OBJECTIVE: To compare the experience of patients with moderate to severe plaque psoriasis treated with BKZ vs. SEC in the randomized, double-blinded, active comparator-controlled phase 3b trial, using three key items of the P-SIM: itch, pain, and scaling.

METHODS: Patients were randomized 1:1 to BKZ 320 mg every 4 weeks (Q4W) or SEC 300 mg weekly to week 4, then Q4W. At week 16, patients receiving BKZ were re-randomized to 320 mg Q4W or every 8 weeks (Q8W). The proportions of patients achieving marked clinically meaningful improvements (4-point or more reduction from baseline) in the three P-SIM items are reported (only patients with baseline score 4 or greater for each item were included). Data are reported for two analysis sets: the intention-to-treat (ITT) population (all randomized patients) and the maintenance set (received 1 or more doses of study treatment at week 16 or later). Nominal *P* values for comparisons between treatment groups were based on the stratified Cochran-Mantel-Haenszel test for the general association and were not controlled for multiple comparisons. Missing data were imputed as nonresponse (NRI).

RESULTS: A total of 373 patients were randomized to BKZ, and 370 to SEC. Baseline mean P-SIM scores for all patients randomized to BKZ and SEC were: 6.6 and 6.8 for itch; 4.5 and 4.8 for pain; 6.7 and 6.8 for scaling. At week 4, the proportions of patients receiving BKZ Q4W vs. SEC who achieved a 4-point or greater reduction from baseline were 256/309 (82.8%) vs. 234/319 (73.4%) for itch (nominal $P = 0.003$); 195/221 (88.2%) vs. 183/235 (77.9%) for pain (nominal $P = 0.006$); 286/328 (87.2%) vs. 241/324 (74.4%) for scaling (nominal *P* less than 0.001).

At week 48, the proportions of patients in the ITT population receiving BKZ (Q4W or Q8W) vs. SEC who achieved a 4-point or greater reduction from baseline were 259/309 (83.8%) vs. 238/319 (74.6%) for itch (nominal $P = 0.005$); 187/221 (84.6%) vs. 175/235 (74.5%) for pain (nominal $P = 0.009$); 286/328 (87.2%) vs. 252/324 (77.8%) for scaling (nominal $P = 0.002$). Responses were consistent between the Q4W and Q8W BKZ maintenance dosing regimens (maintenance set; Table).

CONCLUSIONS: Through 48 weeks, more patients reported marked clinically meaningful improvements in itch, pain, and scaling with BKZ vs. SEC. Response with BKZ was consistent with both maintenance dosing regimens.

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TABLE. Proportions of patients achieving ≥4-point reduction from baseline in the itch, pain, and scaling items of the P-SIM at week 48[a] (maintenance set;[b] NRI)

	BKZ 320 mg Q4W[c] n/N (%)	BKZ 320 mg Q8W[c] n/N (%)	SEC 300 mg Q4W n/N (%)	BKZ Q4W vs SEC nominal *P* value	BKZ Q8W vs SEC nominal *P* value
Itch	112/127 (88.2)	147/172 (85.5)	238/304 (78.3)	0.014	0.061
Pain	79/91 (86.8)	108/122 (88.5)	175/223 (78.5)	0.083	0.028
Scaling	123/136 (90.4)	163/183 (89.1)	252/309 (81.6)	0.016	0.033

[a]Only patients with a baseline score ≥4 for each item were included; [b]The maintenance set includes all patients who received ≥1 dose of study treatment at week 16 or later; cAll patients randomized to BKZ received BKZ 320 mg dosed Q4W through weeks 0-16 and were rerandomized at week 16 to BKZ 320 mg dosed Q4W or Q8W. BKZ: bimekizumab; NRI: nonresponder imputation; P-SIM: Psoriasis Symptoms and Impacts Measure; SEC: secukinumab; Q4W: every 4 weeks; Q8W: every 8 weeks.

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LP, CC: Employees and shareholders of UCB Pharma.

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ABSTRACT 21

Recommendations to Optimize Patient Care in Hidradenitis Suppurativa Clinics: Our Experience

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PURPOSE: Given the recent increase in Hidradenitis Suppurativa (HS) awareness, more providers are recognizing this entity and referring patients to dermatologists. As a result, the demand for HS specialty clinics has increased. The purpose of this presentation is to provide novel recommendations to efficiently manage patients in HS specialty clinics.

METHODS: We describe our experience with three Quality Improvement (QI) initiatives at our institution's HS specialty clinic focused on shortening appointment lead-time delays, improving clinical documentation via patient intake forms and note templates, and creating educational videos explaining HS-specific procedures.

FINDINGS: To improve lead time delay, we referred severe, refractory HS patients to our HS clinic, while less-severe patients were managed in resident or general dermatology clinics. We created an internal set of HS treatment guidelines that was available at our institution's general dermatology clinics to assist providers and residents to manage mild or moderate HS cases and to refer more severe cases to the HS clinic. By instituting these measures over a span of 2 years, lead time delays decreased by 30%, from 52.7 days to 36.5 days for new patients, and decreased by 26% from 54.8 days to 40.6 days for returning patients. We also have patients complete intake forms describing their recent HS history and treatment, which decreased time spent on history taking and allowed providers to spend more time counseling patients. Lastly, we created educational videos that explain how specific HS procedures are performed and the subsequent wound care process. We found that 82% of residents were able to educate patients on the procedure in less than 7 minutes using the video, while 67% of residents needed more than 7 minutes to educate patients using the PowerPoint presentation. We also found that the same percentage of patients (50%) found both presentation methods to be equally effective and felt extremely prepared for the procedures, indicating no negative impact on patient care.

CONCLUSIONS: By sharing our experiences, we hope to encourage other HS clinics to share their best practices in order to foster a culture that ultimately promotes higher-quality accessible health care for HS patients.

ABSTRACT 22

Roflumilast Cream, a Once-Daily, Potent Phosphodiesterase-4 Inhibitor, in Chronic Plaque Psoriasis Patients: Efficacy and Safety from DERMIS-1 and DERMIS-2 Phase 3 Trials

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BACKGROUND: Novel nonsteroidal topical therapies for psoriasis have not been approved in more than 20 years. Recent data suggest roflumilast 0.3% cream, a potent phosphodiesterase-4 inhibitor, may represent a highly effective, well-tolerated, nonsteroidal, once-daily treatment for long-term management of chronic plaque psoriasis, including the face and intertriginous areas.

OBJECTIVES: Two identical phase 3, randomized, double-blind, vehicle-controlled, multi-center trials (DERMIS-1 [n = 439; NCT04211363] and DERMIS-2 [n = 442; NCT04211389]) were conducted in patients 2 years old or older with chronic plaque psoriasis involving 2%-20% of body surface area.

METHODS: Patients were randomized 2:1 to receive roflumilast cream 0.3% or vehicle once daily for 8 weeks. The primary efficacy endpoint was Investigator Global Assessment (IGA) success at week 8.

RESULTS: Significantly more roflumilast-treated patients reached IGA success (DERMIS-1: 42.4%; DERMIS-2: 37.5%) than vehicle-treated patients (DERMIS-1: 6.1%; DERMIS-2: 6.9%, *P* less than 0.001 for both). In patients with intertriginous area involvement, significantly more roflumilast-treated patients reached intertriginous-IGA (I-IGA) success at week 8 than vehicle-treated (DERMIS-1: 71.2% vs. 13.8%, *P* less than 0.0001; DERMIS-2: 68.1% vs. 18.5%, *P* = 0.0004). A majority of these patients achieved I-IGA = 0. Approximately 40% of patients achieved 75% reduction in Psoriasis Area Severity Index (PASI 75) by week 8 (DERMIS-1: 41.6% vs. 7.6%; DERMIS-2: 39.0% vs. 5.3%, *P* less than 0.0001). Patients with baseline Worst Itch-Numeric Rating Scale (WI-NRS) equal to or greater than 4 achieved a 4-point reduction in WI-NRS at week 8 (DERMIS-1: 67.5% vs. 26.8%; DERMIS-2: 69.4% vs. 35.6%, *P* less than 0.0001). Itch improvement was notable by 2 weeks, the earliest time point measured (DERMIS-2: *P* = 0.0026). Incidence of treatment-emergent adverse events (TEAE) was low and similar between roflumilast and vehicle groups. Pooled rates of TEAE leading to discontinuation (1.0% roflumilast vs. 1.3% vehicle) and application site pain (1.0% roflumilast vs. 0.3% vehicle) were low and comparable to vehicle.

CONCLUSIONS: Roflumilast cream 0.3% demonstrated favorable safety and tolerability while delivering statistically superior efficacy vs. vehicle across multiple endpoints in patients with chronic plaque psoriasis.

ABSTRACT 23

Safety and Efficacy of Mesenchymal Stem Cells for Treatment of Canine Atopic Dermatitis

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BACKGROUND: Canine atopic dermatitis (cAD) is a common skin disorder affecting approximately 10%-15% of dogs worldwide (Hillier A and Griffin CE. Vet Immunol Immunopathol. 2001 Sep 20;81(3-4):363-83). Available therapies only eliminate clinical signs periodically and may be associated with adverse effects. Canine mesenchymal stem cells (MSCs) have been examined in the treatment of cAD with controversial results, with all previous studies lacking placebo control groups and good manufacturing practice (GMP) conditions for MSCs.Canine mesenchymal stem cells (MSCs) have been examined in the treatment of cAD with controversial results, with all previous studies lacking placebo control groups and MSCs manufactured in non–good manufacturing practice (non-GMP) conditions (de Oliveira Ramos F et al. J Adv Vet Anim Res. 2020;7(3):554-65; Enciso N et al. Vet World. 2019 Nov;12(11):1747-54; Hall MN et al. Vet Ther. 2010 Summer;11(2):E1-14; Villatoro AJ et al. Vet Rec. 2018 Dec 1;183(21):654).

OBJECTIVE: To conduct a double-blinded placebo-controlled clinical trial to evaluate the efficacy and safety of the allogenic canine adipose-derived MSCs manufactured in GMP conditions for treatment of dogs with AD by subcutaneous administration.

METHODS: Following strict inclusion and exclusion criteria, and published guidelines for diagnosis of cAD, 20 dogs were enrolled, of which 15 completed the study. Patients were randomly divided into placebo (phosphate-buffered saline), low-dose (5x105 cells/kg), and high-dose (5x106 cells/kg) treatment groups. Each patient received three treatments at 4-week intervals with injections at five sites. Patients were monitored by physical exams, pruritus visual analog scale (PVAS) signed by the owner, canine atopic dermatitis extent and severity index-4 (CADESI-4) by two veterinarians, and complete blood count and serum chemistry analysis along with laboratory analysis for potential biomarkers. Clinical and laboratory monitoring and biomarker data were also collected at day 90 and day 180 after the first treatment. Patients were kept off any immune-modulating drugs during the study period; however, oral antibiotics and topicals (shampoos, sprays) were used for managing pruritus and secondary infections.

Results: The PVAS score and serum miR-483 levels were significantly lower in the high-dose group compared with the placebo at day 90 post–first treatment (30 days after the last subcutaneous treatment). No severe adverse effects were observed in any patient in this study.

CONCLUSIONS: Our double-blinded placebo-controlled clinical trial shows that subcutaneous treatment with high dose MSCs is efficacious in alleviating the clinical signs of cAD until 30 days after the last administration. This is supported by serum levels of miRNA-483, which may be a reliable prognostic biomarker for cAD. The MSCs' efficacy and potential biomarker should be further explored at a larger scale clinical trial for cAD.

ABSTRACT 24

Secukinumab Provides Sustained Improvement on Clinical and Patient-Reported Outcomes Through 12 Months in Both Biologic-Naive and Biologic-Experienced Patients With Psoriasis in a U.S. Real-World Setting

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BACKGROUND: In prior CorEvitas' Psoriasis Registry studies, patients with psoriasis (PsO) initiating secukinumab exhibited meaningful responses in clinical and patient-reported outcomes (PROs) at 6, 12, and 18 months (Strober B et al. J Dermatolog Treat. 2020; Bagel J et al. AAD VMX 2021 [abstract]); however, the majority of patients in these studies used other biologics prior to secukinumab and not all patients had data at each follow-up visit.

OBJECTIVE: To describe real-world effectiveness outcomes of patients with PsO who initiated and maintained secukinumab through 12 months stratified by prior biologic use.

METHODS: This study included patients with PsO who initiated secukinumab in CorEvitas' Psoriasis Registry at or after enrollment and had subsequent 6- and 12-month follow-up visits at which they remained on secukinumab (April 2015 to Dec. 2020). Demographics, clinical characteristics, treatment history, disease activity (IGA, PASI, and BSA), and PRO measures (DLQI, EQ VAS, patient global assessment, itch, skin pain, and WPAI) were evaluated at secukinumab initiation and follow-up. Analyses were stratified by prior biologic exposure status at therapy initiation (naive vs. experienced).

RESULTS: Among 1,518 patients who initiated secukinumab, 326 had both 6- and 12-month follow-up visits and were included in this analysis (82 [25.2%] naive, 244 [74.8%] experienced). Of the patients who remained on secukinumab through 12 months, mean age at PsO diagnosis was 38.7 years and 33.1 years and 35.0% and 58.0% had comorbid psoriatic arthritis for biologic-naive and biologic-experienced patients, respectively. Both biologic-naive and biologic-experienced patients demonstrated improvements from baseline to 6- and 12-month visits in IGA (mean change from baseline to 6 or 12 months; experienced: –1.7, –1.6; naive: –2.0, –2.0), PASI (–5.5, –5.2; –7.6, –7.5), EQ VAS (9.8, 7.0; 9.0, 11.2), and percent work impairment due to PsO (–8.2, –11.2; –9.8, –9.3) (**Figure 1**). The proportion of patients with low disease activity based on clinical and PRO measures increased from baseline to 6- and 12-month visits: IGA clear/almost clear (baseline, 6 months, 12 months; experienced: 8.6%, 64.8%, 61.1%; naive: 7.4%, 75.3%, 74.1%) and DLQI no effect (experienced: 18.7%, 55.2%, 51.9%; naive: 7.4%, 72.8%, 79.0%) (**Figure 2**).

CONCLUSION: In this real-world study of individuals with PsO who initiated and maintained treatment with secukinumab, on average, patients exhibited sustained improvements in disease activity and PRO measures at both follow-up visits, regardless of past biologic use. These findings suggest that effectiveness is sustained in patients who remain on secukinumab, even among biologic-naive patients, and is a viable first-line biologic for PsO.

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Disclosures:

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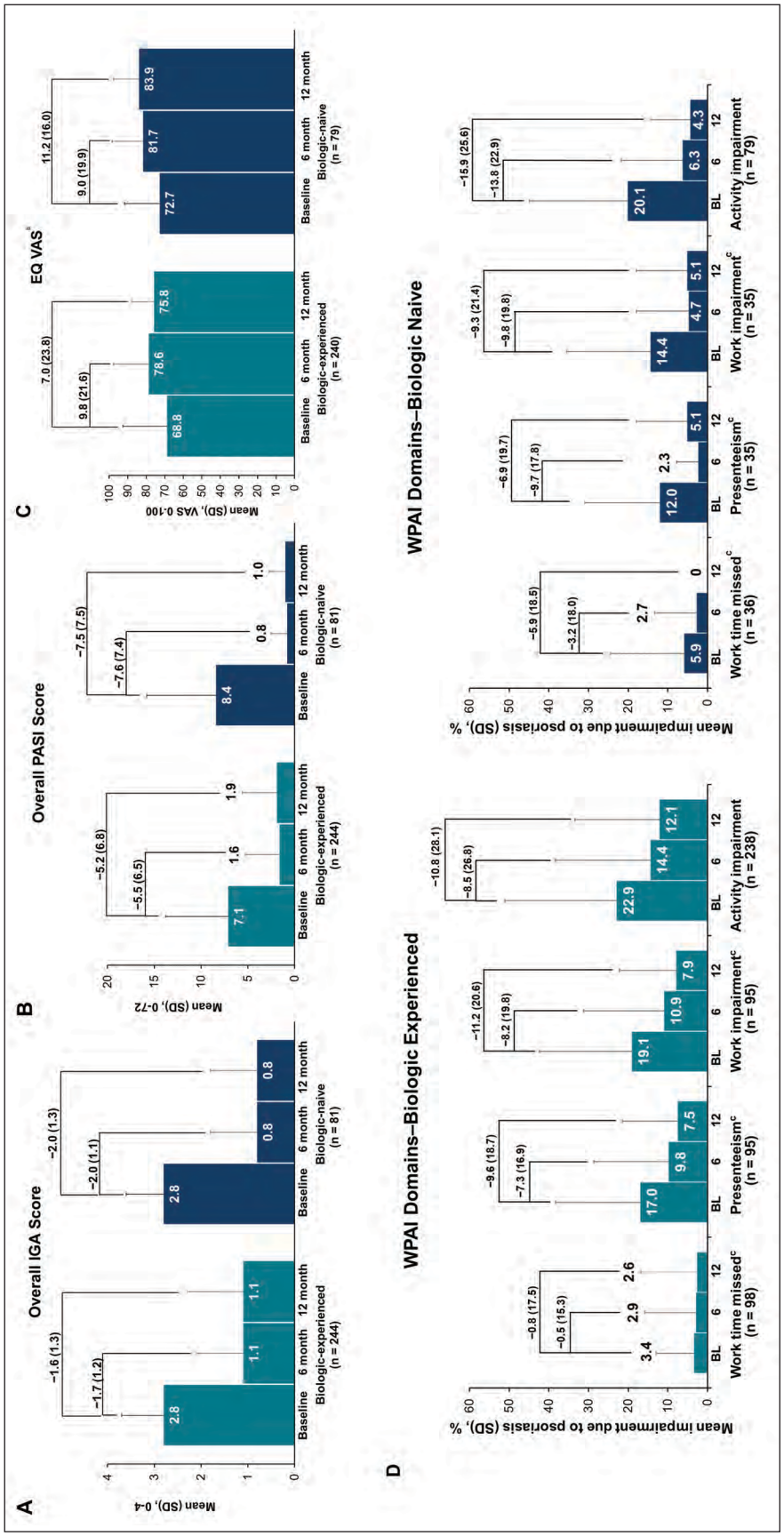

FIGURE 1. Mean (A) IGA, (B) PASI, (C) EQ VAS, and (D) WPAI Scores and Calculated Mean (SD) Differences From Baseline at 6- and 12-Month Follow-Up Among Patients With Psoriasis Who Initiated and Maintained Secukinumab at Both Visits[a]

BL, baseline; IGA, 5-point Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment.

[a]Labels across baseline and follow-up visits represent mean (SD) differences.

[b]For EQ VAS, an increase in mean VAS score denotes an improvement from baseline.

[c]Work time missed, presenteeism, and work impairment values are based on patients with psoriasis who worked full time.

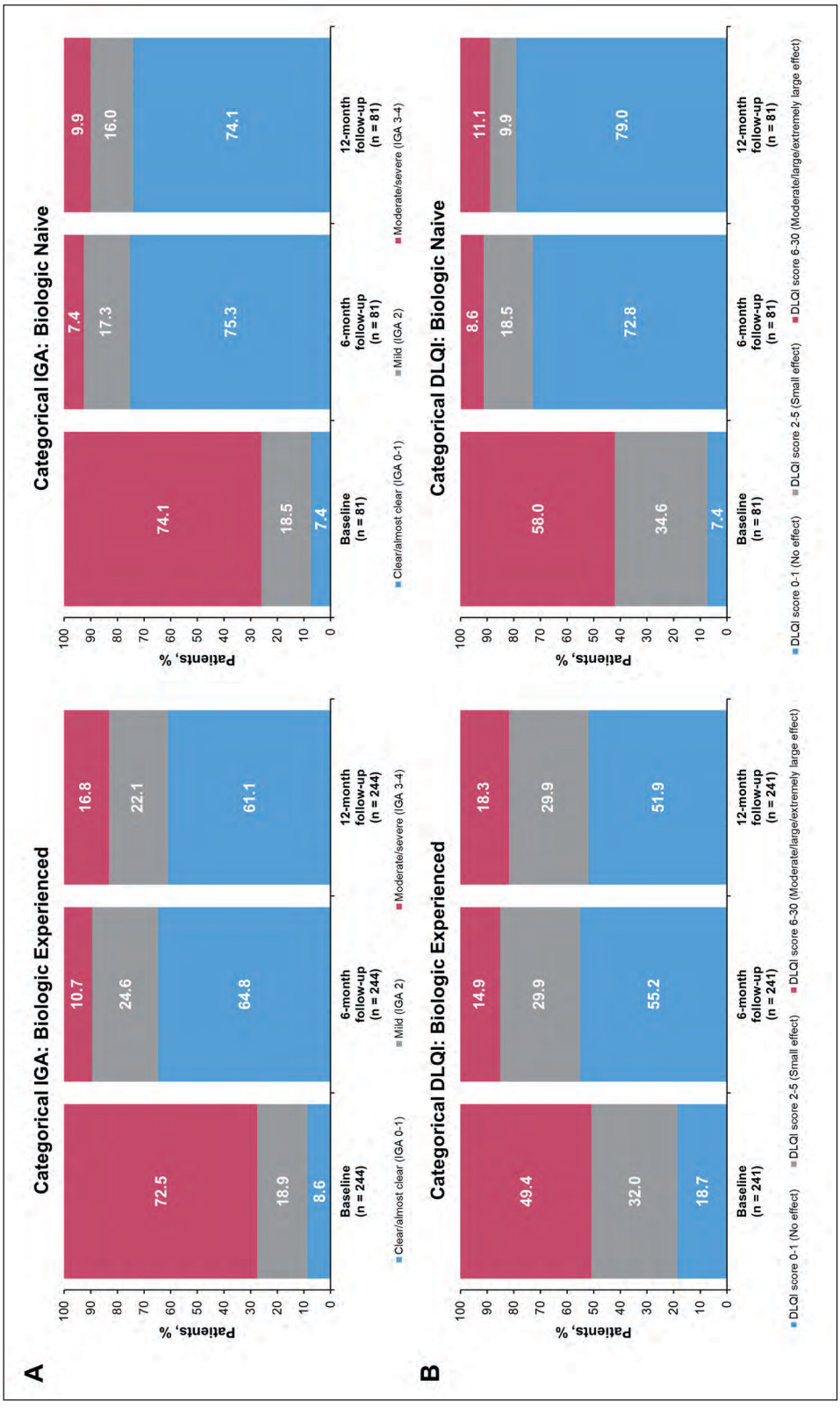

FIGURE 2. Patients in (A) IGA and (B) DLQI Categories From Baseline to 6-Month and 12-Month Follow-Up Visits in Biologic-Experienced and Biologic-Naive Patients With Psoriasis Who Initiated and Maintained Secukinumab at Both Visits

DLQI, Dermatology Life Quality Index; IGA, 5-point Investigator's Global Assessment.

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ABSTRACT 25

Secukinumab Treatment Demonstrated High Efficacy and Safety in Pediatric Patients With Moderate to Severe Plaque Psoriasis: 52-Week Results From a Randomized Trial

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BACKGROUND: Plaque psoriasis affects adults and children, but efficacy and safety trials for pediatric psoriasis are limited (Eichenfield LF et al. Pediatr Dermatol 2018; Napolitano M et al. Dermatol Ther [Heidelb] 2016; Burden-Teh E et al. Br J Dermatol 2016; Burden AD CED 1999; Farber EM et al. Cutis 1999; Benoit S et al. Clin Dermatol 2007). Secukinumab, a fully human monoclonal anti–interleukin-17A antibody, has proven efficacious in adults in the long-term treatment of multiple manifestations of psoriatic disease, with a favorable safety profile (Reich K et al. ISDS 2018; Zeichner JA et al. J Clin Aesthet Dermatol 2016).

OBJECTIVE: To report efficacy and safety of two secukinumab regimens in pediatric patients with moderate to severe plaque psoriasis through week 52.

METHODS: In this randomized, open-label, multicenter study (NCT03668613), patients (6-18 years) with moderate to severe plaque psoriasis were stratified by weight (less than 25kg/25-50kg/more than 50kg) and disease severity to receive low-dose (LD; 75/75/150mg; n = 42) or high-dose (HD; 75/150/300mg; n = 42) subcutaneous secukinumab. Efficacy (nonresponder imputation; Psoriasis Area Severity Index [PASI] 75/90/100 and Investigator's Global Assessment modified 2011 [IGA] 0/1 responses over time), Children's Dermatology Life Quality Index (CDLQI0/1; last observation carried forward), and safety were evaluated through week 52.

RESULTS: PASI75/90 and IGA0/1 responses were superior to historical placebo at week 12 (primary and secondary endpoints; Magnolo N et al. EADV 2020 [poster]). PASI75 and IGA0/1 increased through week 16 (LD: 92.9%/88.1%; HD: 90.5%/85.7%) and week 24 (LD: 95.2%/88.1%; HD: 95.2%/92.9%) and were sustained through week 52 (LD: 88.1%/85.7%; HD: 90.5%/83.3%), respectively. PASI90/100 responses at week 52 were 76.2%/52.4% (LD) and 83.3%/69.0% (HD). Absolute PASI change (mean [SD]) at week 52 from baseline was –17.3 (4.96) and –18.2 (6.96), a percentage change of –94.3% and –94.5% for LD and HD, respectively. Greater than 70% of evaluable patients achieved CDLQI0/1 at week 52 (LD: 70.7%; HD: 70.3%). The safety profile was consistent with that of adults with no new safety signals.

CONCLUSION: The efficacy of secukinumab continued to increase beyond week 12 (primary endpoint) and was sustained through week 52 in pediatric patients with moderate to severe plaque psoriasis.

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N. Magnolo has been a principal investigator in studies performed by AbbVie, Asana, Boehringer Ingelheim, Celgene, Dr. Reddy's Laboratories, Eli Lilly, Galderma, Genentech, Incyte, Janssen, Kyowa Kirin, LEO Pharma, Novartis, MSD, Pfizer, Regeneron, Sun Pharma, and UCB and is a consultant or speaker for AbbVie, LEO Pharma, and UCB. **K. Kingo** has received fees for serving as an investigator in studies sponsored by Celgene, Merck, Mitsubishi Tanabe Pharma, Novartis, Regeneron Pharmaceuticals, and Sandoz. **V. Laquer** is an investigator for AbbVie, Amgen, Biofrontera, Cara Therapeutics, Celgene, ChemoCentryx, Dermavant, Dermira, Eli Lilly, Galderma, Incyte, Kiniksa, LEO Pharma, Novartis, Pfizer, Regeneron, Sun Pharma, and UCB. **J. Browning** is an investigator for Amryt, Arcutis, Brickell Biotech, Celgene, ChemoCentryx, Eli Lilly, Galderma, Incyte, Lenus, LEO Pharma, Mayne, Novartis, Pfizer, Regeneron, and Valeant; a consultant for Dermavant and LEO Pharma; and a speaker for Dermira, Regeneron, and Pfizer. **A. Reich** is a principal investigator or subinvestigator in clinical trials sponsored by AbbVie, Drug Delivery Solutions Ltd, Galderma, Genentech, Janssen, Kymab Ltd, LEO Pharma, Menlo Therapeutics, MetrioPharm AG, MSD, Novartis, Pfizer, UCB and Trevi Therapeutics and a consultant or speaker for AbbVie, Bioderma, Celgene, Chema-Elektromet, Eli Lilly, Galderma, Janssen, LEO Pharma, Medac, Menlo Therapeutics, Novartis, Pierre Fabre, Sandoz, and Trevi Therapeutics. **JC Szepietowski** is an AB member of Abbvie, Leo Pharma, Novartis, Pierre-Fabre, Menlo Theraputics, Sienna Biopharmaceuticans, Trevi, principal investigator for Abbvie, Novartis, Menlo Thepapeutics, Trevi, Janssen, Merck, Regeneron, Amgen, Boehringer Ingelheim, Galapagos, Galderma, InflaRX, Kymab Ltd., Pfizer, UCB, Helm, Incyte and a speaker for Abbvie, Novartis, Janssen, Eli Lilly, Sanofi-Genzyme, Sunfarm, Berlin-Chemie Mennarini. **D. Keefe** is an employee of Novartis Pharmaceuticals Corporation. **R. Mazu**r, **P. Forrer**, and **M. Patekar** are employees of Novartis Pharma AG.

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ABSTRACT 26

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

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BACKGROUND: Tapinarof cream 1% once daily (QD) demonstrated significant efficacy versus vehicle and was well tolerated in adults with mild to severe plaque psoriasis in two identical 12-week, pivotal phase 3 trials (PSOARING 1 and 2) (Lebwohl M et al. SKIN The Journal of Cutaneous Medicine. 2020;4(6):s75).. Furthermore, in a 12-week phase 2b trial, efficacy was maintained 4 weeks post treatment, warranting investigation of a potential remittive effect (Robbins K et al. J Am Acad Dermatol. 2019 Mar;80(3):714-21).

OBJECTIVES: Interim analysis of a long-term, open-label, multicenter extension trial assessing safety, efficacy, durability of response, and duration of remittive effect of tapinarof cream 1% QD in adults with plaque psoriasis (PSOARING 3) (Strober B et al. Innovations in Dermatology. 2021).

METHODS: Eligible patients completing the 12-week pivotal trials could enroll for 40 weeks of tapinarof treatment with 4 weeks' follow-up in PSOARING 3. Patients entering with Physician Global Assessment (PGA) score of 1 or greater received tapinarof until complete disease clearance (PGA = 0). Patients entering with or achieving PGA = 0 discontinued treatment and were monitored for duration of remittive effect (maintenance of PGA = 0 or 1, off-therapy). Patients with disease worsening (PGA of 2 or greater) were re-treated with tapinarof until PGA = 0. Patients were followed for durability of response on therapy (absence of tachyphylaxis), adverse events (AEs), and local tolerability. Efficacy endpoints included median time from PGA = 0 to first worsening, and proportion of patients with PGA = 0 or 1 after treatment.

RESULTS: All enrolled patients (n = 763) were included in the analysis. Most common AEs were folliculitis, contact dermatitis, and upper respiratory tract infection, similar to the pivotal trials. Incidence/severity of folliculitis and contact dermatitis remained stable with long-term use and led to a low study discontinuation rate (1.2% and 1.4%, respectively). Investigators assessed 90% or more of patients as having no irritation and 8%-–93% of patients reported "none/slight" or "mild" burning/stinging and itching over 40 weeks of treatment. Complete disease clearance was

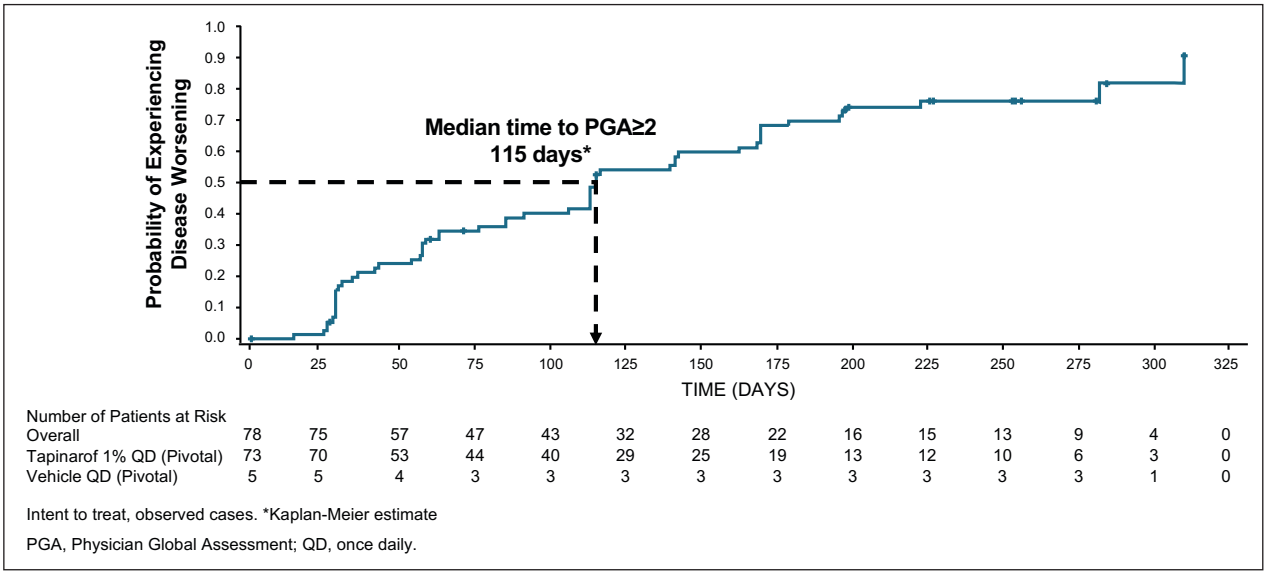

FIGURE 1. Approximately 4-month duration of remittive effect among patients entering with a PGA of 0 (clear) and maintaining a PGA of 0 or 1 (almost lcear) while off therapy

achieved by 39.2% of patients (n = 299). Patients entering with PGA = 0 (n = 78) had a median duration of remittive effect of 115 days (**Figure 1**). Response measures improved beyond the 12-week pivotal trials, with 57.3% of patients entering with PGA of 2 or more achieving a PGA = 0 or 1 during the study. Durability of response (on-therapy absence of tachyphylaxis) was up to 52 weeks.

CONCLUSIONS: Tapinarof cream 1% QD was well tolerated, with a consistent safety profile with long-term use. A high rate of complete disease clearance, an approximate 4-month remittive effect off therapy, lack of tachyphylaxis, and good tolerability – even in sensitive areas – are key attributes differentiating tapinarof from other topical psoriasis therapies.

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ABSTRACT 27

Tapinarof Cream 1% Once Daily for Plaque Psoriasis: Patient-Reported Outcomes From Two Pivotal Phase 3 Trials

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BACKGROUND: Tapinarof is a novel therapeutic aryl hydrocarbon receptor modulating agent (TAMA) in development for the treatment of psoriasis and atopic dermatitis. Tapinarof cream 1% once daily (QD) demonstrated statistically significant efficacy vs. vehicle QD at 12 weeks and was well tolerated in adults with mild to severe plaque psoriasis in two identical phase 3 trials (PSOARING 1 and PSOARING 2) (Lebwohl M et al. SKIN The Journal of Cutaneous Medicine. 2020;4(6):s75).

OBJECTIVES: To present patient-reported efficacy and tolerability outcomes from the pivotal phase 3 trials, PSOARING 1 and PSOARING 2.

METHODS: Two identical, randomized, double-blind, vehicle-controlled trials assessed the efficacy and safety of tapinarof cream 1% QD in patients with mild to severe plaque psoriasis. Adults with baseline Physician Global Assessment score of 2 or greater and body surface area involvement 3%–20% were randomized 2:1 to tapinarof cream 1% or vehicle QD for 12 weeks. Patient-reported outcomes included the proportion of patients achieving 4-point or greater improvement of Peak Pruritus Numeric Rating Scale (PP-NRS) score and the mean change from baseline to week 12 in PP-NRS, Dermatology Life Quality Index (DLQI), and Psoriasis Symptom Diary (PSD) scores. Local tolerability was evaluated by physicians and patients, with scores representing an average across all application sites.

RESULTS: Mean baseline scores for tapinarof vs. vehicle in PSOARING 1 and 2, respectively, were: PP-NRS, 5.7 vs.

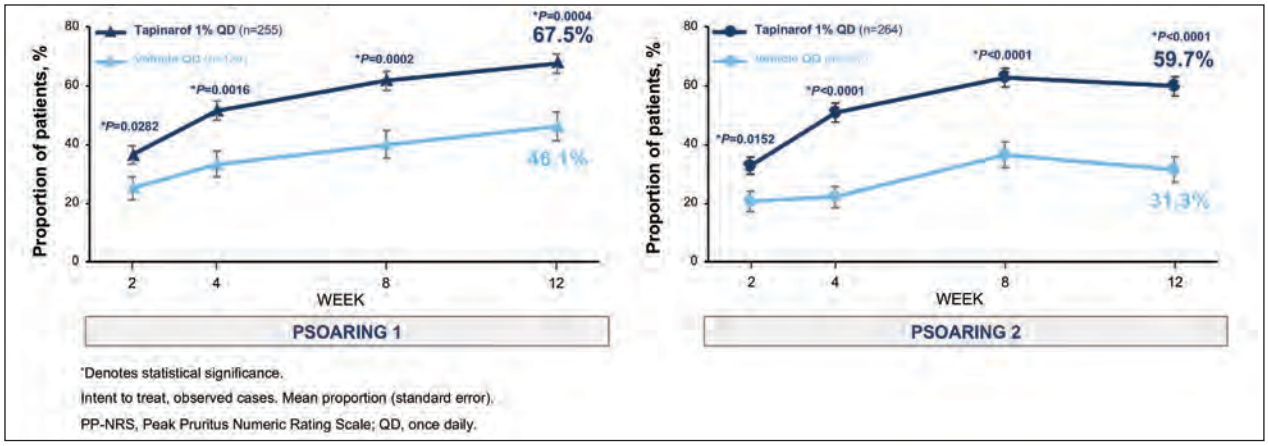

FIGURE 1. Figure 1. ≥4-point improvement in PP-NRS score from baseline at weeks 2, 4, 8, and 12

6.1 and 5.9 vs. 6.1; DLQI, 8.2 vs. 8.7 and 8.5 vs. 8.6; PSD, 73.1 vs. 74.9 and 74.0 vs. 76.0. The proportion of patients achieving 4-point or greater improvement in PP-NRS was significantly higher vs. vehicle from week 2 onward, reaching 67.5% vs. 46.1% (P = 0.0004) and 59.7% vs. 31.3% (both P less than 0.0001) at week 12 in PSOARING 1 and 2, respectively (**Figure 1**). Mean PP-NRS scores significantly improved with tapinarof vs. vehicle from week 2 onward, reaching –3.9 vs. –2.9 (P = 0.0002) and –3.0 vs. –1.4 (P less than 0.0001) at week 12 in PSOARING 1 and 2, respectively. Significant improvements in mean DLQI were achieved by week 4 with minimal clinically important difference (–4.0) at week 12 vs. vehicle: –5.0 vs. –3.0 and –4.7 vs. –1.6 (both P less than 0.0001) in PSOARING 1 and 2, respectively. Significant improvements were reported with tapinarof vs. vehicle from week 2 onward on the PSD, reaching –51.9 vs. –34.6 and –43.5 vs –17.1 (both P less than 0.0001) by week 12 in PSOARING 1 and 2, respectively. Tapinarof was well tolerated regardless of anatomic location treated, as reported subjectively by patients and measured objectively by investigators.

CONCLUSIONS: Tapinarof cream 1% QD demonstrated rapid, statistically significant, and clinically meaningful improvements in patient-reported outcomes and was well tolerated, which is consistent with previously reported significant clinical efficacy and good tolerability (Lebwohl M, et al. SKIN The Journal of Cutaneous Medicine. 2020;4(6):s75).

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ABSTRACT 28

Tapinarof Cream 1% Once Daily for the Treatment of Moderate to Severe Atopic Dermatitis in Children and Adults: The Pivotal Phase 3 ADORING Clinical Program

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BACKGROUND: There is a need for efficacious nonsteroidal topical therapies for atopic dermatitis (AD) without restrictions on duration, extent of use, or application site. Tapinarof is a novel therapeutic aryl hydrocarbon receptor modulating agent (TAMA) in development for the treatment of psoriasis and AD. In a 12-week phase 2b trial, tapinarof cream 1% once daily (QD) demonstrated significant efficacy versus vehicle and was well tolerated in adolescents and adult patients with moderate to severe AD. Furthermore, efficacy was generally maintained through the last study visit, 4 weeks after completing treatment, warranting further investigation of a potential remittive effect.

OBJECTIVES: To assess the efficacy and safety of tapinarof cream 1% QD in children and adults with moderate to severe AD in two pivotal phase 3 trials (ADORING 1 and 2) and a long-term extension phase 3 trial (ADORING 3).

METHODS: ADORING 1 and 2 are two identical, phase 3, multicenter, double-blind, vehicle-controlled, randomized trials aiming to recruit 800 patients overall (**Figure 1**). Male or female patients aged 2 or more years, with a clinical diagnosis of AD, a validated Investigator Global Assessment for Atopic Dermatitis™ (vIGA-AD) score of 3 or above, and body surface area (BSA) involvement of 5%-35% (excluding the scalp) are randomized 2:1 to

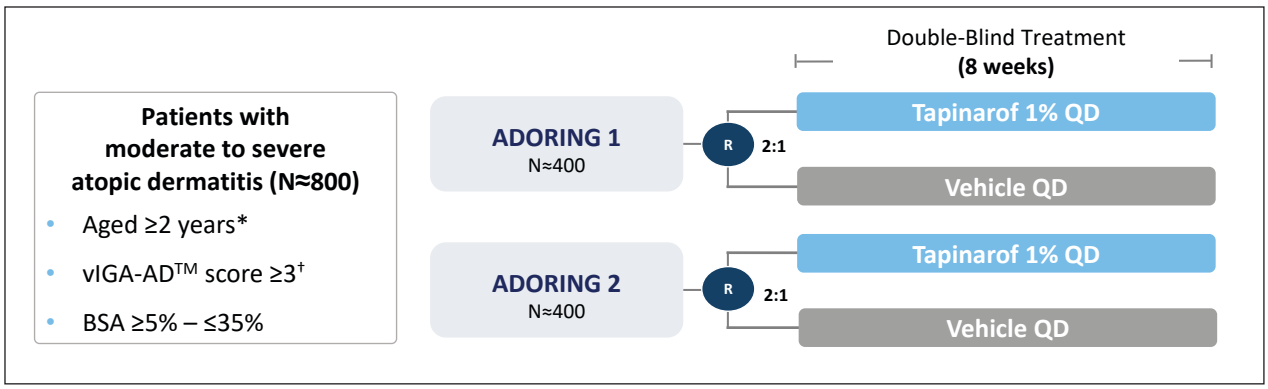

FIGURE 1. Two identically designed, Phase 3, multicenter, double-blind, vehicle-controlled randomized trials enrolling patients aged ≥2 years old with vIGA AD score ≥3 (moderate to severe) and ≥5–≤35% %BSA affected, randomized to tapinarof cream 1% QD or vehicle QD for 8 weeks.

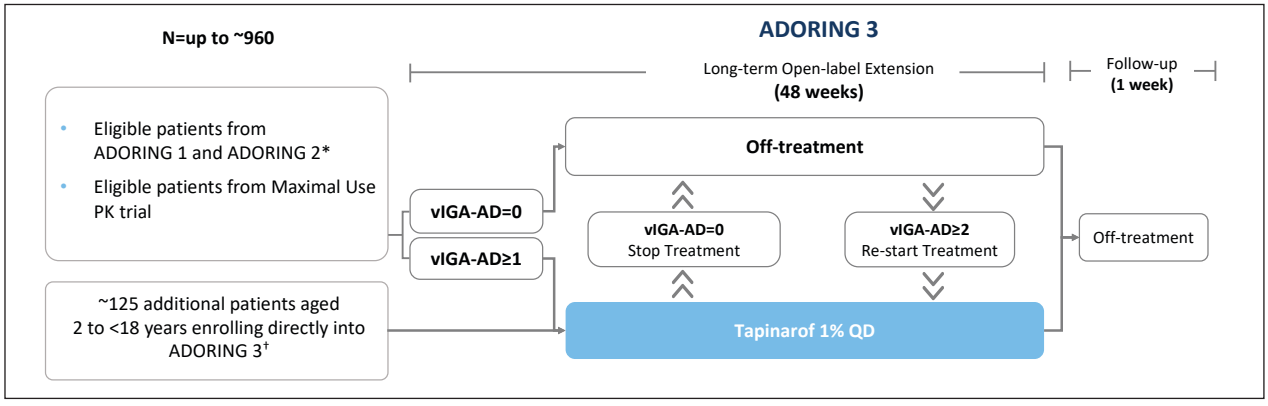

FIGURE 2. A long-term, open-label, multicenter extension trial to evaluate the safety and efficacy of tapinarof 1% QD in eligible patients completing ADORING 1, ADORING 2, or a Maximal Use Pharmacokinetics trial. In addition to ~125 patients (aged 2 to <18 years) screened for ADORING 1 or 2 but not meeting vIGA-AD and/or BSA requirements.

tapinarof cream 1% or vehicle cream QD for 8 weeks. The primary efficacy endpoint of ADORING 1 and 2 is the proportion of patients with a vIGA-AD score of clear (0) or almost clear (1) and a 2-grade or greater improvement from baseline to week 8. Additional efficacy endpoints include assessments on Eczema Area Severity Index, %BSA affected, and Peak Pruritus-Numeric Rating Scale scores from baseline to week 8.

Patients who complete ADORING 1 or 2 will have the option to enroll in the 48-week, open-label, long-term extension trial, ADORING 3 (**Figure 2**). In ADORING 3, patients entering with vIGA-AD score of 1 or greater receive tapinarof until complete disease clearance (vIGA-AD = 0). Patients entering with, or achieving, vIGA-AD = 0 discontinue treatment and are monitored for duration of remittive effect: off-therapy maintenance of vIGA-AD score of clear (0) or almost clear (1). Patients with disease worsening (vIGA-AD of 2 or greater) are re-treated with tapinarof until vIGA-AD = 0. Across all trials, safety assessments include adverse events and patient- and investigator-rated local tolerability.

CONCLUSIONS: This comprehensive phase 3 clinical trial program assesses the efficacy, safety, tolerability, durability, and potential remittive effect of tapinarof cream 1% QD for the treatment of children and adults with moderate to severe AD in more than 800 patients down to 2 years of age.

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ABSTRACT 29

Tazarotene 0.045% Lotion for Acne: Formulation, Application Characteristics, and Clinical Efficacy and Safety

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

BACKGROUND: Tazarotene (TAZ) 0.045% lotion is the most recently approved retinoid for the treatment of acne. It was developed using novel polymeric emulsion technology to provide uniform and rapid distribution of the active ingredient and hydrating excipients at the skin surface and efficiently deliver TAZ into the skin. Tolerability may be improved by the vehicle design and the homogenous nature of the delivery as well as the lower dose of TAZ used compared with all other TAZ formulations.

OBJECTIVES: Review the formulation, efficacy, safety, application characteristics, and subject perception of TAZ 0.045% lotion across multiple studies.

METHODS: The vehicle lotion for TAZ 0.045% was assessed for skin hydration and epidermal barrier maintenance (via in vivo corneometry and transepidermal water loss; n = 30). Subject perception of the vehicle lotion was evaluated via questionnaire (n = 15). Skin coverage with TAZ 0.045% lotion was compared with trifarotene 0.005% cream in a double-blind split-body study (n = 30). In vivo skin deposition of TAZ was assessed at 6 hours post application of TAZ 0.045% lotion and TAZ 0.1% cream (n = 10); tape strips were used to serially remove skin layers from stratum corneum and epidermis and analyzed for TAZ. In a 12-week phase 2 clinical trial, participants (12 years or older; n = 210) were randomized (2:2:1:1) to TAZ 0.045% lotion, TAZ 0.1% cream, lotion vehicle, or cream vehicle. Lesion count reductions, treatment success, and adverse events (AEs) were assessed.

RESULTS: The lotion vehicle for TAZ 0.045% significantly improved skin moisture content and barrier function versus untreated skin as early as 15 minutes post application. These results are supported by subjects' favorable responses to the vehicle, which was perceived as moisturizing, hydrating, nongreasy, and lightweight. TAZ 0.045% lotion was highly spreadable, covering on average almost 30% more skin than the same amount of trifarotene cream. After application of TAZ 0.045% lotion and 0.1% cream, TAZ concentration was highest at the skin surface for both formulations, though the concentration was about twice as high for cream than lotion at both superficial and deeper skin layers. These findings are consistent with clinical trial results, in which TAZ 0.045% lotion had comparable efficacy but approximately half the rate of treatment-related AEs than 0.1% cream.

CONCLUSIONS: TAZ 0.045% lotion utilizes innovative polymeric emulsion technology to enhance hydration, moisturization, and skin barrier function. There is superior tolerability of TAZ 0.045% lotion versus TAZ 0.1% cream, with similar clinical efficacy. This easy-to-apply lotion appears to have enhanced skin coverage compared with trifarotene cream. Overall, this novel TAZ lotion formulation is an effective and well-tolerated option for the treatment of acne, with sensory and aesthetic properties preferred by patients.

Funding: Ortho Dermatologics

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ABSTRACT 30

The Gut-Skin Connection: Using Gut Microbiome Tests to Treat Acne

Julie Greenberg, ND, MBA

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BACKGROUND: Acne is a chronic inflammatory skin disease that affects both adolescents and adults. While functional medicine acknowledges that there is a "gut-skin connection," few studies have assessed the microbiome of acne patients. After seeing hundreds of functional medicine gut microbiome tests, Dr. Greenberg felt that her acne patients had a pattern of higher levels of *Helicobacter pylori*, *Candida* and protozoa than her other dermatological patients and has achieved high success rates of clearing acne by treating these conditions.

OBJECTIVE: The objective was to analyze the microbiome of acne patients using functional medicine tests (stool tests and organic acid tests (OAT)) to reveal if there are specific patterns of dysbiosis in acne, including but not limited to *H. pylori*, *Candida* and protozoa.

METHODS:

Patients: Thirty-six of the most recent patients with an ICD10 diagnosis code of "acne vulgaris" or "acne unspecified" and who had performed functional medicine tests (stool test + organic acid test (OAT)) were selected from The Center for Integrative Dermatology patient database.

Design study:

- Stool tests: 36 GI MAP stool tests by Diagnostic Solutions Laboratory (DSL), plus one Doctor's Data (DD) GI360 test were used in the evaluation.
- Organic Acid Tests (OATs): 34 OATs (urine) from Great Plains Labs (GPL) and 1 Genova Diagnostics Metabolic Panel (urine) were used in the evaluation.

- Tests
- 33 patients had 1 GI MAP + 1 GPL OAT
- 1 patient had 1 GI MAP + 1 Genova Metabolic panel
- 1 patient had 1 GI MAP, 1 DD GI360 + 1 GLP OAT
- 1 patient had 1 GI MAP

ASSESSMENTS: Stool tests were used to assess bacterial (ex: *H. pylori*), parasitic (ex: protozoa), and fungal microbiome (ex: *Candida*). OATs were used to assess fungal microbiome (ex: *Candida*). Data was compared to overall data from Biocanic and Diagnostic Solutions Laboratory.

RESEARCH QUESTIONS:

Are there higher levels of *H. pylori*, *Candida* and protozoa in acne patients?

- Are there additional patterns of dysbiosis that can be identified in acne patients?

ANALYSIS:

- We present combined results for the 36 patients' stool tests and OATs
- Analysis was performed by hand by Dr. Greenberg as well as by Biocanic software. Biocanic is a HIPAA compliant Software as a Service (SaaS) integrative health and medicine platform for practitioners. Biocanic automatically processes and extracts the data from functional lab tests and aggregates the data into a cloud storage system. All lab data has been de-identified in accordance with HIPAA regulations and analyzed using Microsoft Excel. The following criteria were used:
- ***H pylori***
  - DSL: either present [any finding that's not "dl"] or high [any finding that's >1.0e3]
- **Parasites**
  - DSL: any finding that's not "<dl" for protozoa: *Giardia, Entamoeba histolytica, Cryptosporidium, Blastocystis homini, Chilomastix mesnili, Cyclospora spp., Dientamoeba fragilis, Endolimax nana, Entamoeba coli, Pentatrichomonas hominis*
  - DD: Any positive finding for Cryptosporidium (*C. parvum and C. hominis*), *Entamoeba histolytica, Giardia duodenalis*
- ***Candida***
  - DSL: Present [any finding that's not "<dl" for *Candida albicans* or *Candida spp*]; or high [any finding that's >5.0e2 for *Candida albicans* or >5.0e3 *Candida spp*]
  - GPL: Present Females Arabinose >15; Males Arabinose >10. High Females Arabinose >29; Males Arabinose >20

COMPARISON DATA:

- The 36 acne patients test results were compared against Diagnostic Solutions Laboratory datasets, Biocanic datasets and published research.
- Biocanic: a total of 2,940 GI-Map (Diagnostic Solutions Laboratory) were analyzed by Biocanic for comparison data for this poster.
- DSL: a total of 18,390 ranging from Jan-March of 2021 were analyzed by DSL for comparison data for this poster.
- Published Research: PubMed was searched to find healthy control data for comparison:
  - *H. pylori* Published Research (1): Hooi, James KY, et al. "Global prevalence of Helicobacter pylori infection: systematic review and meta analysis." Gastroenterology 153.2 (2017): 420-429.
  - *Candida* Published Research (2): Standaert-Vitse, Annie, et al. "Candida albicans colonization and ASCA in familial Crohn's disease." American Journal of Gastroenterology 104.7 (2009): 1745-1753.

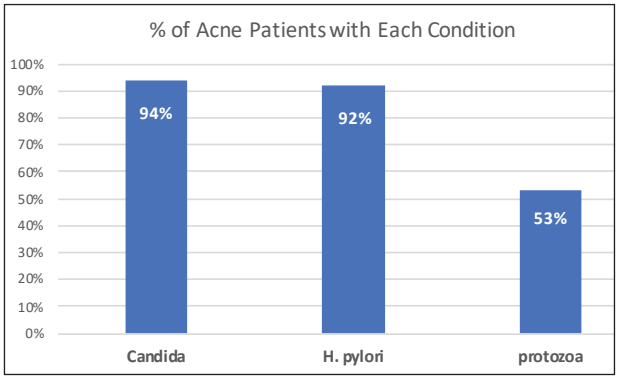
RESULTS:

Patient Demographics

- Total of 36 patients: 28 females, 8 males
- Ages 13-40; Mean=25 years old; Median=25 years old

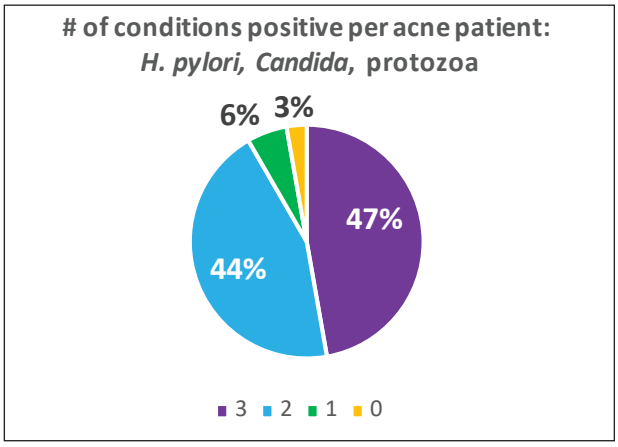
Gut Microbiome Results

- *Candida* present in (34/36) 94%
- *H. pylori* present (33/36) 92%
- Protozoa present in (19/36) 53% (and 95% of those had *H. pylori*)

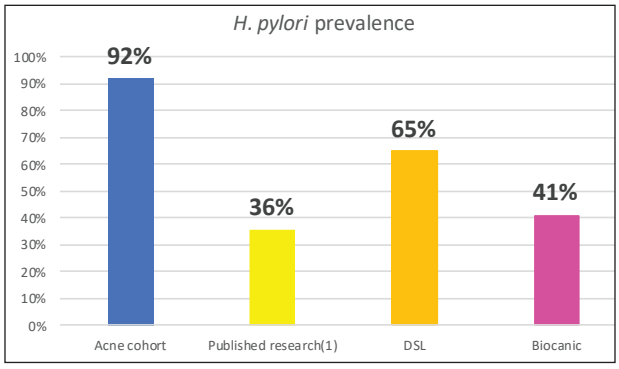


***Candida, H. pylori* and protozoa in acne patients:**

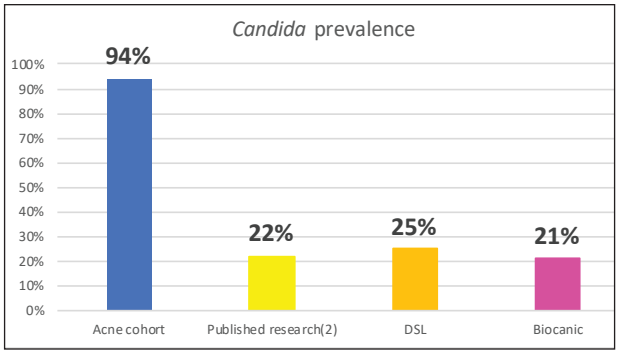
- 47% (17/36) have all 3 conditions
- 44% (16/36) have 2/3 conditions
- 6% (2/36) have 1/3 conditions
- 3% (1/36) have 0/3 conditions



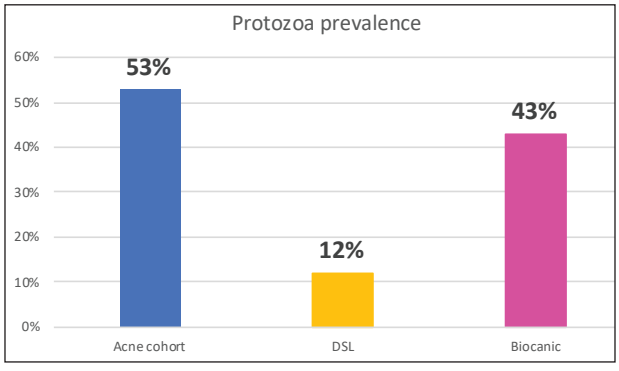
Comparison of Acne Cohort to other populations:
H. Pylori



Candida



Protozoa



LIMITATIONS:

It would be helpful in the future to:

- compare against a non-acne age-matched cohort from the same geographic regions
- show how the gut microbiome measures shifted after treatment

CONCLUSION:

- The gut microbiomes of acne patients show higher levels of *H. pylori, Candida* and protozoa than the other general cohorts analyzed.
- It is possible to use functional medicine tests in acne patients to assess the gut microbiome.
- These functional medicine tests are being used in clinical practice at the Center for Integrative Dermatology to successfully treat the root cause of acne by addressing these gut dysbiosis issues.
- Further studies are needed to compare acne to non-acne patients to evaluate the potential of using gut microbiome testing as a diagnostic approach treating patients with acne.

Acne Case Studies: before and after photos (video if available in poster software, and/or pictures)

SUMMARY:

Acne is a chronic inflammatory skin disease that affects both adolescents and adults. While functional medicine acknowledges that there is a "gut-skin connection", few studies have assessed the microbiome of acne patients. The objective was to analyze the microbiome of acne patients using functional medicine tests (stool and organic acid tests) to reveal if there are specific patterns of dysbiosis in acne, including but not limited to *H. pylori, Candida* and protozoa. Thirty six of the most recent patients with an ICD10 diagnosis code of "acne vulgaris" or "acne unspecified" and who had performed functional medicine tests (stool test + organic acid test (OAT)) were selected from The Center for Integrative Dermatology patient database. Results were that 94% of patients had *Candida* elevated or high, 92% had *H. pylori* present and 53% had protozoa present. 47% of patients had all three conditions and 44% had at least two conditions. This research demonstrates that the gut microbiome of acne patients has higher levels of *H. pylori, Candida* and protozoa than the general population.

ABSTRACT 31

The Nutricosmeceutical: Topical 4',7-Isoflavandiol (Equol) Plus Other Active Ingredients Improves Skin Parameters in Adult and Postmenopausal Women More than Equol Treatment Alone

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BACKGROUND: Equol is a polyphenolic/isoflavonoid molecule derived from intestinal metabolism, dairy, eggs, and dietary plant sources (Mayo B et al. Nutrients. 2019 Sep 16;11(9):2231). It has the unique characteristic to bind specifically 5 alpha-dihydrotestosterone (5 alpha-DHT) by sequestering 5 alpha-DHT from the androgen receptor, thus decreasing androgen hormone action to improve prostate (Lephart OJ. Urology. 2013) and skin health (Oyama A et al. Menopause. 2012 Feb;19(2):202-10; Magnet U et al. Internat J Cosmet Sci. 2017 Oct;39(5):535-42; Lephart ED and Naftolin F. Dermatol Ther. 2021;11:53-69). From a previous topical clinical study examining Equol skin parameters, women reported improvement in their overall skin health. Objective: This single-center, randomized clinical study examined the effects of topically applied Equol plus the natural ingredients (grape-seed extract, vitamin C, and hyaluronic acid) formulation, twice a day (morning and evening) for 12 weeks in 42 women (40-70 years old) to determine whether the combination treatment improved skin health over the Equol treatment alone.

METHODS: All subjects gave informed consent, and there were no adverse events reported. Fitzpatrick Skin Types ranged from Type I to III. Glogau photoaging I and III (wrinkling) was mild to moderate. To determine topical compliance, each subject was asked to keep a pocket dosing journal and bring in the remaining product/bottle at each visit. The primary efficacy was measured by self-assessment questionnaire covering eight skin parameters at baseline and 2, 4, 8, and 12 weeks. Results: The female subjects reported the tolerance of the treatment was excellent. The combination Equol plus natural ingredients improved the eight skin parameters over the treatment interval (compared with baseline or Equol alone values). Compliance was 92% for subjects (recommended dose per day), with 8% underdosed.

CONCLUSIONS: Topically applied Equol plus natural ingredients provided well-tolerated and valuable therapy for skin health in women. This nutricosmeceutical formulation can be used alone or with other current topical dermal personal care products. The efficacy of Equol plus the other natural ingredients observed in this study is because of its multiple positive biological actions (Lephart and Naftolin 2021) not present in current nutraceutical products. Finally, the Equol plus the other natural active ingredients represents a synergistic mechanism by which this novel nutricosmeceutical formulation yielded significantly greater improvement of the skin parameters examined in this study compared with Equol alone.

TABLE. Self-Assessment Questionnaire Analysis – Facial Features

Efficacy
Percentage of subjects who perceived improvement with the Equol plus the Natural Ingredients (ENI) over the baseline (parameters 1-8) (data not shown) and/or compared to the Equol Treatment Alone (ETA) at 12 weeks.

Week 12	Equol Plus Natural Ingredients *and*	Increase over (ETA)
1. Skin Firmness	91%*	18%
2. Smoothness	100%*	61%
3. Even Skin Tone	100%*	43%
4. Frown Lines/ Wrinkles	89%*	24%
5. Radiance/ Brightness	100%*	37%
6. Pore Size	93%*	82%
7. Spots/Discoloration	84%*	53%
8. Hydration	95%*	34%
Number of Subjects	42	59
Mean Age (years + SEM)	57.3 + 7.3	56.1 + 7.8
Age Range (years)	40-70	40-70
White (number subjects)	23	30
Chinese (number subjects)	4	8
Japanese (number subjects)	15	21

Amenorrheic for at least 2 years in the ENI group was 78% versus the ETA group that was 76%
* = Significantly greater compared with Equol Treatment Alone (ETA)

ABSTRACT 32

Virtual Simulation-Based CME Improves Treating to Target in Psoriasis

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INTRODUCTION: This study examined whether continuing medical education (CME) with online virtual patient simulation (VPS) experiences improved dermatologists' performance in the management of psoriasis.

METHODS: A CME case-based intervention in an online VPS platform allowed learners to interact with patients via video, order lab tests, make diagnoses, and order treatments supported by an extensive database of diagnostic and treatment possibilities matching the scope and depth of actual practice. Clinical decisions were analyzed, and learners received clinical guidance (CG) based on current evidence and expert recommendations. Learners were able to modify their decisions post-CG. Pre- (baseline) to post-CG decisions were compared using a McNemar's test. The intervention launched on May 27, 2020, and data were collected through Aug. 26, 2020.

RESULTS: Dermatologists had significant improvements in the diagnosis and treatment of patients with psoriasis as a result of participating in the intervention (pre- vs. post-CG, case 1, and pre- vs. post-CG, case 2, P less than .01), including the following:

- Evaluation of psoriasis severity by objective and subjective measures (21% vs. 44% and 31% vs. 45%)
- Assessment of treatment efficacy and potential treatment modification (45% vs. 57% and 68% vs. 85%)
- Providing patient education and counseling to facilitate shared decision-making (76% vs. 84% and 66% vs. 81%)
- Prescribing guideline-recommended biologic treatments ixekizumab and secukinumab (7% vs. 17% and 14% vs. 32%)

DISCUSSION: Dermatologists who participated in an online VPS educational module significantly improved their evaluation, diagnosis, and treatment of patients with psoriasis. Despite these improvements, gaps remain in diagnosing moderate to severe psoriasis and in selecting treatments that are appropriate for the severity of psoriasis.

Reference:
Soung J and Weinberg J. 2020 May 17. https://www.medscape.org/viewarticle/924069.

Disclosure:
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ABSTRACT 33

What is Everyone Learning About Hidradenitis Suppurativa? A Cross-Sectional Analysis of Popular Content on TikTok

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BACKGROUND
TikTok is a social media platform used by millions of people worldwide, traditionally for entertainment purposes. TikTok's widespread reach has the potential to improve awareness and understanding of health conditions for conditions that classically have a delayed diagnosis, such as hidradenitis suppurativa (HS).

OBJECTIVE
The purpose of this study was to analyze TikTok's HS popular content and identify areas to improve patient outcomes.

METHOD
We searched TikTok for videos tagged with #hidradenitis-suppurativa on April 1, 2021, with the aim of analyzing the top 100 videos. Video characteristics were collected and the DISCERN tool was used to analyze the content quality. The Pearson correlation coefficient was then calculated to determine inter-rater reliability.

RESULTS
We found that 84 videos (84%) were uploaded by nonphysicians with a mean DISCERN score of 1.63, whereas 13 videos (13%) were uploaded by physicians with a mean DISCERN score of 2.65. Although DISCERN scores were higher amongst physicians compared with nonphysicians, physicians scored low on referencing sources and describing the risks and benefits of treatments.

CONCLUSION
Whereas physicians produced content with higher DISCERN scores, there is a need for improved content quality and increased physician representation on TikTok. Physicians can improve their content quality by providing references, discussing the risks and benefits of treatments, and advising patients to consult their local physicians.

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