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INNOVATIONS IN DERMATOLOGY

FALL ABSTRACT COMPENDIUM

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ACNE AND ROSACEA

Abstract: AR-01

Efficacy and Safety of 1% Clascoterone Cream Through 12 Weeks in Patients ≥ 12 years of Age with Facial Acne Vulgaris: Pooled Data Analyses of Two Phase 3 Randomized Clinical Trials

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BACKGROUND: Two identical, vehicle-controlled, double-blind, phase 3 studies (CB-03-01/25/CB-03-01/26) were conducted to evaluate efficacy and safety of 1% clascoterone cream in patients with moderate to severe facial acne vulgaris (grade 3 or 4 on the Investigator's Global Assessment [IGA] scale) after 12 weeks (W) of treatment.
OBJECTIVES: We present the pooled data analysis from these studies in the subgroup of patients ≥ 12 years of age.
METHODS: Patients were randomized 1:1 to treatment of the whole face twice daily for 12W with clascoterone or vehicle. The primary efficacy outcomes were the proportion of patients achieving "success" (IGA score of "clear"/"almost clear" [0/1] with ≥ 2-point reduction in baseline IGA score) and absolute change from baseline (CFB) in noninflammatory lesion counts (NILC) and inflammatory lesion counts (ILC) at W12. Safety analyses included assessments of local skin reactions (LSR) through W12.
RESULTS: Overall, 709 patients received clascoterone and 712 received vehicle. Baseline characteristics were balanced between treatment arms; among patients treated with clascoterone and vehicle, 63.9% and 60.4% were female, and 91.0% and 90.3% were white, with mean ± standard deviation age 19.8 ± 6.1 and 19.5 ± 6.1 years, respectively. At W12, 19.9% of clascoterone-treated patients achieved treatment success based on IGA vs 7.7% of vehicle-treated patients ($P < .0001$). The mean absolute CFB in NILCs was -20.8 vs -11.9 ($P < .0001$) and the mean absolute CFB in ILCs was -19.7 vs -14.0 ($P < .0001$) in patients treated with clascoterone vs vehicle. The frequencies of each LSR were low and similar between treatment groups; at W12, the proportion of patients with LSRs of minimal to mild severity ranged from 0.3% (striae rubrae) to 12.9% (erythema). All LSRs were considered moderate to severe in < 3% of patients.
CONCLUSIONS: Clascoterone is efficacious based on IGA and lesion counts and has a favorable safety profile in the treatment of facial acne vulgaris in patients ≥ 12 years of age, with low rates of LSRs.
DISCLOSURES: Studies were funded by Cassiopea S.p.A. and writing support was provided by Sun Pharmaceutical Industries, Inc.

Abstract: AR-02

Efficacy and Safety of a Fixed-Dose Clindamycin 1.2%, Benzoyl Peroxide 3.1%, and Adapalene 0.15% Gel for Moderate to Severe Acne: Randomized Phase 2 and Phase 3 Studies of the First Triple-Combination Drug

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BACKGROUND: A three-pronged approach to acne treatment—combining an antibiotic, an antibacterial, and a retinoid—may provide greater efficacy and tolerability than single/double treatments while potentially reducing antibiotic resistance and increasing patient compliance. Clindamycin 1.2% / benzoyl peroxide (BPO) 3.1% / adapalene 0.15% (IDP-126) gel is the first triple-combination, fixed-dose topical acne product in development that addresses the major pathophysiological abnormalities in acne patients.
OBJECTIVES: Evaluate the efficacy, safety, and tolerability of clindamycin 1.2% / BPO 3.1% / adapalene 0.15% fixed-dose gel (IDP-126) in phase 2 and 3 studies of patients with moderate to severe acne.
METHODS: A phase 2 (N = 741; NCT03170388) and two phase 3 (N = 183; N = 180; NCT04214639; NCT04214652), double-blind, randomized, 12-week studies enrolled participants aged ≥ 9 years with moderate to severe acne. Participants were randomized to receive once-daily IDP-126 or vehicle; the phase 2 study included three additional randomization arms containing dyad gels: BPO/adapalene; clindamycin phosphate/BPO; and clindamycin phosphate/adapalene (data not shown). Endpoints included participants achieving ≥ 2-grade reduction from baseline in Evaluator's Global Severity Score and clear/almost clear skin (treatment success) and least-squares mean percent change from baseline in inflammatory and noninflammatory lesion counts. Treatment-emergent adverse events (TEAEs) were also assessed.
RESULTS: In all 3 studies at week 12, half of participants achieved treatment success with IDP-126 (phase 2: 52.5%; phase 3: 49.6%, 50.5%) vs less than one-fourth with vehicle (8.1%; 24.9%, 20.5%; $P < .01$, all). IDP-126 resulted in over 70% reduction in inflammatory and noninflammatory lesions at week 12, significantly greater than vehicle (range: inflammatory, 75.7% to 80.1% vs 50.4% to 59.6%; noninflammatory, 71.0% to 73.3% vs 45.8% to 49.0%; $P < .001$, all). Most TEAEs were of mild to moderate severity, and < 4% of IDP-126-treated participants discontinued study/treatment due to adverse events (AEs).
CONCLUSION: The innovative fixed-dose, triple-combination IDP-126 gel was efficacious and well tolerated in 3 clinical studies of children, adolescents, and adults with moderate to severe acne.
FUNDING: Ortho Dermatologics

Abstract: AR-03

Efficacy and Safety of Ruxolitinib Cream in Adolescent Patients With Vitiligo: Pooled Analysis of the 52-Week TRuE-V Phase 3 Studies

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BACKGROUND: Vitiligo is a chronic autoimmune disease that results in skin depigmentation and substantial psychosocial burden, particularly in adolescent patients *(Ezzedine K, et al. Am J Clin Dermatol 2021). A* cream formulation of the Janus kinase (JAK) 1/JAK2 inhibitor ruxolitinib demonstrated clinically meaningful repigmentation in 2 randomized, double-blind, vehicle-controlled, 52-week phase 3 studies in adults and adolescents with vitiligo (TRuE-V1 [NCT04052425]; TRuE-V2 [NCT04057573]).
OBJECTIVES: Pooled efficacy and safety data for adolescent patients aged 12 to 17 years from the TRuE-V studies are reported here.
METHODS: TRuE-V1 and TRuE-V2 were conducted in North America and Europe. Patients ≥ 12 years old diagnosed with nonsegmental vitiligo with depigmentation covering ≤ 10% total body surface area (BSA), including facial and total Vitiligo Area Scoring Index (F-VASI/T-VASI) scores ≥ 0.5 / ≥ 3, were eligible. Patients were randomized 2:1 to twice-daily 1.5% ruxolitinib cream or vehicle for 24 weeks, after which all patients could apply 1.5% ruxolitinib cream through week 52. Efficacy endpoints included proportions of patients achieving ≥ 75%, ≥ 50%, and ≥ 90% improvement from baseline in F-VASI (F-VASI75, F-VASI50, F-VASI90); proportion of patients achieving ≥ 50% improvement from baseline in T-VASI (T-VASI50); proportion of patients achieving a Vitiligo Noticeability Scale (VNS) rating of 4 or 5; and percentage change from baseline in facial BSA (F-BSA). Safety and tolerability were also assessed.
RESULTS: In total, 72 adolescent patients were included in this analysis (ruxolitinib cream, n = 55; vehicle, n = 17). At week 24, substantially more adolescents who applied ruxolitinib cream vs vehicle achieved F-VASI75 (32.1% vs 0%). Response rates at week 52 for patients applying

ruxolitinib cream from day 1 were as follows: F-VASI75, 48.0%; F-VASI50, 70.0%; F-VASI90, 24.0%; T-VASI50, 60.0%; VNS score of 4/5, 56.0%; and F-BSA mean percentage change from baseline, -41.9%. Efficacy at week 52 among crossover patients (after 28 weeks of ruxolitinib cream) was consistent with week 24 data in patients who applied ruxolitinib cream from day 1. Overall, efficacy results in adolescents were similar to those in the adult population. Among adolescents who applied ruxolitinib cream at any time during the study, treatment-related adverse events (TRAE) occurred in 12.9% of patients. Serious adverse events (SAE) occurred in 1.4% of patients; none were considered related to treatment.

CONCLUSIONS: In summary, adolescent patients with nonsegmental vitiligo achieved substantial repigmentation with ruxolitinib cream vs vehicle at week 24, with a higher proportion of patients responding at week 52. Ruxolitinib cream was well tolerated with no SAEs considered related to treatment.

DISCLOSURES: DR has received honoraria as a consultant for AbbVie, Abcuro, AltruBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert Pharmaceuticals, Dermavant Sciences, Dermira, Incyte Corporation, Janssen Pharmaceuticals, Kyowa Kirin, Eli Lilly and Company, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, Sanofi, Sun Pharma, UCB, and Viela Bio; has received research support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Dermira, Galderma, Incyte Corporation, Janssen Pharmaceuticals, Eli Lilly and Company, Merck & Co., Inc., Novartis, Pfizer Inc., and Regeneron Pharmaceuticals; and has served as a paid speaker for AbbVie, Amgen, Celgene, Janssen Pharmaceuticals, Eli Lilly and Company, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, and Sanofi.

JS has received grants and/or honoraria from AbbVie, Bristol Myers Squibb, Calypso Biotech, Eli Lilly and Company, Incyte Corporation, LEO Pharma, Novartis, Pfizer Inc., Pierre Fabre, Sanofi, Sun Pharma, and Viela Bio; and has patents on MMP9 inhibitors and uses thereof in the prevention or treatment of a depigmenting disorder and a three-dimensional model of depigmenting disorder.

PG has served as a consultant for Aclaris Therapeutics, Clarify Medical, DermaForce, Incyte Corporation, Procter & Gamble, and Versicolor Technologies; and as a principal investigator for Aclaris Therapeutics, Allergan/SkinMedica, Clinuvel Pharmaceuticals, Incyte Corporation, Johnson & Johnson, L'Oreal, Merz Pharma, Pfizer Inc., Thync Global, Inc., and VT Cosmetics.

SRD has received fees and/or honoraria as a consultant for Almirall, Avita Medical, Bristol Myers Squibb, Cassiopea SpA, Dermavant Sciences, Dermira, Ferndale Laboratories, Foamix Pharmaceuticals, Galderma Laboratories, LP, Incyte Corporation, MC2 Therapeutics, Ortho Dermatologics, Pfizer Inc., Scientis Pharma, Senté Labs, SkinCeuticals LLC, UCB, and Verrica Pharmaceuticals Inc.; has received stock options as a consultant for Gore Range Capital; has received honoraria as a speaker for Almirall and Ortho Dermatologics; has received grants/research funding as an investigator for AbbVie, AOBiome LLC, Atacama Therapeutics, Brickell Biotech, Dermavant Sciences, Incyte Corporation, Novan, and SkinMedica; has served as an advisory board member for the Foundation for Research & Education of Dermatology; is a stockholder of Gore Range Capital; and is a shareholder in PDP of Texas.

AGP has served as an investigator for Aclaris Therapeutics, Immune Tolerance Network, Incyte Corporation, and Pfizer Inc.; as a consultant for AbbVie, Arcutis, Avita Medical, Chromaderm, Immune Tolerance Network, Incyte Corporation, Pfizer Inc., Twi Pharmaceuticals, Inc., Viela Bio, and Villaris Therapeutics; and holds stock options for Tara Medical and Zerigo Health.

DK, MW, and KB are employees and shareholders of Incyte Corporation.

KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer Inc., Pierre Fabre, Sanofi, and Viela Bio.

REFERENCE

Ezzedine K, et al. Psychosocial effects of vitiligo: a systematic literature review. *Am J Clin Derm.* 2021;22(6):757-774.

Abstract: AR-04

Exploratory Quality of Life and Treatment Satisfaction in Two Phase 3 Studies of Ruxolitinib Cream in Vitiligo

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BACKGROUND: Ruxolitinib (Janus kinase [JAK] 1/JAK2 inhibitor) cream demonstrated clinically meaningful repigmentation and was well tolerated in two phase 3 studies in adolescents and adults with vitiligo (TRuE-V1/TRuE-V2).

OBJECTIVES: This analysis assessed quality of life (QoL) and treatment satisfaction in patients from TRuE-V1/TRuE-V2.

METHODS: Patients ≥ 12 years old with nonsegmental vitiligo (depigmentation ≤ 10% total body surface area) were randomized 2:1 to twicedaily 1.5% ruxolitinib cream or vehicle. After 24 weeks, all patients could apply ruxolitinib cream

through week 52. QoL was assessed using the World Health Organization-Five Well-Being Index (WHO-5) *(Topp CW, et al. Psychother Psychosom 2015)*, Vitiligo-specific QoL instrument (VitiQoL) (Lilly E, et al. *J Am Acad Dermatol* 2013), and the Hospital Anxiety and Depression Scale (HADS) (Snaith RP, Health Qual Life Outcomes 2003); higher scores indicate worse QoL or anxiety/depression. Treatment satisfaction was assessed using the Treatment Satisfaction Questionnaire for Medication (TSQM) (Atkinson MJ, et al. *Health Qual Life Outcomes* 2004); higher scores indicate greater satisfaction.

RESULTS: TRuE-V1/TRuE-V2 included 330/331 patients (ruxolitinib, n = 221/222; vehicle, n = 109/109) in the intent-to-treat population. The mean age was 40.2/38.7 years, and 21.5%/33.8% had Fitzpatrick skin phototypes IV–VI. No clear pattern of change from baseline was observed at week 24 for WHO-5, VitiQoL, or HADS among patients who applied ruxolitinib cream vs vehicle (Table). For patients who continued to apply ruxolitinib cream, VitiQoL scores were further decreased at week 52 (mean change from baseline, -9.39/-7.13) vs week 24 (-6.34/-6.07), indicating a possible trend of improved QoL with additional treatment over time. At week 24, mean scores were significantly higher for ruxolitinib cream vs vehicle for TSQM overall satisfaction (66.28/61.03 vs 51.79/49.06; $P < .0001$) and effectiveness scores (59.03/53.49 vs 42.22/39.74; $P < .0001$).

CONCLUSIONS: In summary, ruxolitinib cream was associated with improved treatment satisfaction vs vehicle. Effects on QoL assessed by WHO-5, VitiQoL, and HADS were not apparent at week 24, although a possible trend of improved QoL with additional treatment through week 52 was observed for some QoL assessments.

AUTHOR DISCLOSURES: DR has received honoraria as a consultant for AbbVie, Abcuro, AltruBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert Pharmaceuticals, Dermavant Sciences, Dermira, Incyte Corporation, Janssen Pharmaceuticals, Kyowa Kirin, Eli Lilly and Company, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, Sanofi, Sun Pharma, UCB, and Viela Bio; has received research support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Dermira, Galderma, Incyte Corporation, Janssen Pharmaceuticals, Eli Lilly and Company, Merck & Co., Inc., Novartis, Pfizer Inc., and Regeneron Pharmaceuticals; and has served as a paid speaker for AbbVie, Amgen, Celgene, Janssen Pharmaceuticals, Eli Lilly and Company, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, and Sanofi.

TP has received grants and/or honoraria from AbbVie, ACM Pharma, Almirall, Amgen, Astellas Pharma, Bristol Myers Squibb, Celgene, Galderma Laboratories, LP, Genzyme/Sanofi, GlaxoSmithKline, Incyte Corporation, Janssen Pharmaceuticals, LEO Pharma, Eli Lilly and Company, Novartis, Pfizer Inc., Sun Pharma, and UCB; is the cofounder of YUKIN Therapeutics; and has patents on WNT agonists or GSK3b antagonist for

TRuE-V1/TRuE-V2 Exploratory Quality-of-Life and Treatment Satisfaction Endpoints

	Week 24		Week 52	
	Vehicle	Ruxolitinib Cream	Vehicle to 1.5% Ruxolitinib Cream	Ruxolitinib Cream
WHO-5 mean change from baseline	–0.31/–0.42	0.02/–0.47	0.27/–0.12	0.90/0.15
VitiQoL mean change from baseline	–6.37/–2.64	–6.34/–6.07	–7.78/–6.89	–9.39/–7.13
HADS mean change from baseline				
Depression	–0.06/0.09	–0.32/0.01	0.21/–0.01	–0.39/0.14
Anxiety	–0.62/–0.07	–0.75/–0.14	–0.66/–0.74	–0.89/–0.15
Mean TSQM				
Overall satisfaction	51.79/49.06	66.28****/ 61.03****	65.48/62.11	69.78/65.71
Effectiveness	42.22/39.74	59.03****/53.49****	56.10/51.23	63.39/58.69
Convenience	65.56/64.91	69.32/67.03	68.29/66.53	69.20/65.60

Data presented as TRuE-V1/TRuE-V2.

Week 24 data available for 195/198–199 and 90/97–98 patients in the ruxolitinib and vehicle groups, respectively. Week 52 data available for 173/176–177 and 82/81 patients.

**** P<0.0001 for ruxolitinib cream vs vehicle analyzed using a mixed model at Week 24.

HADS, Hospital Anxiety and Depression Scale; TSQM, Treatment Satisfaction Questionnaire for Medication; VitiQoL, Vitiligo-specific quality-of-life instrument; WHO-5, World Health Organization-Five Well-Being Index.

repigmentation of vitiligo and on the use of CXCR3B blockers in vitiligo.

AGP has served as an investigator for Aclaris Therapeutics, Immune Tolerance Network, Incyte Corporation, and Pfizer Inc.; as a consultant for AbbVie, Arcutis, Avita Medical, Chromaderm, Immune Tolerance Network, Incyte Corporation, Pfizer Inc., Twi Pharmaceuticals, Inc., Viela Bio, and Villaris Therapeutics; and holds stock options for Tara Medical and Zerigo Health.

PG has served as a consultant for Aclaris Therapeutics, Clarify Medical, DermaForce, Incyte Corporation, Procter & Gamble, and Versicolor Technologies; and as a principal investigator for Aclaris Therapeutics, Allergan/SkinMedica, Clinuvel Pharmaceuticals, Incyte Corporation, Johnson & Johnson, L'Oreal, Merz Pharma, Pfizer Inc., Thync Global, Inc., and VT Cosmetics.

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SRD has received fees and/or honoraria as a consultant for Almirall, Avita Medical, Bristol Myers Squibb, Cassiopea SpA, Dermavant Sciences, Dermira, Ferndale Laboratories, Foamix Pharmaceuticals, Galderma Laboratories LP, Incyte Corporation, MC2 Therapeutics, Ortho Dermatologics, Pfizer inc., Scientis Pharma, Senté Labs, SkinCeuticals LLC, UCB, and Verrica Pharmaceuticals Inc.; has received stock options as a consultant for Gore Range Capital; has received honoraria as a speaker for Almirall and Ortho Dermatologics; has received grants/research funding as an investigator for AbbVie, AOBiome LLC, Atacama Therapeutics, Brickell Biotech, Dermavant Sciences, Incyte Corporation, Novan, and SkinMedica; has served as an advisory board member for the Foundation for Research & Education of Dermatology; is a stockholder of Gore Range Capital; and is a shareholder in PDP of Texas.

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JS has received grants and/or honoraria from AbbVie, Bristol Myers Squibb, Calypso Biotech, Eli Lilly and Company, Incyte Corporation, LEO Pharma, Novartis, Pfizer inc., Pierre Fabre, Sanofi, Sun Pharma, and Viela Bio; and has patents on MMP9 inhibitors and uses thereof in the prevention or treatment of a depigmenting disorder and three-dimensional model of depigmenting disorder.

AW is a dermatologist at the Netherlands Institute for Pigment Disorders and the Department of Dermatology at the Amsterdam University Medical Center; has served as principal investigator for Avita Medical, Incyte Corporation, and Novartis; has served as an advisory board member for Incyte Corporation; has received research grants from Avita Medical and Lumenis; and has received devices from Humeca and PerfAction Ltd.

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Abstract: AR-05

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

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BACKGROUND: Vitiligo is a chronic autoimmune disease characterized by destruction of melanocytes, resulting in pale/white patches of skin (Rodrigues M, et al. *J Am Acad Dermatol* 2017). The population-based global Vitiligo and Life Impact Among International Communities (VALIANT) study sought to understand the impact and burden of vitiligo on quality of life from the patient perspective.

OBJECTIVE: To describe outcomes from VALIANT with a focus on patients with darker skin (Fitzpatrick skin types IV–VI).

METHODS: Participants aged ≥ 18 years from 17 countries self-reporting a vitiligo diagnosis by a healthcare professional were recruited to the online survey and answered questions regarding their mental health, psychosocial burden, and behavior in professional and social situations. Clinical characteristics and outcomes in patients with darker vs fairer (Fitzpatrick skin types I to III) skin were compared using chi-square tests for categorical and t-tests for continuous variables.

RESULTS: Of 3541 patients who participated in VALIANT, 1445 (40.8%) had darker skin (type IV, n = 817; V, n = 525; VI, n = 103). Among patients with darker skin, median (range) age was 38 (18 to 95) years; 58.3% were men; mean (SD) disease duration was 11.6 (11.8) years. The median (range) affected body surface area (BSA) was 6.6% (0% to 73.9%) vs 2.5% (0% to 73.9%) for patients with fairer skin; > 5% BSA involvement for 55.3% vs 38.3%. Mean (SD) total Vitiligo Impact Patient Scale (VIPs) score was higher among patients with darker (31.2 [15.6]) vs fairer (24.5 [15.0]; $P < .0001$) skin; total score > 30 for 52.0% vs 37.5% ($P < .0001$). Across the 20 questions comprising the VIPs, burden was significantly greater among patients with darker vs fairer skin ($P < .0001$ for all questions). Vitiligo had a significantly greater impact on daily activities among patients with darker vs fairer skin ($P < .0001$ for all activities assessed); the most highly affected activities in patients with darker skin included determining what clothes to wear (62.1% vs 50.5% of patients with fairer skin) and going to the beach/pool (57.6% vs 46.6%). Patients with darker skin experienced substantial burden in emotional well-being, including self-esteem/stigma, relationships, and work/promotion, which was generally greater than that experienced by patients with fairer skin; 61.0% of patients with darker skin missed personal obligations due to time needed for medical treatment for vitiligo (vs 41.6%; $P < .0001$) and 60.6% missed obligations because of anxiety related to vitiligo (vs 37.6%; $P < .0001$). Diagnosed mental health conditions, especially anxiety disorders (34.7% vs 24.7%) and depression (29.1% vs 21.3%), were significantly more common among patients with darker vs fairer skin, ($P < .0001$ for all conditions).

CONCLUSIONS: In this global survey, patients with darker skin living with vitiligo were more likely to alter their behavior, experience high burden, and have symptoms consistent with depression than those with fairer skin.

AUTHOR DISCLOSURES: PG has served as a consultant for Aclaris Therapeutics, Clarify Medical, DermaForce, Incyte Corporation, Procter & Gamble, and Versicolor Technologies; and a principal investigator for Aclaris Therapeutics, Allergan/SkinMedica, Clinuvel Pharmaceuticals, Incyte Corporation, Johnson & Johnson, L'Oréal, Merz Pharma, Pfizer Inc., Thync Global, Inc., and VT Cosmetics.

IHH has served as an advisory board member for AbbVie; a consultant for Boehringer Ingelheim, Galderma Laboratories, LP, Incyte Corporation, Pfizer Inc., and UCB; a principal investigator for Avita Medical, Bayer, Estée Lauder, Ferndale Laboratories, Incyte Corporation, Lenicura, L'Oréal, Pfizer Inc., and Unigen Pharma; a subinvestigator for Arcutis; president of the HS Foundation; and a board member of the Global Vitiligo Foundation.

KB, AL, JG, and HR are employees and shareholders of Incyte Corporation.

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

NvG is a consultant and/or investigator for AbbVie, Incyte Corporation, Merck & Co., Inc., Pfizer Inc., and Sun Pharma; and is Chair of the Vitiligo Task Force for the European Academy of Dermatology and Venereology (EADV).

DP has served as an expert or primary investigator for Incyte Corporation, Pfizer Inc., and Sun Pharma.

JG has served as a consultant for AbbVie, Avita Medical, Concert Pharmaceuticals, Incyte Corporation, Mitsubishi Tanabe Pharma Corporation, and Pfizer Inc.

YV is CEO of the Vitiligo Research Foundation, and has served as a scientific advisor at Temprian Therapeutics and as an invited professor at Guglielmo Marconi University.

GTM is the founder of Beyond Vitiligo South Africa and cofounder of Beyond Vitiligo Botswana.

KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer Inc., Pierre Fabre, Sanofi, and Viela Bio.

Abstract: AR-06

Tazarotene 0.045% Lotion for Truncal Acne: Efficacy, Tolerability, and Spreadability

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

BACKGROUND: Topical treatment of truncal acne is complicated by large body surface area involvement, necessitating spreadable formulations that are non-irritating and provide rapid drug delivery. Tazarotene 0.045% lotion was developed using polymeric emulsion technology to provide uniform/rapid distribution of tazarotene and moisturizing/hydrating excipients in a highly spreadable formulation.

OBJECTIVE: To summarize the efficacy, safety, and tolerability of tazarotene 0.045% lotion for truncal acne, as well as its irritation potential and spreadability.

METHODS: Three studies evaluated tazarotene 0.045% lotion on the trunk. Study 1: In a 12-week, phase 4, open-label study, participants (≥ 12 years; N = 19) with moderate truncal acne (Investigator's Global Assessment [IGA] score = 3) were treated with once-daily tazarotene lotion. Outcomes included IGA score, lesion counts, cutaneous tolerability, and adverse events (AEs). Study 2: A modified cumulative irritation patch test was used to assess irritation in healthy adults (N = 20), with repeated placement of patches loaded with tazarotene 0.045% lotion, trifarotene 0.005% cream, or control (no drug) on the upper back over 12 days. Study 3: In a double-blind, split-body study of healthy adults (N = 30), spreadability was compared for tazarotene lotion and trifarotene cream applied to participants' backs.

RESULTS: After 12 weeks of treatment with tazarotene lotion in study 1, 89% of participants (17/19) achieved clear/almost clear truncal skin (IGA score 0 or 1; $P < .001$ vs baseline). Large least-squares mean percent reductions from baseline in inflammatory, noninflammatory, and total lesion counts were observed (83%, 64%, and 82%, respectively; $P < .01$, all). Significant improvements from baseline in IGA score and lesion counts were observed as early as week 4. There were no AEs related to tazarotene treatment. At baseline and week 12, most participants (≥ 74%) had no tolerability issues, and there were no significant changes from baseline to week 12 in erythema, dryness, peeling, oiliness, pruritus, and burning. In the patch test study, tazarotene was associated with minimal irritation over 12 days of exposure; tazarotene lotion was significantly less irritating than trifarotene cream 2 days after the first patch application and continuing through day 12. In the split-body spreadability study, tazarotene lotion covered on average ~30% more skin than the same amount of trifarotene cream.

CONCLUSIONS: Tazarotene 0.045% lotion significantly reduced truncal acne lesions and was well tolerated after 12 weeks of once-daily use. This easy-to-apply lotion—utilizing polymeric emulsion technology to improve drug delivery and limit irritation—was less irritating and had greater skin coverage than trifarotene 0.005% cream. Overall, tazarotene 0.045% lotion is an effective and well-tolerated option for treatment of truncal acne, with sensory and aesthetic properties preferred by patients.

FUNDING: Ortho Dermatologics

AESTHETICS

Abstract: AS-01

Are There Patterns of Hair Regrowth in Patients with Alopecia Areata? Results of Regional SALT Subscores from Two Phase 3 Clinical Trials of Baricitinib

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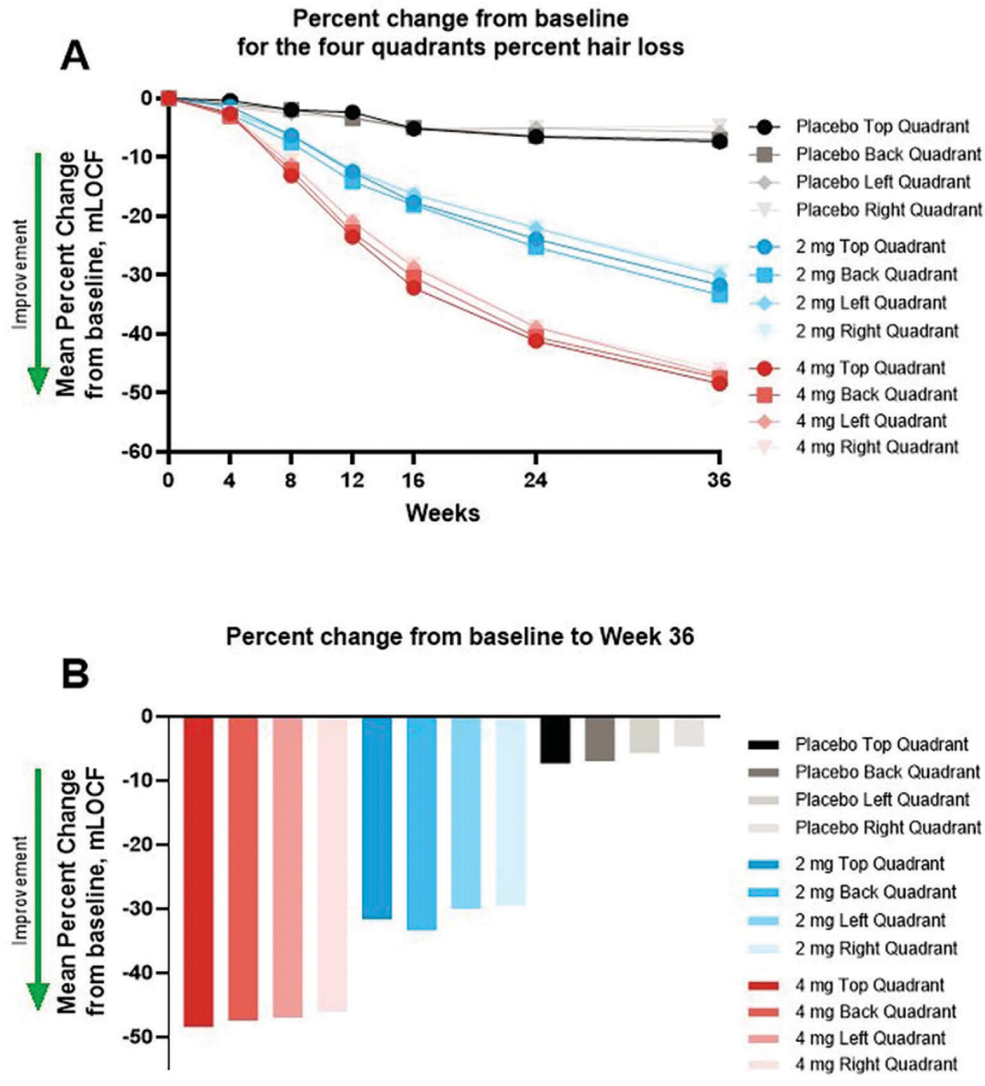
BACKGROUND: Alopecia areata (AA) is an autoimmune hair loss disorder. The BRAVE-AA1/-AA2 randomized, double-blinded, placebo-controlled Phase 2/3 trial results demonstrated that patients with AA who received 2 mg or 4 mg of baricitinib once daily had improved scalp hair regrowth compared to placebo.

OBJECTIVE: Here, we analyzed hair growth improvements within scalp quadrants using BRAVE-AA1/-AA2 data.

METHODS: Adult patients with severe AA (Severity of Alopecia Tool [SALT] score ≥ 50) were randomized to once-daily placebo, baricitinib 2 mg, or baricitinib 4 mg in BRAVE-AA1 (NCT03570749) and BRAVE-AA2 (NCT03899259); data were pooled for this descriptive analysis. Mean percent change from baseline hair loss (measured by SALT region score) was assessed within four separate scalp quadrants (top, left, right, back) in patients with four quadrants affected over 36 weeks. Modified last observation carried forward imputation was applied for missing data.

RESULTS: Of the 1200 patients in the pooled data set, 1198 (99.8%) had all 4 quadrants affected (placebo, n = 344; baricitinib 2 mg, n = 340; baricitinib 4 mg, n = 514) and were included in this analysis. Baseline hair loss was similar between all treatment groups for each quadrant, although baseline hair loss was slightly greater in the left and right quadrants versus the top and back quadrants (Table 1) Up to week 36, patients in the baricitinib 4 mg group had the largest percent improvement in hair regrowth in each of the quadrants, followed by patients in the baricitinib 2 mg group (Figure 1A). Patients treated with baricitinib achieved scalp regrowth in all four quadrants at similar rates at each post-baseline visit (Figure 1A). At week 36, the percent improvement from baseline hair loss among the four scalp quadrants was similar, with slight variations between the quadrants (Figure 1B).

Figure 1. Percent improvements in baseline hair loss for each scalp quadrant in patients with AA treated with baricitinib over time (A) and at Week 36 (B).



Baseline percent hair loss in each of the four quadrants in patients with AA, mean (SD)

	Top Quadrant	Back Quadrant	Left Quadrant	Right Quadrant
Placebo	83.0 (23.0)	84.4 (19.9)	87.0 (19.1)	87.0 (18.9)
Baricitinib 2 mg	84.2 (23.9)	887.1 (18.3)	88.0 (19.3)	88.1 (18.9)
Baricitinib 4 mg	83.2 (23.3)	84.3 (21.0)	87.7 (18.4)	87.9 (18.5)
Total	83.4 (23.4)	85.1 (20.0)	87.6 (18.8)	87.7 (18.7)

CONCLUSION: In patients with AA treated with baricitinib, patterns of hair regrowth among each of the four scalp quadrants were similar within each treatment group.
Disclosures: Study was sponsored by Eli Lilly and Company. Abstract previously presented at 2022 European Academy of Dermatology and Venereology (EADV) Congress.

Abstract: AS-02

Long-Term Efficacy of Baricitinib in Patients with Severe Alopecia Areata: Week-52 Results from BRAVE-AA1 and BRAVE-AA2.

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OBJECTIVE: To report Week-52 integrated results from BRAVE-AA1 (NCT03570749) and BRAVE-AA2 (NCT03899259), two randomized, double-blind, placebo-controlled phase-3 trials evaluating baricitinib for alopecia areata (AA).
METHODS: BRAVE-AA1 and BRAVE-AA2 enrolled 1200 adults with severe AA (Severity of Alopecia Tool [SALT] score ≥50). Patients randomized to baricitinib (4mg or 2mg, once-daily) at Baseline retained their treatment allocation through Week-52, while placebo non-responders were rescued at Week-36 (primary endpoint). Efficacy outcomes included the proportion of patients achieving SALT score ≤20 (≤20% scalp hair loss) and the proportion of patients achieving Clinician-Reported Outcomes (ClinRO) for Eyebrow Hair Loss™ and Eyelash Hair Loss™ scores of 0 or 1 (full coverage or minimal gaps) with ≥2-point improvements from baseline (among those with baseline scores ≥2 [significant gaps to no notable hair]). Data were censored after treatment discontinuation or if collected remotely due to COVID-19.
RESULTS: At Week 36, SALT score ≤20 was achieved in 175/515 (34.0%) and 67/340 (19.7%) of baricitinib 4 mg and 2 mg patients, and ClinRO score of 0 or 1 was achieved in 103/307 (33.6%) and 24/200 (12.0%) for Eyelash, and 115/349 (33.0%) and 38/240 (15.8%) for Eyebrow. At week 52, SALT score ≤ 20 was achieved in 201/515 (39.0%) and 77/340 (22.6%) of baricitinib 4 mg and 2 mg patients, and ClinRO score of 0 or 1 was achieved in 139/307 (45.3%) and 51/200 (25.5%) for Eyelash, and 154/349 (44.1%) and 55/240 (22.9%) for Eyebrow.
CONCLUSION: Overall, there was further increase in the proportion of patients achieving scalp, eyebrow, and eyelash hair regrowth during the long-term extension phase with baricitinib.
DISCLOSURES: Study was sponsored by Eli Lilly and Company. Abstract previously presented at 2022 American Academy of Dermatology 80th Annual Meeting.

Abstract: AS-03

Photographic Representation of Severity of Alopecia Tool (SALT) Scores: Implications for Clinical Practice

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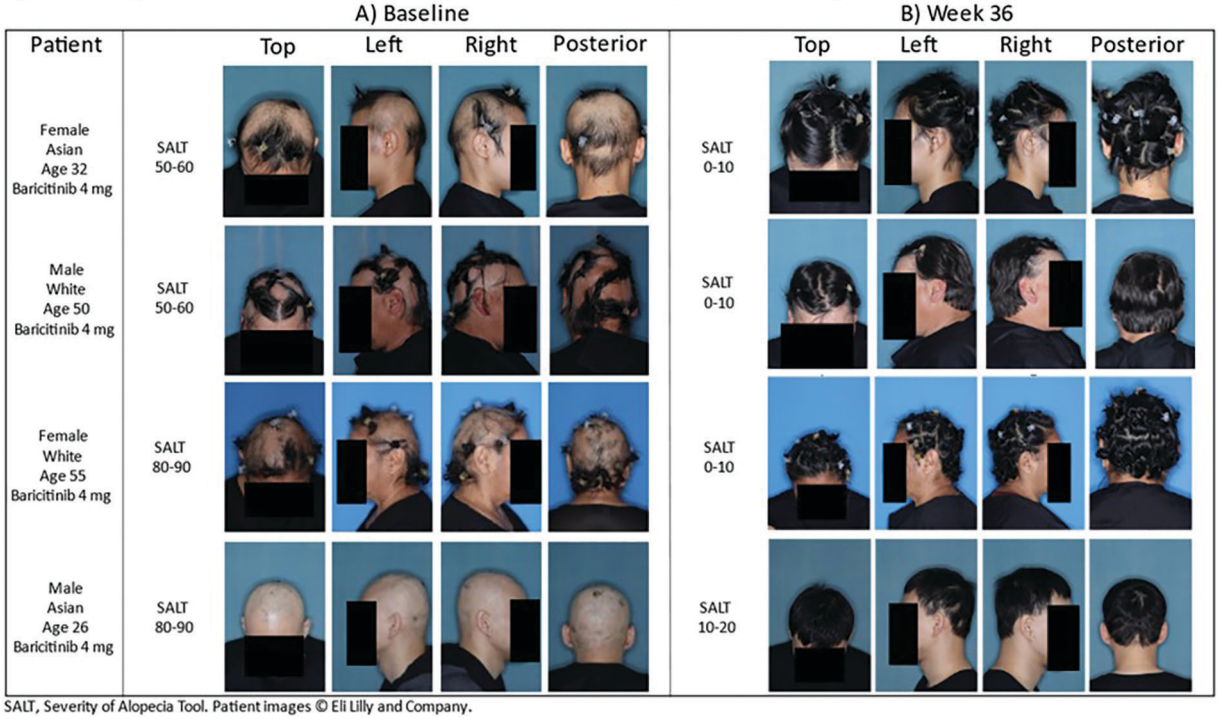
INTRODUCTION: The Severity of Alopecia Tool (SALT) is a method of measuring scalp hair loss in alopecia areata (AA). A SALT score ≤ 20 (≤ 20% scalp hair loss) has been identified as a successful treatment outcome for patients with ≥ 50% scalp hair loss and is used as the primary endpoint in clinical trials of drug therapies for severe AA. However, clinicians may be unfamiliar with assessing these scores in practice. Here, we present images from a clinical trial to represent SALT scores of patients with severe AA before and after successful treatment.
METHODS: BRAVE-AA1 (NCT03570749) is an adaptive, double-blind, placebo-controlled phase 2/3 study of

Figure 1. Images of patients with severe alopecia areata taken at A) baseline and B) after clinical response at Week 36.



SALT, Severity of Alopecia Tool. Patient images © Eli Lilly and Company.

baricitinib in adults with severe AA (SALT score ≥ 50). At baseline and week 36, investigators obtained photographs of the four planes of the scalp (left, right, posterior, and top of head). Images from 722 enrolled patients who provided informed photographic consent were compiled into a repository. Images were selected to demonstrate SALT scores across the spectrum of disease severity at baseline and after achieving clinical response following baricitinib therapy. Selected images were of male and female patients who were randomized to baricitinib 2 mg or 4 mg, had photographs at baseline and week 36, and achieved the primary endpoint of SALT score ≤ 20 at week 36. Photographs were de-identified.

RESULTS: Four-plane images of patients who met the selection criteria are presented. Figure 1 shows examples of patients with severe scalp hair loss at baseline (SALT score ≥ 50), including one 32-year-old Asian female, one 50-year-old White male, one 55-year-old White female, and one 26-year-old Asian male treated with baricitinib 4 mg. Photographs after 36 weeks of treatment demonstrate a successful response, with clinically meaningful hair regrowth in each area of the scalp (SALT score ≤ 20). The final presentation of photographs demonstrates the full range of SALT scores (0 to 100) for both 4 mg and 2 mg treatment.

CONCLUSION: Patient images from a clinical trial were used to represent examples of SALT scores of patients with severe AA before and after successful treatment. The photographs include a diverse set of patients, demonstrating unique patterns of hair loss and regrowth in individuals with AA. The images represent SALT scores commonly used as eligibility criteria and endpoints in clinical trials, which may be useful in identifying patients eligible for systemic treatment and in visualizing therapeutic response.

DISCLOSURES: Study was sponsored by Eli Lilly and Company. Abstract previously presented at 2022 European Academy of Dermatology and Venereology (EADV) Congress.

Abstract: AS-04

Serious Adverse Events with Injectable Fillers: Retrospective Analysis of 7659 Patient Outcomes

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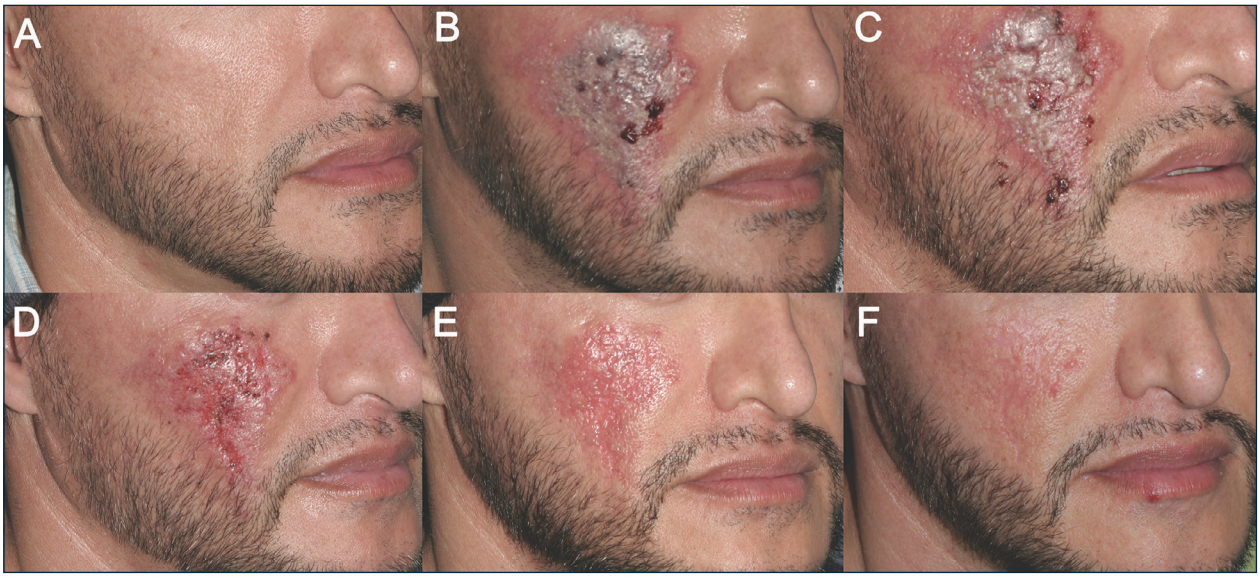

TABLE 1: 34-year-old man with progressive tissue necrosis and subsequent healing following administration of 1.5 cc of calcium hydroxylapatite filler to the right medial cheek. Patient was treated with hyperbaric oxygen, topical wound care with silicone dressings, and fractionated laser resurfacing, and achieved complete resolution of epidermal scaring.

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BACKGROUND: In total, 2.7 million injectable filler treatments were performed in 2019 in the United States. Although generally considered to be a safe treatment modality, adverse events may occur in rare situations.
OBJECTIVE: Analyze serious adverse events from injectable filler treatments—including infections, cutaneous necrosis, blindness, or delayed-onset nodule formation—spanning 11 years for 3 board certified dermatologists, and review their incidence, management, and outcomes.
METHODS: A retrospective analysis was performed of injectable filler treatments spanning 11 years at a multipractitioner outpatient clinic. Serious adverse events were identified and treatment measures were documented. A literature search was performed to determine recent trends and outcomes for comparison.
RESULTS: Between January 2009 and August 2020, 18,013 mL of injectable filler was administered to 7659 patients. Of the 18,013 mL administered, 74.1% comprised hyaluronic acid derivatives, 19.19% poly-L-lactic acid, and 6.71% calcium hydroxylapatite. Four serious adverse events were identified. Three events were delayed-onset skin nodule formation. One adverse event was related to vascular compromise and subsequent cutaneous necrosis (Figure). After appropriate treatment, all adverse events resolved without significant long-term sequelae (Table 1).
CONCLUSION: Serious adverse events associated with injectable fillers, when performed by board certified dermatologists, are extremely rare and can be successfully managed with appropriate treatment.

ATOPIC DERMATITIS

Abstract: AD-01

Conjunctivitis in Adolescent Patients Aged 12 to 17 Years With Moderate to Severe Atopic Dermatitis Treated With Tralokinumab Up to Week 52: Results From the Phase 3 ECZTRA 6 Trial

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BACKGROUND: Conjunctivitis is common in atopic dermatitis (AD) and can increase with biologics targeting the type 2 pathway; the frequency of conjunctivitis as an adverse event of special interest (AESI) in tralokinumab-treated adults (pooled data) is 7.5% (rate [R] 26.6 events/patient years [pt yrs] of exposure*100).
OBJECTIVES: The objective of this study was to examine conjunctivitis rates in tralokinumab-treated adolescents.
METHODS: Participants received tralokinumab 150 mg (n = 98) or 300 mg (n = 97) or placebo (PBO; n = 94) every 2 weeks (wks) from wks 0 to 16, then were transferred to maintenance or open label until wk 52. The broad AESI term conjunctivitis included the preferred terms (PT) conjunctivitis, conjunctivitis allergic, conjunctivitis bacterial and conjunctivitis viral.
RESULTS: By wk 16, 2 patients (pts) (2.1%; 3 events; R 10.7) in the PBO arm had conjunctivitis (AESI) vs 4 pts (4.1%; 4 events; R 13.6) receiving tralokinumab 150 mg and 3 pts (3.1%; 3 events; R 10.2) receiving 300 mg; only 2 events of conjunctivitis based on PT occurred, both in the 150 mg arm. Most events (7/10) were considered mild by the investigator; 2 moderate events occurred in the tralokinumab 150 mg arm and 1 in the 300 mg arm. Most events (9/10) recovered/resolved during wks 0 to16 and 0 led to permanent tralokinumab discontinuation. During wks 16 to 52, 3 pts (6%; R 11.9) had a conjunctivitis (AESI) event in the maintenance phase (pooled tralokinumab arms) as did 11 pts (4.7%; 14 events; R 9.3) in open label.
CONCLUSIONS: Conjunctivitis frequency in adolescents was similar between tralokinumab and PBO arms and numerically lower vs adults through wk 16; events were mild or moderate and did not increase through wk 52.
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Abstract: AD-02

Dupilumab Ameliorates Sleep Disturbance and Relieves Itch in Adults With Moderate to Severe Atopic Dermatitis Over 24 Weeks

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INTRODUCTION: Sleep disturbance is a prominent symptom of atopic dermatitis (AD); daytime fatigue and impaired quality of life arise primarily from night-time itching and scratching, affecting the ability to fall and stay asleep. Previous results from the phase 4 DUPISTAD study (NCT04033367) demonstrated dupilumab significantly improved sleep quality from baseline to week (W)12 in adults with moderate to severe AD.

MATERIALS AND METHODS: DUPISTAD, a phase 4, randomized, placebo-controlled study has a 12-week double-blinded period followed by a 12-week open-label period. Adults with moderate to severe AD and Sleep Numeric Rating Scale (NRS) average score ≥ 5 were randomized 2:1 to dupilumab 300 mg every 2 weeks (q2w) or placebo (PBO) for 12 weeks, with both randomized groups receiving open-label dupilumab 300 mg q2w for a further 12 weeks. Concomitant topical corticosteroids were permitted as needed. The primary endpoint was mean percent change from baseline to W12 in Sleep NRS (0 = worst possible sleep; 10 = best possible sleep); this was then reversed to analyze sleep disturbance. Exploratory endpoints included mean percent change from baseline to W24 in Sleep NRS and Peak Pruritus NRS, and mean change from baseline to W24 for SCORing Atopic Dermatitis (SCORAD; scored 0 to 103) and SCORAD Sleep Visual Analog Score (VAS; scored 0 to 10). Formal statistical comparisons were not performed on data from the open-label observation period. Safety to W24 was also assessed.

RESULTS: 188 patients were randomized: 127 to continuous dupilumab (dupilumab–dupilumab) and 61 to PBO to W12 then dupilumab to W24 (PBO–dupilumab). Baseline demographics and disease characteristics were balanced. At W24, the dupilumab–dupilumab and PBO–dupilumab groups had similar decrease in Sleep NRS score (-57.2% and -57.0%, respectively). The PBO–dupilumab group demonstrated improvements in mean Sleep NRS score of -32.4% from W12 to W24, and continued improvement of -12.5% was seen from W12 to W24 with dupilumab–dupilumab. An improvement in Peak Pruritus NRS from baseline to W24 was also seen in both groups, with mean changes in score of -62.1% and -66.2% with dupilumab–dupilumab and PBO–dupilumab groups and mean changes from W12 to W24 of -7.8% and -52.5%, respectively. Changes from baseline to W24 for SCORAD were -44.2 and -46.6 for the dupilumab–dupilumab and PBO–dupilumab groups, while mean changes from baseline to W24 in SCORAD Sleep VAS score were -5.5 and -5.3, respectively. Treatment-emergent adverse events (TEAEs) through W24 occurred in 70.1% of dupilumab–dupilumab-treated patients vs 75.4% of PBO–dupilumab patients; serious TEAEs occurred in 2.4% vs 1.6%, respectively.

DISCUSSION: Dupilumab provides sustained improvements in sleep quality measures through 24 weeks in adults with moderate to severe AD, with PBO patients showing rapid improvement in sleep quality after switching to dupilumab at W12. The dupilumab safety profile is consistent with the known safety profile.

Abstract: AD-03

Dupilumab Significantly Improves Itch and Skin Lesions in Patients with Prurigo Nodularis: Results From a Second Phase 3 Trial (LIBERTY-PN PRIME)

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INTRODUCTION: Prurigo nodularis (PN) is a chronic inflammatory pruritic skin disease that results in persistent inflammatory, hyperkeratotic, and fibrotic nodules on the extensor surfaces of the limbs and trunk, which cause a high disease burden and a negative impact on quality of life. Currently, there are no FDA- or EMA-approved systemic therapies for PN. Initial results from the phase 3 trial LIBERTY-PN PRIME2 (NCT04202679) have shown that dupilumab significantly reduces itch and skin lesions in PN.

MATERIALS AND METHODS: LIBERTY-PN PRIME (NCT04183335) was a randomized, double-blind, placebo-controlled, multi-centre, parallel-group, phase 3 trial in adults with PN with ≥ 20 nodules and severe itch, inadequately controlled with topical prescription therapies or for whom these are inadvisable. Patients received 300 mg dupilumab subcutaneously (600 mg loading dose; n = 75) or matching placebo (n = 76) every 2 weeks for 24 weeks. The primary endpoint was proportion of patients with ≥ 4-point reduction in the weekly average 24h Worst-Itch Numerical Rating Scale (WI-NRS, range: 0 to 10) from baseline to week 24. The key secondary endpoint was proportion of patients with an Investigator's Global Assessment PN-Stage (IGA PN-S, score range: 0 to 4) of 0 or 1 (clear or almost clear; defined as 5 or fewer nodules) at week 24.

RESULTS: At baseline, the mean (SD) WI-NRS score was 8.5 (1.0); 71.3% had ≥ 20 to 100 nodules (IGA PN-S = 3) and 28.7% had > 100 nodules (IGA PN-S = 4). At week 24, 60.0% vs 18.4% of patients treated with dupilumab vs placebo achieved ≥ 4-point reduction in WI-NRS score ($P < .0001$). Furthermore, 48.0% vs 18.4% of patients treated with dupilumab vs placebo achieved IGA PN-S of 0 or 1 at week 24 ($P = .0004$). The rate of treatment-emergent adverse events was 70.7% vs 62.7% for dupilumab vs placebo. The most commonly observed adverse events were headache (5.3% vs 5.3%) and nasopharyngitis (5.3% vs 4.0%) for dupilumab vs placebo.

DISCUSSION: Dupilumab demonstrated clinically meaningful and statistically significant improvements in itch response and skin lesions vs placebo in adult patients with PN, confirming the results reported in the PRIME2 study. The safety profile of dupilumab was generally consistent with the known safety profile in its approved indications.

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Abstract: AD-04

Dupilumab Treatment is Not Associated With an Increased Overall Risk of Infections in Patients Aged 6 Months to 5 Years With Moderate to Severe Atopic Dermatitis

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BACKGROUND: Patients with atopic dermatitis (AD) present an increased risk of infections, including skin infections. Previous studies in children aged 6 to 11 years and adolescents showed that dupilumab is not associated with an increased risk of overall infections and is associated with lower risks of skin infections compared with placebo. Here we report the impact of dupilumab treatment on infections, including skin infections, in children aged 6 months to 5 years with moderate to severe AD.

METHODS: In LIBERTY AD PRESCHOOL, a double-blind, placebo-controlled trial (NCT03346434, part B), children aged 6 months to 5 years with moderate to severe AD (Investigator's Global Assessment score ≥ 3) were randomized 1:1 to subcutaneous dupilumab every 4 weeks (200 mg if baseline weight was ≥ 5 to < 15 kg, 300 mg if weight was ≥ 15 to < 30 kg) or placebo with concomitant low-potency topical corticosteroids for 16 weeks. Exposure-adjusted rates (patients with ≥ 1 event per 100 patient-years [nP/100PY]) and percentage of patients with ≥ 1 skin infections were used to compare treatment groups.

RESULTS: 162 patients were randomized to dupilumab (n = 83) or placebo (n = 79). During the 16-week treatment period, total infections rates were numerically lower in the dupilumab-treated group (nP/100PY: 185.2) compared with the placebo-treated group (nP/100PY: 245.7). Rates of fungal infections were not significantly different with dupilumab (nP/100PY: 0) than with placebo (nP/100PY: 4.2; $P = 1$ vs placebo). Bacterial infections were significantly less frequent in dupilumab-treated (nP/100PY: 3.9) than placebo-treated patients (nP/100PY: 45.6; $P < 0.05$ vs placebo). There was no significant difference in viral infections rates between the dupilumab (nP/100PY: 64.8) and placebo group (nP/100PY: 55.2; $P = 0.681$ vs placebo). No helminthic infections were reported in either group. The percentage of patients with ≥ 1 skin infections was numerically lower in the dupilumab group (12.0%) than in the placebo group (24.4%). Overall safety of dupilumab was consistent with the known safety profile.

CONCLUSION: Dupilumab treatment is associated with lower overall infections and significantly lower bacterial infections than placebo in children aged 6 months to 5 years with moderate to severe AD.

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Abstract: AD-05

Dupilumab Treatment Normalizes Skin Barrier Function and Improves Clinical Outcomes in Patients With Atopic Dermatitis

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BACKGROUND: Skin barrier dysfunction is well recognized in atopic dermatitis (AD). Type 2 inflammation, mediated by interleukin 4 and interleukin-13, influences keratinization,

integrity of tight junction, composition of lipids, microbiome diversity, filaggrin expression, and natural moisturizing factors.

OBJECTIVES: We evaluated the effect of dupilumab on skin barrier function and clinical outcomes in adults and adolescents with moderate to severe AD compared to matched healthy volunteers.

METHODS: The dupilumab skin BArrier function and LIpidomics STudy in Atopic Dermatitis (BALISTAD, [NCT04447417]) was a 16-week, open-label study in patients with AD aged 12 to 65 years. Adult patients with AD received dupilumab 300 mg every 2 weeks (q2w); adolescent patients with AD received dupilumab 200 mg q2w if baseline weight was < 60 kg and 300 mg q2w if weight was ≥ 60 kg. Serial assessment of transepidermal water loss (TEWL) before and after skin tape stripping (STS) was performed on lesional and non-lesional skin of 26 patients with AD treated with dupilumab and on the normal skin of 26 matched healthy volunteers. We also evaluated AD signs and symptoms using the Eczema Area and Severity Index (EASI) and SCORing Atopic Dermatitis (SCORAD) score.

RESULTS: The median TEWL after 5 STS in AD lesions was significantly reduced from baseline starting at week 2 ($P < .0001$), and the reduction was sustained through week 16 ($P < .0001$). At week 16, there were no statistically significant differences in the adjusted least squares mean TEWL in lesional and non-lesional skin in AD patients vs matched healthy volunteers ($P = .225$ and $P = .1634$, respectively). The mean (standard deviation [SD]) EASI improved from 31.2 (16.3) at baseline to 9.8 (6.5) at week 16. The mean (SD) SCORAD score improved from 61.3 (17.7) at baseline to 24.0 (12.0) at week 16. For both outcomes, the improvement was significant vs baseline as early as week 2 ($P < .0001$) and continued through week 16 ($P < .0001$). Overall safety was consistent with the known dupilumab safety profile.

CONCLUSIONS: Dupilumab treatment led to normalization of epidermal barrier function as seen from the significant reduction in TEWL in lesional skin of adults and adolescents with moderate to severe AD, which was associated with a significant improvement in signs and symptoms of AD.

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Abstract: AD-06

Efficacy and Safety of Lebrikizumab in Combination With Topical Corticosteroids in Patients With Moderate to Severe Atopic Dermatitis: A Phase 3, Randomized, Placebo-Controlled Trial (ADhere)

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OBJECTIVE: To report efficacy and safety of lebrikizumab (LEB) vs placebo (PBO) in combination with topical corticosteroids (TCS) in patients (pts) with moderate to severe atopic dermatitis (AD) in phase 3 ADhere study.

METHODS: During 16-week (W) treatment, 228 pts (adults [≥ 18 years]/adolescents [≥ 12 years; ≥40 kg]) were stratified and randomized 2:1 to receive either LEB 250 mg (loading dose = 500 mg at Baseline [BL]; W2) + TCS or PBO subcutaneously every 2W (Q2W) + TCS. Co-primary efficacy endpoints were pts (%) achieving an IGA score of 0/1 and 75% improvement in EASI from BL (EASI75) at W16. Key secondary endpoints (W16) were pts (%) achieving 90% improvement in EASI from BL (EASI90), % change in EASI from BL, Pruritus Numeric Rating Scale (NRS) ≥ 4-point improvement in score and Pruritus NRS % change from BL, pts (%) with a Pruritus NRS score of ≥ 4 points at BL who achieve both EASI75 and ≥ 4-point reduction in Pruritus NRS score from BL, Dermatology Life Quality Index (DLQI) ≥ 4-point improvement in score, change from BL in Sleep-Loss score, measuring interference of itch on sleep.

RESULTS: Efficacy/safety analyses were conducted for 211 pts; 17 pts from a single site were excluded due to good clinical practices (GCP) issues. At W16, IGA 0/1 was achieved by 41.2% (n = 60/145) pts receiving LEB 250 mg + TCS vs 22.1% (n=15/66) receiving PBO + TCS (P = .011). A significantly higher proportion of pts achieved EASI75 (69.5% vs 42.2%, P < .001) and EASI90 (41.2% vs 21.7%, P < .008) in LEB 250mg + TCS vs PBO + TCS arm, respectively. There was a significant decrease (P < .001) in the % change in EASI from BL in LEB 250 mg + TCS vs PBO + TCS arm (-76.8 vs -53.1, respectively). At W16, a higher proportion pts in LEB 250 mg + TCS arm achieved ≥ 4 points reduction in Pruritus NRS score vs PBO + TCS (50.6% vs 31.9%, P =.017) and a significant % change from BL in Pruritus NRS (-50.7 vs -35.5, respectively; P = .017). Pts in LEB 250 mg + TCS arm had a significantly greater combined EASI75 and Pruritus NRS scores at W16 vs PBO + TCS group (38.3% vs 16.8%, respectively; P = .005). Those receiving LEB 250 mg + TCS achieved significant DLQI ≥ 4-point improvement vs PBO + TCS group (77.4% vs 58.7%, P = .036). A significant change from BL in Sleep-Loss score was also observed in pts receiving LEB 250 mg + TCS vs PBO + TCS (-1.1 vs -0.8, P = .025). TEAEs reported in ≥ 2% in either treatment group were conjunctivitis, headache, hypertension, nasopharyngitis, atopic dermatitis, dry eye, and upper respiratory tract infection. Serious adverse events were similar in the PBO + TCS (1.5%) and LEB 250 mg + TCS arms (1.4%).

CONCLUSION: LEB 250 mg + TCS demonstrated efficacy and safety in a placebo-controlled phase 3 trial, consistent with previous lebrikizumab monotherapy studies in pts with moderate to severe AD.

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Abstract: AD-07

Efficacy And Safety of Lebrikizumab in Moderate to Severe Atopic Dermatitis: 52-Week Results of Two Randomized, Double-Blinded, Placebo-Controlled Phase 3 Trials (ADvocate1 and ADvocate2)

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INTRODUCTION: Here we report 52-week efficacy and safety results of lebrikizumab (LEB) in moderate to severe atopic dermatitis (AD) from phase 3 ADvocate1 (Adv1) and ADvocate2 (ADv2) trials.

METHODS: Patients who responded to LEB 250 mg every two weeks (LEB Q2W) at the end of a 16-week induction period were re-randomized 2:2:1 to receive LEB Q2W, LEB 250 mg every 4 weeks (LEB Q4W), or placebo Q2W (LEB withdrawal) for 36 additional weeks.

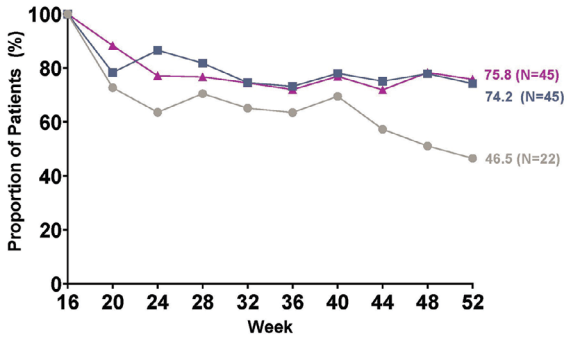
RESULTS: A greater proportion of patients on LEB Q2W (ADv1 =75.8%; ADv2 = 64.6%) and LEB Q4W (ADv1 = 74.2%; ADv2 = 80.6%) maintained an Investigator's Global Assessment of 0 or 1 (≥ 2-point improvement) vs those in the LEB withdrawal arm (ADv1 = 46.5%; ADv2 = 49.8%) at week 52. A 75% reduction in Eczema Area and Severity Index from baseline (EASI75) was maintained by 79.2% (ADv1) and 77.4% (ADv2) patients on LEB Q2W, 79.2% (ADv1) and 84.7% (ADv2) patients on LEB Q4W, and 61.3% (ADv1) and 72.0% (ADv2) patients in the LEB withdrawal arm at week 52. A ≥ 4-point improvement from baseline to week 52 on the Pruritus Numeric Rating Scale was maintained by 81.2% (ADv1) and 90.3% (ADv2) of patients on LEB Q2W, 80.4% (ADv1) and 88.1% (ADv2) patients on LEB Q4W, and 65.4% (ADv1) and 67.6% (ADv2) patients in the LEB withdrawal arm. Overall, 58.1% (ADv1) and 68.1% (ADv2) LEB-treated patients reported any treatment-emergent adverse event.

DISCUSSION: After a 16-week induction with LEB Q2W, both LEB Q2W and LEB Q4W maintained improvement of the signs and symptoms of moderate to severe AD with a safety profile consistent with previously published data.

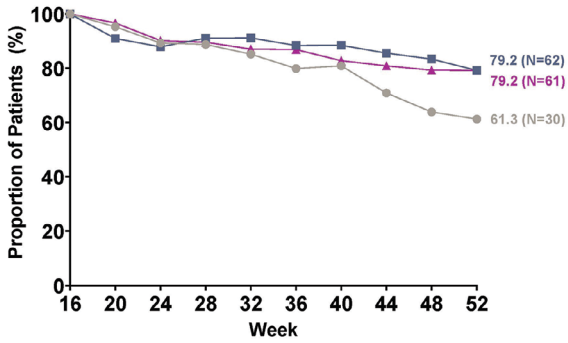
Maintenance of Response Over Time

ADvocate1 (MPP, MCMC-MI)

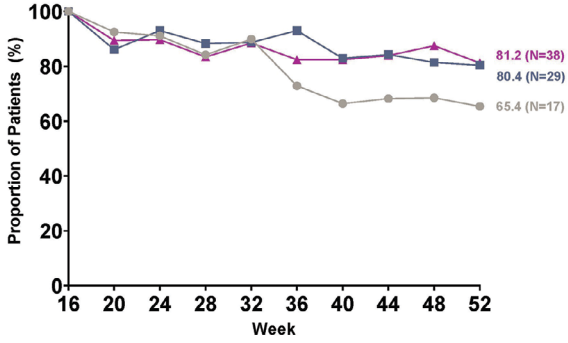
IGA (0,1) and ≥2-point Improvement



EASI75

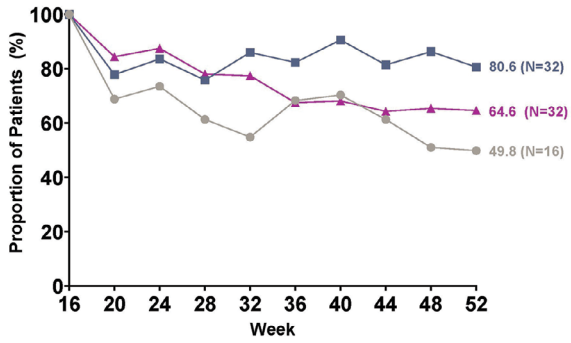


Pruritus NRS ≥4-point Improvement



ADvocate2 (mMPP*, MCMC-MI)

IGA (0,1) and ≥2-point Improvement



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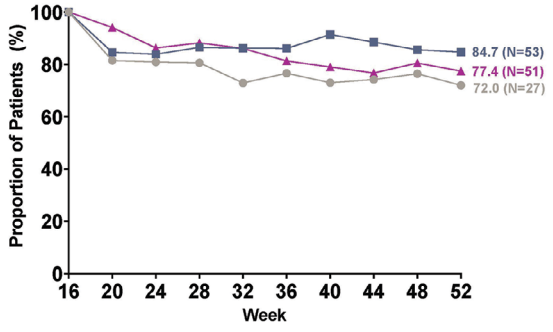

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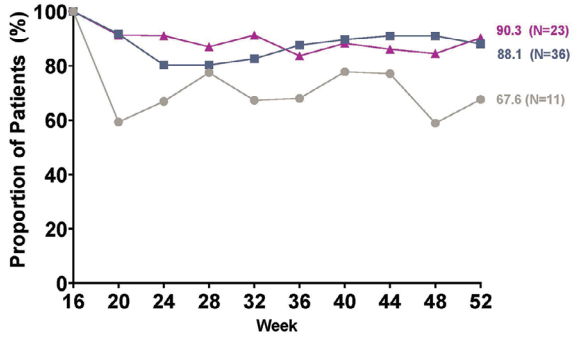

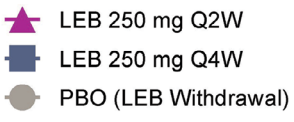

EASI=Eczema Area and Severity Index; EASI75=75% improvement in EASI; IGA=Investigator's Global Assessment; LEB=lebrikizumab; MCMC-MI=Markov chain Monte Carlo multiple imputation; MPP=Maintenance Primary Population; mMPP=modified MPP; NRS=numeric rating scale; PBO=placebo; Q2W=every 2 weeks; Q4W= every 4 weeks.

*ADvocate2 analyses were performed on a modified population, excluding 18 patients from a single study site whose eligibility could not be confirmed. Of these patients, 17 entered into the Maintenance Period and were excluded from Maintenance efficacy analyses.

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DISCLOSURE: This study was funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company.

Abstract: AD-08

Efficacy and Safety of Roflumilast Foam 0.3% in Patients With Seborrheic Dermatitis in a Phase 3 Trial

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INTRODUCTION: Roflumilast is a selective, nonsteroidal, highly potent phosphodiesterase-4 inhibitor once-daily foam under investigation for the treatment of seborrheic dermatitis (SD). Efficacy, safety, and local tolerability of roflumilast foam 0.3% in patients with SD were demonstrated in a phase 2a and subsequent open-label trial (NCT04091646 and NCT04445987, respectively). Here, we present efficacy, safety, and local tolerability in a phase 3 trial of roflumilast foam 0.3% in patients with SD (NCT04973228).
MATERIALS AND METHODS: This phase 3, randomized, parallel group, double-blind, vehicle-controlled trial was conducted in patients ≥ 9 years old with at least moderate SD affecting scalp and/or non-scalp areas. Patients were randomized 2:1 to apply once-daily roflumilast foam 0.3% (n = 304) or vehicle (n = 153) for 8 weeks. The primary efficacy endpoint was Investigator Global Assessment (IGA) Success (IGA of Clear or Almost Clear plus ≥ 2-grade improvement from baseline) at week 8. Statistical significance was concluded at the 1% significance level (2-sided). Secondary efficacy endpoints included IGA score of Clear at week 8, achievement of ≥ 4-point improvement from baseline in Worst Itch Numeric Rating Score (WI-NRS) among patients with baseline score ≥ 4 (WI-NRS Success), Overall Assessment of Erythema score of 0, and Overall Assessment of Scaling score of 0. WI-NRS was evaluated at $\alpha = .0033$ and other secondary endpoints at $\alpha = .0067$. Safety and local tolerability were also evaluated.
RESULTS: Overall, significantly more roflumilast-treated patients than vehicle-treated patients achieved the primary efficacy endpoint of IGA Success (80.1% vs 59.2%; $P < .0001$) and IGA status of Clear (50.7% vs 28.2%; $P < .0001$) at week 8. Percentages of patients achieving IGA Success and IGA Clear at weeks 2 and 4 were also greater with roflumilast. Significantly greater percentages of roflumilast- than vehicle-treated patients achieved secondary endpoints of 1) WI-NRS success at weeks 2, 4, and 8 (63.6% vs 42.3%; $P = .0002$); 2) Overall Assessment of Erythema score of 0 (57.9% vs 32.7%; $P < .0001$) at week 8; and 3) Overall Assessment of Scaling score of 0 (58.2% vs 37.5%; $P = .0001$) at week 8. Local tolerability was favorable, with ≥ 98.9% of patients having no evidence of irritation at weeks 4 and 8 on investigator-rated assessments and ≥ 92.3% of patients reporting a score of 0 (no sensation) or 1 (slight warm, tingling sensation; not really bothersome) after application on patient-rated tolerability. Overall incidence of treatment-emergent adverse events (TEAEs), serious adverse events, and TEAEs leading to discontinuation were low, with similar rates between roflumilast and vehicle.
CONCLUSIONS: Once-daily roflumilast foam provided improvement across multiple efficacy endpoints vs vehicle while demonstrating favorable safety and tolerability in patients ≥ 9 years old with SD affecting scalp and/or non-scalp body areas.

Abstract: AD-09

Efficacy and safety of tralokinumab in adolescents with moderate-to-severe atopic dermatitis: results of the phase 3 ECZTRA 6 trial

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BACKGROUND: Atopic dermatitis (AD) is a chronic, inflammatory skin disease that commonly develops in early childhood and is associated with a substantial psychosocial burden in adolescents (Peters AS, et al. *J Allergy Clin Immunol* 2010; Weidinger S, et al. *Nat Rev Dis Primers* 2018; Ghio D, et al. *Br J Health Psychol* 2021). Tralokinumab is a human monoclonal antibody that targets interleukin (IL)-13, a key driver of AD pathogenesis (Bieber T. Allergy 2020; Tsoi LC, et al. *J Invest Dermatol* 2019; Popovic B, et al. *J Mol Biol* 2017). Phase 3 trials established tralokinumab efficacy and safety for up to 52 weeks in adults with moderate to severe AD (Wollenberg A, et al. *Br J Dermatol* 2021; Silverberg JI, et al. *Br J Dermatol* 2021). The ECZTEND trial is providing long-term efficacy and safety data in adults and adolescents.

OBJECTIVES: The objective of this study is to evaluate tralokinumab efficacy and safety in adolescents with moderate to severe AD in the phase 3 ECZTRA 6 trial (NCT03526861).

METHODS: Adolescents (aged 12 to 17 years) were randomized to subcutaneous tralokinumab 150 mg (n = 100), 300 mg (n = 101), or placebo (n = 100) every 2 weeks. Primary endpoints were IGA 0/1 and EASI-75 at week 16. Patients initially treated with tralokinumab and achieving primary endpoints without use of rescue treatment (TCI, TCS, or systemic) were considered responders and re-randomized to one of four groups for 36 weeks maintenance treatment: tralokinumab 150 mg Q2W/Q4W or 300 mg Q2W/Q4W. Nonresponders (including those with missing data) were transferred to open-label treatment (300 mg Q2W + optional TCI/TCS).

RESULTS: At week 16, statistically significantly greater proportions of tralokinumab-treated patients (150 mg/300 mg vs placebo) achieved IGA 0/1 (21.4%/17.5% vs 4.3%), EASI-75 (28.6%/27.8% vs 6.4%) and ≥ 4-point improvement in pruritus NRS (23.2%/25.0% vs 3.3%). Tralokinumab treatment was also associated with statistically significantly greater improvements than placebo in SCORAD and CDLQI. At week 52, approximately 60% of week 16 responders maintained IGA 0/1 (22/35) or EASI-75 (25/47) without rescue treatment. For patients not achieving the primary endpoints at week 16, 33.3% and 57.8% of 135 patients initially treated with tralokinumab and transferred to open-label treatment at week 16 achieved IGA 0/1 or EASI-75 at week 52. Through week 16, percentages of adverse events (AEs; 67.3/64.9 vs 61.7), serious AEs (3.1/1.0 vs 5.3), AEs leading to discontinuation (1.0/0 vs 0), and conjunctivitis events (4.1/3.1 vs 2.1) were similar between tralokinumab and placebo. The safety profile of tralokinumab through week 52 was consistent with that at week 16.

CONCLUSIONS: In adolescents, tralokinumab demonstrated safety and efficacy at week 16 comparable to the phase 3 adult trials. At week 52, safety was maintained, a majority of week 16 responders maintained their response without rescue treatment, and a substantial portion of nonresponders at week 16 showed progressive efficacy.

ACKNOWLEDGEMENTS: Medical writing and editorial support from Alphabet Health by Clair Geary, PhD, and Krista Mills, was funded by LEO Pharma A/S, Ballerup, Denmark. This work was previously presented at the 21st European Society for Pediatric Dermatology (ESPD) Annual Meeting; Munich Germany, May 20-22, 2022.

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

Andreas Wollenberg has received grants, personal fees, or nonfinancial support from AbbVie, Almirall, Beiersdorf, BIODERMA, Chugai, Eli Lilly and Company, Galapagos, Galderma Laboratories, LP, Hans Karrer, LEO Pharma, L'Oréal, Maruho Co., Ltd., MedImmune, Novartis, Pfizer Inc., Pierre Fabre, Regeneron Pharmaceuticals, Santen, and Sanofi-Aventis.

Andrew Blauvelt is a scientific adviser and clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arena, Arcutis, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, EcoR1 Capital, Eli Lilly and Company, Evommune, Forte, Galderma Laboratories, LP, Incyte Corporation, Janssen Pharmaceuticals, Landos Biopharma, LEO Pharma, Novartis, Pfizer Inc., RAPT Therapeutics, Regeneron Pharmaceuticals, Inc., Sanofi Genzyme, Sun Pharma, UCB, and Vibliome Therapeutics.

Weily Soong has served on the advisory board and received research grants from AbbVie, Genentech, LEO Pharma, Novartis, Pfizer Inc., and Teva; served on the advisory board, received research grants, and was a speaker for Amgen, AstraZeneca, GlaxoSmithKline, Regeneron Pharmaceuticals, and Sanofi; received research grants and was a speaker for Optinose; and received research grants from Aimmune Therapeutics, Avillion, Galderma Laboratories, LP, Gossamer Bio, LEO Pharma, and 3M.

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Chih-ho Hong is a researcher, consultant, and/or advisor for AbbVie, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Celgene, Dermavant Sciences, Dermira, DS Biopharma, Eli Lilly and Company, Galderma Laboratories, LP, GlaxoSmithKline, Incyte Corporation, Janssen Pharmaceuticals, LEO Pharma, MedImmune, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, Roche, Sanofi Genzyme, Sun Pharma, and UCB.

Marie L.A. Schuttelaar has served on advisory boards for AbbVie, Eli Lilly and Company, Galderma Laboratories, LEO Pharma, LP, Pfizer Inc., and Sanofi Genzyme; as an investigator for AbbVie, Galderma Laboratories, LP, Novartis, Regeneron Pharmaceuticals, Inc., and Sanofi Genzyme; as a consultant for

Regeneron Pharmaceuticals, Inc.; and has received research grants from Novartis and Sanofi Genzyme.

Kevin C Mills, Petra Amoudruz, Azra Kurbasic, Lise Soldbro, and Katja Lophaven are employees of LEO Pharma.

Michael Cork has served as a clinical trial investigator for Astellas Pharma, Galapagos, Johnson & Johnson, LEO Pharma, La Roche-Posay, Merck Sharp & Dohme, Novartis, Perrigo, Regeneron Pharmaceuticals, Sanofi Genzyme, and Stiefel; has served as an advisory board member, consultant, and/or invited lecturer for Amgen, Astellas Pharma, Bayer, Johnson & Johnson, LEO Pharma, L'Oréal, Merck Sharp & Dohme, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, Sanofi Genzyme, Stiefel, and Unilever; has received honoraria from Astellas Pharma, Johnson & Johnson, LEO Pharma, Novartis, Regeneron Pharmaceuticals, Sanofi Genzyme, and Stiefel; and has received research funding from Bayer.

Anthony Bewley has been a consultant for and received consultancy fees or travel bursaries from AbbVie, Almirall, Eli Lilly and Company, Galderma Laboratories, LP, Janssen Pharmaceuticals, LEO Pharma, Novartis, Sanofi, and UCB.

Eric Simpson is a consultant and investigator for AbbVie, Celgene, Dermira, Eli Lilly and Company, Genentech, GlaxoSmithKline, LEO Pharma, Menlo Pharmaceuticals, MedImmune, Pfizer Inc., and Regeneron/Sanofi.

Amy Paller has served as an investigator for AbbVie, AnaptysBio, Incyte Corporation, Janssen Pharmaceuticals, Krystal Biotech, LEO Pharma, Regeneron Pharmaceuticals, and UCB; received honorarium for consultancy from AbbVie, Abeona Therapeutics, Almirall, AnaptysBio, Arena Pharmaceuticals, Azitra, Inc., BiomX, Boehringer Ingelheim, Castle Biosciences, Catawba Research, Dermira, Eli Lilly and Company, Exicure, Inc., Forté, Kamari Pharma, LEO Pharma, LifeMax, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, Sanofi Genzyme, Seanergy, and UCB; and served on a Data Safety Monitory Board for AbbVie, Galderma Laboratories, LP, and Novan.

Abstract: AD-10

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

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BACKGROUND: Tralokinumab is a high affinity monoclonal antibody that specifically neutralizes the interleukin-13 (IL-13) cytokine. The phase 3 ECZTRA 7 trial (NCT03761537) met its primary endpoint of EASI-75 at week 16, confirming tralokinumab plus topical corticosteroids (TCS) is superior to placebo plus TCS in treating severe atopic dermatitis (AD) in patients not adequately controlled by, or with contraindications to, oral cyclosporine A. There can be inadequate disease control with currently available treatment options and many patients with severe AD continue to experience high disease burden.

OBJECTIVES: This post hoc analysis aims to describe the efficacy and safety of tralokinumab in a subgroup of ECZTRA 7 patients with prior history of dupilumab treatment.

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

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

CONCLUSIONS: This post hoc subgroup analysis indicates that dupilumab-experienced patients, including those who discontinued dupilumab due to lack of efficacy or because of adverse events, can benefit from tralokinumab + TCS as needed. Overall frequencies of adverse events in dupilumab-experienced patients treated with tralokinumab + TCS as

needed were consistent with results in the pooled analysis of tralokinumab phase 2 and 3 trials (Simpson E, et al. Presented at 29th EADV Congress, October 29-31, 2020; Abstract 1464).

ACKNOWLEDGEMENTS: The ECZTRA 7 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark. Medical writing and editorial support from Alphabet Health by Clair Geary, PhD, and Krista Mills, was funded by LEO Pharma A/S. This work was previously presented at the 3rd Annual Revolutionizing Atopic Dermatitis (RAD) 2021 Conference (Virtual).

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

Jan Gutermuth reports honoraria as a consultant/advisory board member/ speaker and/or received grants from or is involved in clinical trials with AbbVie, Almirall, Eli Lilly and Company, Genzyme, LEO Pharma, Pfizer Inc., Regeneron Pharmaceuticals, and Sanofi.

Andrew E. Pink has acted as an advisor/speaker for AbbVie, Almirall, Eli Lilly and Company, Janssen Pharmaceuticals, La Roche-Posay, LEO Pharma, Novartis, Pfizer Inc., Sanofi, and UCB.

Margitta Worm has served as a scientific advisor and/or clinical trial investigator and/or paid speaker for AbbVie, Aimmune Therapeutics, ALK, Allergopharma, Boehringer Ingelheim, Dermira, Eli Lilly and Company, Galderma Laboratories, LP, Janssen Pharmaceuticals, LEO Pharma, Mylan, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, and Sanofi Genzyme.

Lise Soldbro, Thomas Mark, Joshua Corriveau, Kevin C Mills, and Christian Bjerregård Øland are employees of LEO Pharma A/S.

Stephan Weidinger is co-principal investigator of the German Atopic Eczema Registry TREATgermany. He has received institutional research grants from La Roche-Posay, LEO Pharma, and Sanofi Deutschland GmbH; has performed consultancies for AbbVie, Eli Lilly and Company, Kymab, LEO Pharma, Novartis, Pfizer Inc., Regeneron Pharmaceuticals, and Sanofi Genzyme; he has also lectured at educational events sponsored by AbbVie, Galderma Laboratories, LP, LEO Pharma, Novartis, Regeneron Pharmaceuticals, and Sanofi Genzyme; and is involved in performing clinical trials with many pharmaceutical industries that manufacture drugs used for the treatment of psoriasis and atopic eczema.

Abstract: AD-11

Feasibility of a Novel, Noninvasive Sample Collection Technique to Develop a Molecular Test Guiding Therapeutic Selection for Patients With Atopic Dermatitis and Psoriasis

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BACKGROUND: Recent advances in understanding the molecular pathways underlying the development of atopic dermatitis (AD) led to the development of multiple novel systemic drugs targeting those pathways. As more therapeutics are approved for treatment of AD, it will be important to make informed decisions about each individual patient's therapeutic plan. However, choosing a systemic therapy for AD may not be straightforward. Indeed, currently approved therapeutics target interleukin (IL)-4 and IL-13 cytokines or the JAK/ STAT pathway, and clinical trials show promise for additional therapeutic options. Further confounding therapeutic selection, a subset of AD can mimic psoriasis (PSO). Therefore, understanding an individual patient's disease at the molecular level could better inform treatment decisions. However, developing a test to incorporate each patient's personal molecular biology into guiding therapeutic selection requires a clinically feasible test. The objective of this study is to determine the feasibility of a quick noninvasive skin scraping technique to yield sufficient RNA to assess differentially expressed molecular biomarkers in the epidermis of patients with AD and PSO.

METHODS: The superficial epidermis of lesional and non-lesional skin from 20 patients with AD and 20 patients with PSO from two dermatology centers in the United States was collected by gently scraping the skin 10 times with a curette and immediately preserving in an RNA-preserving buffer. Samples were shipped at ambient temperature and frozen at -80 degrees Celsius upon receipt. RNA was isolated and quantified by Nanodrop, converted to cDNA, pre-amplified, and run on TaqMan OpenArray Real-Time polymerase chain reaction (PCR) plates to assess relative gene expression of 28 genes by 2 separate operators. For gene expression analysis, the average 2-CT was compared between lesional and non-lesional skin for AD and PSO. A log2 fold change > 1.0 was considered an increase and a log2 fold change < -1.0 was considered a decrease in gene expression.

RESULTS: Across 28 genes assessed, expression of 6 genes was increased in lesional AD compared to non-lesional AD skin samples. Further, in lesional PSO samples, expression of 7 genes was increased and 1 gene was decreased relative to non-lesional PSO. Compared to lesional PSO, AD samples exhibited increased expression of 7 genes and decreased expression of 3 genes. Further, 2 of 7 genes with increased expression in lesional AD also demonstrated increased expression in non-lesional AD relative to non-lesional PSO samples. Interoperator variability was low with a Pearson's correlation of > 0.99 observed between operators for average CT values for each gene by disease state.

CONCLUSIONS: A noninvasive skin scraping technique produces sufficient RNA to assess replicable gene expression by quantitative RT-PCR in lesional and non-lesional AD and PSO for the purposes of developing a gene expression profile to help guide personalized therapeutic decision-making.

Abstract: AD-12

Improvement in Disease Severity and Quality of Life in Patients With Atopic Dermatitis (AD) Treated With Dupilumab for up to 18 Months: Real-World Evidence From the PROSE Registry

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BACKGROUND: Dupilumab provides rapid and sustained long-term efficacy with an acceptable safety profile in patients with moderate to severe atopic dermatitis (AD) in clinical trials. We assessed AD patients for up to 18 months (M18) after initiating dupilumab treatment, using real-world data from the PROSE registry.

METHODS: PROSE (NCT03428646) is an ongoing registry in the United States and Canada in patients aged ≥ 12 years with moderate to severe AD initiating real-world dupilumab treatment for AD per approved prescribing information. Assessments included body surface area (BSA) affected; Eczema Area and Severity Index (EASI); Dermatology Life Quality Index (DLQI); Peak Pruritus Numerical Rating Scale (PP-NRS), Patient-Oriented Eczema Measure (POEM), and Patient Global Assessment of Disease (PGAD) questionnaire scores. Data are presented as observed, including all patients with available values at baseline and M18, at the time of data cutoff (09/2020). No formal statistical hypothesis testing was performed.

RESULTS: 563 patients were included (42.5% male, 95% aged ≥ 18 years). Baseline mean (SD) age was 41.0 (17.9) years; mean (SD) duration of AD was 17.8 (16.6) years. 70 (12.4%) patients withdrew from the study. Dupilumab treatment for 18 months improved (mean [SD]): EASI (baseline: 16.4 [12.9], M18: 3.0 [5.4]; mean change from baseline: -15.2 [13.2]) and % BSA affected (baseline: 25.4 [22.5], M18: 6.2 [12.5]; mean change from baseline: -22.6 [23.1]). Dupilumab treatment for 18 months also improved patient-reported PP-NRS scores, DLQI, and POEM scores and the proportion of patients reporting "very good/excellent" in the PGAD questionnaire.

CONCLUSION: In the PROSE registry, dupilumab provided up to 18 months of sustained improvement in signs, symptoms, and quality-of-life in real-world patients with moderate to severe AD.

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Abstract: AD-13

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

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

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

METHODS: Surface plasmon resonance (SPR) was used to assess competitive binding of anti-IL-13 monocolonal antibodies (mAbs) to recombinant glycosylated human IL-13. Cendakimab and tralokinumab were immobilized on separate flow cells of a CM4 chip. Sequential injections of human IL-13 (100 nM) and either cendakimab, lebri, tralokinumab, or control IgG (5 μg/mL) were made to assess binding. To investigate whether lebri interfered with IL-13 binding to IL-13Ra2, first, IL-13Rα2 expression was induced on HaCaT cells, a spontaneously transformed keratinocyte cell line from adult human skin, using a co-treatment of IL-4 and TNF-alpha. Confocal microscopy live cell imaging were performed where the cells were pre-incubated with 0.1 μg/mL Hoechst 33342 for nuclear stain and different combination of 5 μg/mL anti-IL-13Rα2-Alexa Fluor (AF)488 or 5 μg/mL anti-IL-13Rα1-AF488 for receptors staining or anti-IL-13Rα1 for IL-13Rα1 blocking or 500 ng/mL IL-13-AF568 or 7.5 μg/mL lebrikizumab-AF647 or 7.5 μg/mL cendakimab-AF647 or 24.8 μg/mL

tralokinumab-AF647 or 7.5 μg/mL isotype control-AF647 for 1 hour. These experiments were conducted in the presence of an IL-13Rα1 inhibitory antibody to ensure the observed binding is only through IL-13Rα2.

RESULTS: Through competitive binding experiments using SPR, we confirmed that lebri can bind to the tralokinumab/IL13 and cendakimab/IL13 complexes. These data showed that lebri binds to IL13 at a different epitope. From the fluorescently stained cells, we confirmed the increased expression of IL-13Rα2 with the IL-4/TNF-α cotreatment. From live-cell confocal imaging, we observed that IL13 can bind IL13Ra2 and is internalized into the cells. Importantly, we also observed binding and internalization of the IL13/lebri complex, while IL13/tralokinumab and IL13/cendakimab complexes do not bind to the IL-13Rα2 receptor and are not internalized into the cells. The internalized IL13/lebri complex colocalized with a lysosome marker, indicating that it is likely to be degraded in lysosomes.

CONCLUSION: In summary, lebri allows IL13 to bind and internalize through the IL13Rα2. This mode of action differentiates it from tralokinumab and cendakimab, since lebri allows natural clearance of IL13 levels through IL13Rα2.

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DISCLOSURE: Study was funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company.

Abstract: AD-14

Lebrikizumab Monotherapy Improves Itch and Sleep, Which Impacts Quality of Life in Two Phase 3 Trials

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BACKGROUND: Lebrikizumab improved itch, interference of itch on sleep, and quality of life (QoL) at 16 weeks compared to placebo in two phase 3 trials.

OBJECTIVE: To evaluate the impact of improvements in itch and sleep loss due to itch on QoL measurements after treatment.

METHODS: Data were from ADvocate1 (NCT04146363) and ADvocate2 (NCT04178967) in subjects with moderate to severe atopic dermatitis (AD). The Dermatology Life Quality Index (DLQI) was evaluated at week 16 in subjects (≥ 17 years of age) who met a 4-point improvement in itch (Pruritus Numeric Rating Scale) and were responders to itch, or a 2-point improvement in effect of itch interference on sleep (Sleep-Loss Scale) and were responders to sleep vs subjects who were not responders in either criteria. The number in each subgroup (n) included subjects treated with placebo and subjects treated with lebrikizumab 250 mg every 2 weeks. The DLQI total scores for these subgroups were analyzed using ANCOVA with imputation of last observation carried forward. Binary endpoints were analyzed using logistic regression, with treatment, geographic region, age group, baseline disease severity, subgroup, and treatment by subgroup interaction as factors with nonresponder imputation.

RESULTS: Significantly greater proportions of itch responders ($P < .0001$) had a clinically meaningful ≥ 4-point DLQI improvement (n = 107: 93.5% and n = 86: 96.5% in ADvocate1 and ADvocate2, respectively) compared to itch nonresponders for each trial (n = 216: 40.3% and n = 216: 34.7%, respectively). Significantly greater proportions of itch responders ($P < .01$) achieved DLQI scores (0,1) (n = 110: 42.7% and n = 87: 34.5% in ADvocate1 and ADvocate2, respectively) compared to itch nonresponders (n = 224: 7.6% and n = 220: 5.0%, respectively) or a ≥ 5-point DLQI improvement in itch responders (n = 102: 74.5% and n = 79: 67.1%, respectively) compared to itch nonresponders (n = 207: 21.3% and n = 200: 19.0%, respectively). Among subjects with a baseline Sleep-Loss Scale ≥ 2, significantly greater proportions of Sleep-Loss Scale responders (2-point improvement) ($P < .001$) had a DLQI improvement of ≥ 4 points (n = 69: 97.1% and n = 41: 97.6% in ADvocate1 and ADvocate2, respectively) compared to nonresponders (n = 176: 44.9% and n = 167: 41.9%, respectively). Significantly greater proportions of Sleep-Loss Scale responders ($P < .05$) achieved a DLQI score of (0,1) (n = 70: 48.6% and n = 41: 31.7% for ADvocate1 and ADvocate2, respectively) or a > 5-point DLQI improvement (n = 67: 79.1% and n = 38: 63.2%, respectively) compared to Sleep-Loss Scale nonresponders (n = 179: 6.1% and n = 169: 4.1% and n = 171: 18.7% and n = 162: 21.0%, respectively).

CONCLUSION: Improvement in itch and itch interference on sleep is associated with improvement in the health-related QoL in patients with AD treated with lebrikizumab.

DISCLOSURE: This study was funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company.

Abstract: AD-15

Long-Term Efficacy of Dupilumab in Adults With Moderate to Severe Atopic Dermatitis (AD): Results From an Open-Label Extension (OLE) Trial up to 4 years

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BACKGROUND: Atopic dermatitis (AD) is a chronic systemic inflammatory disease often requiring long-term management. Here, we present long-term efficacy of dupilumab up to 4 years in adult patients with moderate to severe AD.

METHODS: The OLE (NCT01949311), with an initial duration of 3 years, enrolled adults with moderate to severe AD who participated in a dupilumab parent study. Protocol amendments extended the maximum treatment duration to 5 years. Following protocol amendments in 2017 and 2018, 114 and 272 patients re-entered the trial; 103 and 207 patients had a treatment interruption of > 8 weeks between weeks 148 and 164. Patients were treated with 300 mg dupilumab weekly. In 2019, patients transitioned to 300 mg every 2 weeks to align with approved dosage. Concomitant topical anti-inflammatory treatments were permitted. Data shown are for the overall study population (N = 2677).

RESULTS: 2207/1,065/557/362/352 patients completed up to 52/100/148/172/204 weeks of treatment. 240 patients had treatment duration > 204 weeks. Most withdrawals (59.5%) were due to dupilumab approval; 8.4%/4.3% withdrew due to adverse events/lack of efficacy. At week 204, 95%/91%/76% of patients achieved 50%/75%/90% reductions in Eczema Area and Severity Index from parent study baseline (PSBL). A total of 78.7%/70.8% of patients achieved ≥ 3 / ≥ 4-point reduction in the Peak Pruritus Numerical Rating Scale score from PSBL at week 204. Treatment-emergent adverse events were reported in 2273 (84.9%) patients, with 99 (3.7%) permanently discontinuing treatment.

CONCLUSIONS: Long-term dupilumab treatment showed sustained efficacy substantiated by improvement of AD signs and symptoms in patients with moderate to severe AD up to 204 weeks. Safety data were consistent with prior studies.

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Abstract: AD-16

Safety of Long-Term Dupilumab Treatment in Adults With Moderate to Severe Atopic Dermatitis: Results from an Open-Label Extension (OLE) Trial up to 4 years

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BACKGROUND: Atopic dermatitis (AD) is a chronic systemic inflammatory disease requiring long-term management. We extend the dupilumab safety profile in patients with moderate to severe AD to 204 weeks.

METHODS: The OLE (NCT01949311), with an initial duration of 3 years, enrolled adults with moderate to severe AD who participated in any dupilumab parent study. Protocol amendments allowed for patient re-entry and treatment extension for up to 5 years. Patients were treated with 300 mg dupilumab weekly. In 2019, patients transitioned to 300 mg every 2 weeks to align with approved dosage. Concomitant topical treatments were permitted. Data shown are for the overall study population (N = 2677).

RESULTS: 2207/1,065/557/362/352 patients completed up to 52/100/148/172/204 weeks of treatment. A total of 240 patients had treatment duration of > 204 weeks. Most withdrawals (59.5%) were due to dupilumab approval/commercialization; 8.4%/4.3% withdrew due to adverse events (AEs)/lack of efficacy. Exposure-adjusted incidence rates of treatment-emergent AEs (TEAEs) were lower in this OLE vs the 300 mg weekly + topical corticosteroid arm of the 1-year CHRONOS trial (167.5 vs 322.4 number of patients/100 patient-years). A total of 10.4% of patients had serious TEAEs; 9.8%, severe TEAEs; 1.2%, ≥ 1 serious TEAE related to study drug; and 3.7%, TEAEs resulting in permanent drug discontinuation. The most common TEAEs were nasopharyngitis (28.9%) and conjunctivitis (20.0%, including allergic/bacterial/viral/atopic keratoconjunctivitis). The most common severe TEAEs by MedDRA Preferred Term were dermatitis atopic (0.9%) and conjunctivitis (0.7%). Among patients with conjunctivitis TEAEs, 95% were reported as mild/moderate; 87% of conjunctivitis events were recovered/resolved.

CONCLUSIONS: This analysis extends to 4 years the previous findings demonstrating dupilumab's acceptable long-term safety profile.

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Abstract: AD-17

Spesolimab Safety in Generalized Pustular Psoriasis, Palmoplantar Pustulosis and Atopic Dermatitis

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BACKGROUND: Interleukin (IL)-36 is central to the pathophysiology of generalized pustular psoriasis (GPP). Spesolimab is a first-in-class anti-IL-36 receptor antibody that demonstrated efficacy and safety in patients with GPP flares.

OBJECTIVES: To describe potential adverse events (AEs) of spesolimab across 5 trials: 2 in GPP (1368.11; Effisayil 1) and palmoplantar pustulosis (PPP) (1368.15; 1368.16), and one in atopic dermatitis (AD) (1368.32).

METHODS: All trials had different study designs, durations of treatment, spesolimab doses, and administration routes (Table). Trial 1 (1368.11; NCT02978690): phase 1; 7 patients with GPP flares; 20-week duration. Trial 2 (Effisayil 1; NCT03782792): phase II; 53 patients with GPP flares; 12-week duration. Trial 3 (1368.15; NCT03135548): phase IIa; 59 patients with PPP; 32-week duration. Trial 4 (1368.16; NCT04015518) phase IIb; 152 patients with PPP; 68-week duration. Trial 5 (1368.32; NCT03822832): phase IIa; 51 patients with AD; 44-week duration. Safety is reported up to week 20 in trial 1, week 1 (eosinophils up to week 12) in Effisayil 1 (trial 2), and week 16 in trials 3 through 5. Clinically relevant abnormal laboratory values were repeated until normalization, stabilization, or an alternate explanation was found. Clinically relevant abnormal values were recorded as AEs and graded for intensity. Normal eosinophil values were defined as ≤ 0.57 x 109/L.

RESULTS: Spesolimab was well tolerated across all trials with a safety profile similar to placebo (Table). Total patients across the 5 trials: spesolimab n = 222; placebo n = 100. In 2 of the 4 placebo-controlled trials, infections and infestations were numerically lower in patients who received spesolimab vs those who received placebo (trial 3: 50.0% vs 57.1%; trial 4: 24.8% vs 32.6%). In Effisayil 1 and trial 5, infections were higher in the spesolimab arm than the placebo arm (17.1% vs 5.6%; 33.3% vs 22.2%). Most cases were mild and not indicative of opportunistic infection. The frequency of serious infections and investigator-defined drug-related AEs was similar across study arms and trials. AEs leading to discontinuation were numerically lower in spesolimab than placebo arms in trial 3 (10.5% vs 14.3%) and trial 4 (4.6% vs 11.6%), and numerically higher in trial 5 (21.2% vs 16.7%); no AEs were reported in trial 1 or Effisayil 1. The frequency of hypersensitivity reactions was similar between spesolimab and placebo arms and across trials (Effisayil 1: 8.6% vs 5.6%; trial 4: 11.9% vs 9.3%; trial 5: 33.3% vs 44.4%). The mean maximum on-treatment eosinophil values ranged from 0.14 to 1.15 x 109/L across the 4 placebo-controlled studies with values comparable between spesolimab and placebo arms. There was no evidence of elevated liver enzymes associated with spesolimab.

CONCLUSION: Spesolimab demonstrated a consistent safety profile across conditions in a small population. The frequency and severity of AEs were similar between study arms across trials.

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Table. Overall safety profile of spesolimab across the five trials

	Trial 1 (1368.11 GPP)	Trial 2 (Effisayil 1 GPP)		Trial 3 (1368.15 PPP)		Trial 4 (1368.16 PPP)		Trial 5 (1368.32 AD)	
Safety data up to	Week 20	Week 1		Week 16		Week 16		Week 16	
Patients	Spesolimab (N=7)	Spesolimab (n=35)	Placebo (n=18)	Spesolimab (n=38)	Placebo (n=21)	Spesolimab (n=109)	Placebo (n=43)	Spesolimab (n=33)	Placebo (n=18)
Spesolimab dose	10 mg/kg IV SD	900 mg IV SD	–	900/300 mg IV q4w (pooled)	–	1500/ 3000 mg SC LD; 300/600 mg SC q4w (pooled)	–	600 mg IV q4w	–
Any AE, n (%)	7 (100.0)	23 (65.7)	10 (55.6)	34 (89.5)	18 (85.7)	80 (73.4)	33 (76.7)	24 (72.7)	10 (55.6)
Severe AE (RCTC ≥3), n (%)	0	2 (5.7)	1 (5.6)	4 (10.5)	2 (9.5)	7 (6.4)	3 (7.0)	4 (12.1)	6 (33.3)
Investigator-defined drug-related AE, n (%)	4 (57.1)	10 (28.6)	5 (27.8)	16 (42.1)	9 (42.9)	39 (35.8)	13 (30.2)	4 (12.1)	6 (33.3)
AE leading to drug discontinuation, n (%)	0	0	0	4 (10.5)	3 (14.3)	5 (4.6)	5 (11.6)	7 (21.2)	3 (16.7)
Serious AE*, n (%)	0	2 (5.7)	0	1 (2.6)	1 (4.8)	5 (4.6)	2 (4.7)	3 (9.1)	1 (5.6)
Required or prolonged hospitalisation	0	2 (5.7)	0	1 (2.6)	1 (4.8)	4 (3.7)	2 (4.7)	2 (6.1)	0
Was life threating	0	0	0	0	0	1 (0.9)	0	0	0
Persistent or significant disability or incapacity	0	0	0	0	0	1 (0.9)	0	0	0
Other medically important serious AE	0	0	0	0	0	1 (0.9)	1 (2.3)	1 (3.0)	1 (5.6)
Congenital anomaly or birth defect	0	0	0	0	0	0	0	0	0
Resulted in death	0	0	0	0	0	0	0	0	0

*A patient may have serious AEs with multiple seriousness criteria.
AD, atopic dermatitis; AE, adverse event; GPP, generalized pustular psoriasis; IV, intravenous; LD, loading dose; PPP, palmoplantar pustulosis; q4w, every 4 weeks; RCTC, Rheumatology Common Toxicity Criteria; SC, subcutaneous; SD, single dose.

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Abstract: AD-18

The Impact of Tralokinumab on Quality of Life and School in Patients Aged 12 to 17 Years With Atopic Dermatitis: Results From the Phase 3 ECZTRA 6 Trial

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BACKGROUND: Atopic dermatitis (AD) has a substantial impact on quality of life (QoL) and school in adolescents.
OBJECTIVES: The objective of this study was to examine the impact of tralokinumab on AD-related QoL in school.
METHODS: Adolescents with moderate to severe AD (N = 289) received tralokinumab 150 mg or 300 mg or placebo (PBO) every 2 wks (Q2W). QoL and impact on school was measured by the Children's Dermatology Life Quality Index (CDLQI), a 10-item questionnaire assessing pt/caregiver-reported AD impact. Change and proportion of patients (pts) with ≥ 6 point reduction (minimal important difference) from baseline (BL) to week (wk)16 in total CDLQI was evaluated via linear mixed model for repeated measures and Cochran-Mantel-Haenszel test, respectively. Individual CDLQI domains were evaluated with Pearson chi-square test.
RESULTS: Adjusted mean change from BL in total CDLQI at wk16 was greater with tralokinumab 150 mg (-6.1, $P < .05$) and 300 mg (-6.7, $P < .01$) vs PBO (-4.1); more pts had ≥ 6-point reduction (31.0% [$P < .05$], 39.5% [$P < .001$] vs 15.9%). Association between treatment and school/holiday item was observed at wk16 (150 mg/300 mg vs PBO, $P < .05/.01$). At wk16, AD had "not at all" affected school/holiday over the past 7 days in 54.2/60.0% vs 38.2% pts in tralokinumab 150 mg/300 mg vs PBO, respectively, while it had "very much" affected this item in 3.4/1.5% vs 17.6%. Corresponding BL data were 18.9/29.8% vs 18.0% for "not at all" affected and 22.1/25.5% vs 27.0% for "very much" affected. Trends for improvement with tralokinumab at wk16 were seen in other CDLQI domains.
CONCLUSIONS: Tralokinumab improved QoL in adolescents with moderate to severe AD; benefits were observed in school/holiday and across multiple domains, with largest improvements seen in the 300 mg group.
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DISCLOSURE: The ECZTRA 6 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark.

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Abstract: AD-19

Tralokinumab Demonstrated a Consistent Safety Profile With up to 42 Months of Treatment in Moderate to Severe Atopic Dermatitis: Including Adverse Events of Special Interest

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BACKGROUND: Tralokinumab, which specifically targets interleukin (IL)-13, is approved in multiple countries for treatment of adults with moderate to severe atopic dermatitis (AD). During the initial 12-to-16-week placebo-controlled treatment period of the phase 2 and 3 trials, tralokinumab was well-tolerated with an overall frequency of adverse events (AEs) similar to placebo. An ongoing open-label extension trial, ECZTEND (NCT03587805), is assessing safety and efficacy of tralokinumab up to 5 years after parent trials (PT).

OBJECTIVES: To report an interim safety analysis of patients on tralokinumab for up to 42 months (≤ 1 year in PT and ≤ 2.5 years in the open-label extension ECZTEND), including AEs of special interest (AESI).

METHODS: In ECZTEND, moderate to severe AD patients who completed previous PT received subcutaneous tralokinumab 300 mg every 2 weeks after a 600 mg loading dose; topical corticosteroid use was optional. All AEs were recorded, coded, and classified by severity/causality/outcome. AESIs were predefined in PT based on areas of safety interest for biologics in AD. Event rates are presented as the number of events (nE) per 100 patient-years of exposure (PYE). All AEs described were treatment-emergent AEs, defined as AEs reported after the first dosing of study drug.

RESULTS: As of April 30, 2021, the interim safety analysis included 1442 patients from the PT ECZTRA 1, 2, 3, 4, 5, and 7 who had received ≥ 1 dose of tralokinumab in ECZTEND, with 121.0 weeks mean exposure time on tralokinumab [median 131.5 weeks (IQR 83.4-161.8)]. Total exposure time in ECZTEND was 2446.2 PYE. Overall, 1127 patients experienced an AE (198.7 nE/100 PYE), the majority of which were mild (132.6 nE/100 PYE). The most frequently reported AEs (≥ 5.0% of patients) were the same as in the PT, including viral upper respiratory tract infection (18.2 nE/100 PYE, mainly reported as common cold), atopic dermatitis (17.9 nE/100 PYE), upper respiratory tract infection (5.8 nE/100 PYE), headache (4.4 nE/100 PYE), and conjunctivitis (3.8 nE/100 PYE). The rates of AEs were generally lower as compared to short-term rates in the PT. Most of the serious AEs (SAEs; 4.9 nE/100 PYE) were reported as single events without clustering on type. No events of conjunctivitis AEs were SAEs, and only 5 patients discontinued due to conjunctivitis AEs. AESI eye disorders, skin infections requiring systemic treatment, eczema herpeticum, and malignancies were observed at rates similar to or lower than reported in PT.

CONCLUSIONS: Consistent safety was demonstrated during up to 42 months tralokinumab treatment in patients with moderate to severe AD. Exposure-adjusted incidence rates of AESIs, including eczema herpeticum and skin infections requiring systemic treatment, were generally lower than rates reported during the short-term, placebo-controlled period up to week 16. This analysis supports the long-term benefit-risk profile of targeted IL-13 inhibition with tralokinumab for patients with moderate to severe AD.

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CUTANEOUS MALIGNANCIES

Abstract: CM-01

A Comparison of Surgical Management Techniques for Resection of Porocarcinoma

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INTRODUCTION: Porocarcinoma is a rare, cutaneous neoplasm of eccrine sweat glands, most commonly of the head and neck in older adults. While wide local excision (WLE) has traditionally been the surgical technique of choice for porocarcinoma resection, the number of cases treated using Mohs micrographic surgery (MMS) is increasing. To date, few studies have examined outcomes of MMS as compared to gold standard WLE for the treatment of porocarcinoma.

METHODS: A retrospective chart review was conducted to identify patients diagnosed with eccrine porocarcinoma (EPC) at our institution between January 2015 and February 2020. Pearson chi-square and Fisher's exact test were used to evaluate outcomes in patients treated with WLE as compared to MMS.

RESULTS: Of 19 cases at our institution, 12 had sufficient follow-up to evaluate outcomes following surgical treatment. Patients were most often White (66.67%) with a mean age of 63 years at diagnosis. There were equal numbers of males (M) and females (F) (6 each). Eight patients underwent WLE (4 M and 4 F), and four patients received MMS (2 M and 2 F, $P = .727$). WLE recipients were younger, with an equal number of White and Black patients. All patients in the MMS group were White ($P = .141$) and older ($P = .463$). WLE was performed on the head and neck (6), trunk (1), and lower extremities (1). MMS was most often performed on the head and neck (3), with one case performed on the trunk. Patients with more severe disease underwent WLE. Local recurrence rate was 12.5% in the WLE group (vs 0% for MMS) and 37.5% for recurrence or regional metastasis in remission following additional therapies (vs 25% for MMS). Mortality rate was 25% for each group.

DISCUSSION: Porocarcinoma is a rare skin cancer that is often locally aggressive and potentially fatal. Though surgical excision is the mainstay of treatment, prognosis following WLE is poor. MMS is utilized for treatment of porocarcinoma with increasing frequency. Our results suggest that MMS is a useful modality for the surgical treatment of porocarcinoma. Future studies are necessary to optimize porocarcinoma survival outcomes.

Abstract: CM-02

Clinical Performance of Novel Elastic Scattering Spectroscopy (ESS) in Detection of Skin Cancer: A Blinded, Prospective, Multi-Center Clinical Trial (Initial Results)

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BACKGROUND: Skin cancer incidence is increasing worldwide, and primary care providers (PCPs) have difficulty in identifying skin lesions that are in need of further evaluation. Additionally, access to dermatologists is limited in much of the United States. Leveraging technology may aid PCPs in improving skin cancer detection and associated referrals, thereby reducing associated mortality and morbidity, and lessening the burden on the healthcare system. This study investigated the sensitivity (Se) and specificity (Sp) of a noninvasive, handheld ESS device in evaluating skin lesions compared to that of PCPs' clinical evaluation alone.
METHODS: This blinded, prospective, multi-center study was conducted at 22 primary care study sites across the United States (18 sites) and Australia (4 sites). Patients with lesions suggestive of skin cancer were clinically assessed by PCPs, and then evaluated by the ESS device. Patients and PCPs were blinded to device output. For all enrolled patients, lesions were biopsied per physician assessments and standard of care. Each lesion's diagnosis involved 2 to 5 dermatopathologists dependent on pathology and discordance. Statistical analyses included standard diagnostic test parameters (ie, Se, Sp, NPV, PPV) of the device for detecting skin cancer as well as the influence of lesion and patient factors on device performance.
RESULTS: A total of 1005 patients with 1579 lesions suggestive of skin cancer were enrolled in this study. Among the enrolled patients, 51% were female with a mean age of 59 years, and 73% of patients were Fitzpatrick Skin Type I-III. On average, patients contributed one (65%) or two (21%) lesions to the final dataset. The PCPs diagnosed 807 lesions as "malignant", of which 322 were classified as "melanoma". Dermatopathology evaluation confirmed 224 high risk lesions: 48 melanomas (including highly atypical nevi), 90 basal cell carcinomas (BCCs) and 86 squamous cell carcinomas (SCCs). The ESS device had an overall Se of 96%, which was superior to the PCPs' overall diagnostic Se of 83% ($p<0.0001$). The overall Sp of the device was 21% for ruling out benign lesions. The NPV of the device was 97% and the PPV was 17% (i.e. an NNB of 6:1). Device use has the potential to improve PCP Se for skin cancer from 83% to 96% for abnormal lesions ($p<0.0001$). The Se+Sp logistic regression model of the device demonstrated statistical significance (OR: 4.93, $p<0.0001$).
CONCLUSION: The novel ESS device demonstrated high sensitivity in detecting skin cancer when compared to the gold standard of histopathologic examination. Coupled with clinical exam findings, this device may aid PCPs to improve clinical decisions about suspicious skin lesions (ie, to biopsy, refer, or monitor).

Abstract: CM-03

Hair Stylists Against Skin Cancer – An Interventional Study

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BACKGROUND: Scalp skin cancers can have delayed detection due to their discreet location. Hairstylists are uniquely positioned to educate and aid their clients in skin cancer detection but receive limited education on skin cancer in their training.
OBJECTIVES: This study aimed to assess hairstylists' basic understanding of skin cancer, ability to recognize skin cancer, and confidence in detecting skin cancer before and after an educational intervention.
METHODS: This study received institutional review board (IRB) approval and included sites across multiple cities in Missouri, Ohio, and Kentucky. Hair stylist students were given identical surveys assessing basic understanding, recognition, and confidence in detecting skin cancer before and after an educational lecture. The lecture reviews key concepts and Kodachrome examples of common skin cancers, such as squamous cell carcinoma, basal cell carcinoma, and melanoma, and common benign mimickers like seborrheic keratoses. Knowledge questions were assessed in multiple choice format and scored by percentage of correct answers. Questions assessing confidence in skin cancer detection were scored using a Likert scale. Lectures and data collection were conducted in person between December 2021 and March 2022.
RESULTS: A total of 171 students across five schools participated in the study. The majority of participants (87%) completed both the pre- and post-intervention surveys. Most participants were 20 to 30 years of age (51%), female (97%), White (69%), and had high school as their highest level of education (74%). Regarding skin cancer knowledge,

93 (62.4%) of those participants who completed both a pre- and post-intervention survey increased their overall score, 9 (6%) did worse by 1 or 2 points, and 47 (31.5%) had no change in score. A total of 27 subjects (16.6%) scored 100% on the pre-test, of which 25 (93%) maintained their score of 100% on the pre-test (Figure 1) The knowledge score post-intervention was significantly higher than pre-intervention (mean 9.21, SD 1.13 vs mean 8.05, SD 1.39; $P < .001$). The only significant predictor of improvement in scores was in minority students, having over 2.7 times higher odds of improvement than White students. The intervention made a statistically significant improvement in the percentage of correct answers for 5 of the 10 of the knowledge-based questions. The questions with the most noteworthy improvement included those addressing skin cancer incidence and the ABCDEs of melanoma. Hairstylists also reported significantly increased confidence in educating clients, identifying lesions, and willingness to refer out for suspicious lesions post-intervention (Figure 2).

CONCLUSIONS: This intervention significantly improved hair stylists' knowledge of skin cancer and increased their confidence in recognizing suspicious lesions. More study is

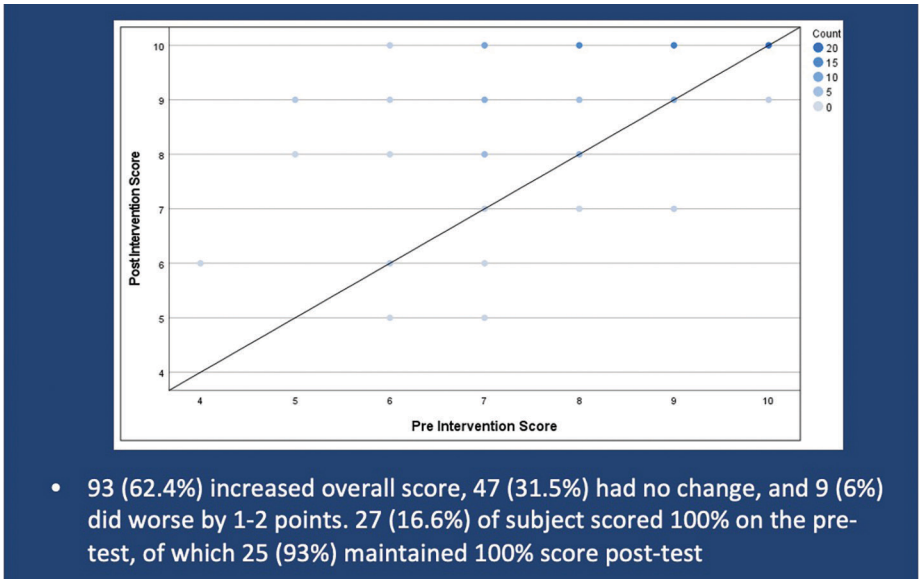

FIGURE 1: Change in Scores Pre- vs Post- Intervention

	Pre-Intervention Median (IQR)	Post-Intervention Median (IQR)	p-value**
Cosmetology school provides enough education on skin conditions, including skin cancer	0 (-1 – 1)	0 (0 – 1)	<0.001
Hairstylists can help doctors find skin cancer in their clients	1 (1 – 2)	1 (1 – 2)	<0.001
I feel comfortable identifying a lesion suspicious for skin cancer on clients	0 (-1 – 1)	1 (1 – 1)	0.000
I feel comfortable informing a client about a lesion suspicious for skin cancer	0 (0 – 1)	1 (1 – 2)	<0.001
I feel comfortable educating clients about skin cancer prevention	0 (-1 – 1)	1 (0 – 1.5)	<0.001
I feel comfortable referring a client to a doctor upon seeing a suspicious skin lesion	1 (0 – 1)	1 (1 – 2)	<0.001
I believe that the topic of this lecture is important	2 (1 – 2)	2 (1 – 2)	0.07

* Scored as: -2: Strongly Disagree, -1: Disagree, 0: Neutral, 1: Agree, 2 Strongly Agree

**Related samples Wilcoxon Signed ranks test

FIGURE 2: Hairstylists' Confidence in Identifying Skin Cancer Pre- vs Post- intervention

needed to determine if engaging hairstylists in skin cancer screening and dermatology referral ultimately improves patient outcomes.

Abstract: CM-04

Incorporating the 31-Gene Expression Profile Test Stratifies Survival Outcomes and Leads to Improved Survival Compared to Clinicopathologic Factors Alone: A Surveillance, Epidemiology, and End Results (SEER) Program Collaboration

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INTRODUCTION AND OBJECTIVES: The 31-gene expression profile (31-GEP) test for cutaneous melanoma (CM) is a validated prognostic test that stratifies patients with stage I to III CM into groups at low (class 1A), intermediate (class 1B/2A), and high (class 2B) risk of recurrence or metastasis. In collaboration with the National Cancer Institute's and Surveillance, Epidemiology, and End Results (SEER) program (covering 34% of the U.S. population during the study period), the study's objectives were to (a) confirm the performance of the 31-GEP for risk stratification in an unselected, prospectively tested cohort; and (b) compare survival outcomes between patients tested with the 31-GEP versus patients not tested with the 31-GEP.

MATERIALS AND METHODS: Patient data, including melanoma-specific survival (MSS) and overall survival (OS), provided by SEER registries (diagnosis 2013-2018), was linked to data for patients with stage I to III CM tested with the 31-GEP (N = 5226). Kaplan-Meier analysis with log-rank test was used to analyze patient survival. To assess whether patients tested with the 31-GEP had higher survival rates than untested patients, a cohort of 31-GEP tested patients (n = 3621) was matched to untested patients (N = 10,863) by 11 covariates in a 1:3 ratio. Matching cases were limited to diagnosis in 2016 and forward, controlling for potential access to adjuvant therapy.

RESULTS: Patients with a 31-GEP class 1A result had higher 5-year MSS (99.2% vs 85.4%) and OS (95.2% vs 74.5%) than patients with a class 2B result. A class 2B result was a significant predictor of MSS (HR = 8.51, $P < .001$) and OS (HR = 2.48, $P < .001$) in multivariable analysis. Age (HR = 1.05, $P < .001$), Breslow thickness (HR = 1.18, $P < .001$), and a positive sentinel lymph node (SLN) (HR = 2.26, $P = .004$) were significant predictors for MSS, and age (HR = 1.09, $P < .001$), Breslow thickness (HR = 1.15, $P < .001$), an unknown SLN status (HR = 1.47, $P = .013$), and positive SLN (HR = 1.56, $P = .032$) were significant predictors for OS. After developing a matched cohort of 31-GEP tested and untested patients (matched by patient age, median follow-up time, T-stage, year of diagnosis, sex, mitotic rate, socioeconomic status (Yost index), SLN assessment and positivity rates, primary tumor site, and race), patients tested with the 31-GEP had a 27% (HR = 0.73, $P = .028$) and 21% (HR = 0.79, $P = .006$) MSS and OSS survival benefit, respectively, compared to untested patients.

CONCLUSIONS: Consistent with prior retrospective and prospective studies, in a large, unselected, prospectively tested cohort of patients with stage I to III CM, the 31-GEP stratified patient mortality risk. Most importantly, patients with 31-GEP test results in addition to traditional clinicopathologic factors had improved survival compared to patients with only traditional clinicopathologic factors available to determine their treatment and follow-up plan.

Abstract: CM-05

Mohs Surgeons' Utilization of Gene Expression Profiling as a Prognostic Test for High-Risk Cutaneous Squamous Cell Carcinoma: A Clinical Impact Study

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BACKGROUND: Cutaneous squamous cell carcinoma (SCC) is often cured with surgery; however, its high prevalence results in more deaths than melanoma annually. Making risk-adjusted patient management decisions for patients with SCC requires accurate risk assessment by clinicians. The 40-gene expression profile [GEP] test has been independently validated to improve risk stratification over clinicopathologic information or traditional staging systems alone, and has demonstrated the ability to guide risk-aligned patient management decisions.

OBJECTIVES: The study aimed to assess how 40-GEP impacts patient management by Mohs surgeons as a clinical specialty who are likely to see high-risk SCC patients frequently.

METHODS: An anonymous survey was distributed to current American College of Mohs Surgery (ACMS) members. The study consisted of demographic questions; familiarity with and use of NCCN guidelines; staging (American Joint Committee on Cancer Staging Manual, 8th Edition [AJCC-8] and Brigham and Women's Hospital [BWH]); and 40-GEP. After providing background on the validation of 40-GEP, the participants evaluated the use of risk factors for assessing patients with SCC within their practice and which of these same risk factors were concerning enough to prompt the use of 40-GEP. Study participants were then presented with a high-risk SCC patient vignette and asked for their risk assessment and treatment approaches pre- and post-40-GEP test results.

RESULTS: The Mohs surgeons were extensively experienced, as 54% see more than 500 cases of SCC annually (total responders N = 39). They utilize BWH staging twice as compared to AJCC-8, with 74% following the recommendations of the NCCN "Always" or "Often." A total of 97% of respondents were at least "Somewhat" familiar with GEP for SCC, with 33% using the 40-GEP test. All NCCN very high-risk factors, as well as immunosuppression and neurological symptoms, were chosen as the clinicopathological risk factors most likely to be associated with metastasis. Surgeons identified multiple risk factors as those they feel would benefit from the additional prognostic information provided by 40-GEP, with invasion beyond the subcutaneous fat or > 6 mm selected most frequently. Regarding various treatment modalities for a high-risk SCC patient vignette, participants elevated their management intensity as the 40-GEP results indicated an increased risk of metastasis (class 2A or class 2B). However, a class 1 test result (low risk of metastasis) consistently caused changes from the intermediate baseline level to a lower level of management intensity. The confidence of surgeons in their management of this vignette increased when incorporating each of the 40-GEP class results.

CONCLUSION: With the integration of 40-GEP results, study participants made risk-aligned management decisions and had greater confidence in these decisions. Overall, 40-GEP can focus treatment options in a risk-aligned manner, thus supporting an optimization of healthcare resources and improved patient outcomes.

Abstract: CM-06

PD1H (VISTA) levels correlates with immune cell infiltration in cutaneous squamous cell carcinoma

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BACKGROUND: The discovery of immune checkpoints, including antibodies against programmed death receptor-1 (PD-1) and its ligand, programmed death-ligand 1 (PD-L1), has changed the landscape of cancer therapy, including advanced cutaneous squamous cell carcinoma (cSCC). About 5% of cSCC are identified at an advanced stage. Prior to the advent of immunotherapy, no surgical or radiochemotherapy treatments had a curative intent for patients with these advanced cancers (Boutros A, et al. *Front Oncol* 2021). Anti-PD-1 therapy for advanced cSCC showed partial or complete response in only about 33% of the patients (Grob JJ, et al. *J Clin Oncol* 2020). This could be due to the presence of other immune checkpoints that are hijacked by cSCC to avoid detection and destruction. Several new immune checkpoints have since been discovered and the majority of them remain poorly understood. Programmed death-1 homolog (PD1H), also known as V-domain Ig-containing suppressor of T-cell activation (VISTA), is a novel immune checkpoint inhibitor. In many cancers, PD1H (VISTA) functions as an inhibitory immune checkpoint similar to PD-1. When stimulated, it leads to a decrease in effector T-cell response allowing immune evasion (Zou W, et al. *Nat Rev Immunol* 2008).

OBJECTIVE: To study PD1H (VISTA) in cSCC and evaluate its expression with regards to the tumor subcompartments and tumor grade. Insights into PD1H (VISTA) function and sublocalization will be crucial in designing therapies to aid patients with advanced cSCC.

MATERIALS AND METHODS: We used multiplexed quantitative immunofluorescence (mQIF) on a primary cSCC tissue microarray (N = 76 cSCCs). We performed correlation matrix of quantitative immunofluorescence (QIF) scores adjusting for multiple comparisons by using Holm-Sidak post hoc analysis.

RESULTS: The highest PD1H (VISTA) expression was noted within the myeloid compartment (CD11b+ cells) as compared to tumors or surrounding stroma in accordance with the literature (Xu W, et al. Cancer Immunol Res 2019). Similarly, PD-L1 expression was localized to the CD68 compartment. PD1H (VISTA) and PD-L1 expression were not significantly correlated with each other nor with the grade of the tumor. Furthermore, we found that tumors with higher PD1H (VISTA) expression also demonstrated increased expression of CD3, CD68, and granzyme B. CD8+ and CD4+/FoxP3+ T-cell counts correlated positively with PD1H (VISTA) expression, but there was no statistically significant correlation with PD-L1. PD1H (VISTA) levels in stroma compared to tumor were significantly correlated with T regulatory and effector T-cell counts. Finally, Ki-67 expression in tumor, but not stroma, correlated positively with CD3 and CD68 levels. Ki-67 expression did not correlate with PD1H (VISTA) levels.

CONCLUSIONS: Our findings indicate that PD1H (VISTA) is expressed in cSCC in all tumor grades. Furthermore, lack of correlation between PD1H (VISTA) and PD-L1 indicates independent processes at play to promote immune evasion. Interestingly, report of increased PD1H (VISTA) expression in cSCC compared to keratoacanthomas, which tend to self-resolve, corroborates our findings (Vesely M, et al. *J Am Acad Dermatol* 2022). Both PD1H (VISTA) and Ki-67 levels correlated independently with immune infiltration in the tumor microenvironment hinting at different mechanisms. Based on the markers used, we identified both effector T cells and regulatory T cells infiltrating PD1H (VISTA) high tumors. Interestingly, mixed immune infiltration, composed of pro- and anti-inflammatory cells, in PD1H (VISTA) high tumors has been noted in 30 types of other cancers found in the The Cancer Genome Atlas (TCGA) database (Huang X, et al. *J Hematol Oncol* 2020). It remains to be identified how the seemingly opposite functions of promoting effector T-cell infiltration into the tumor while inhibiting the function of these cells by PD1H (VISTA) may ultimately play a role in cSCC immune evasion. Further work will need to be done to clarify the role of PD1H (VISTA) in cSCC patient survival.

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Abstract: CM-07

Recurrence of Skin Cancers Among Solid Organ Transplant Recipients

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INTRODUCTION: There is an established relationship between solid organ transplantation (SOT) and increased incidence of skin cancers due to chronic immunosuppression coupled with increased carcinogenesis and persistence of oncogenic viral infections. In patients diagnosed with either keratinocyte carcinoma (KC) or malignant melanoma (MM) prior to organ transplantation, there have been observed increases in both mortality and recurrence; however, little is known regarding recurrence of skin cancers arising for the first-time post-transplant patient. We aimed to further characterize the incidence of such recurrences in SOT recipients (SOTRs).

METHODS: A retrospective review was conducted to identify SOTRs at our institution with recurrence of skin cancer that initially developed post-transplant. Data was analyzed using one-sample t tests.

RESULTS: Between January 1, 2012 and June 1, 2022, 33 SOTRs developed at least 1 recurrent skin cancer (mean 3.97 ± 6.97). Patients with recurrence were most often male (87.9%, *P* value ≤ .001), white (97%, *P* value ≤ .001), kidney transplant recipients (75.7%, *P* value ≤ .001) with a mean age at transplant of 56.52 (± 11.69) years. Risk factors for recurrence include family history of skin cancer (*P* value = .006), heart transplant (*P* value = .006), and the use of post-transplant meds including tacrolimus (*P* value ≤ .001) and cyclosporine (*P* value = .006). First skin cancers were most commonly squamous cell carcinoma (SCC) (66.7%) on the face or scalp (57.5%) (*P* value ≤ .001 each), and invasive at time of diagnosis (63.6%, *P* value ≤ .001).

CONCLUSION: Our results suggest that white kidney or cardiac transplant patients are at high risk for skin cancer recurrence. Transplant recipients should perform monthly cutaneous self-examinations, and those at increased risk should have annual examinations performed by a dermatologist. Additionally, a potential modification of the immunosuppressive treatment regimen should be considered should skin cancer arise.

Abstract: CM-08

Use of Elastic-Scattering Spectroscopy on Patient-Selected Lesions That Are Concerning for Skin Cancer

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BACKGROUND: Elastic-scattering spectroscopy (ESS), an optical tissue sampling technique, distinguishes between normal and abnormal tissue in vivo without the need to remove tissue. Measuring the ESS spectra of skin lesions, a novel handheld device classifies lesions as either malignant or benign with an output of "Investigate Further" or "Monitor". The algorithm was trained and validated with > 11,000 spectral scans from > 3500 skin lesions. "Investigate Further" results include a score of 1 to 10 based on the algorithm's calculated spectral similarity to malignant lesions.

OBJECTIVE: This study aims to investigate the use of a handheld ESS tool in evaluating lesions of concern to patients.

METHODS: This prospective study consisted of primary care providers (PCPs) evaluating skin lesions patients reported as concerning, regardless of the PCPs' level of concern with the lesion. PCPs reported their diagnosis, management decision and confidence level for each lesion, providing physician comparison data. Providers were blinded to device results. The comparison for performance was histopathological results when available, or a 3-dermatologist expert panel review of high-resolution dermoscopic and clinical images. Patient clinical information including prior skin cancer history, risk factors, and physical examination were recorded. Results were evaluated for sensitivity (Se), specificity (Sp), negative predictive value (NPV), and positive predictive value (PPV) with confidence intervals.

RESULTS: A total of 156 patients with 178 lesions were evaluated. The majority of patients were female (64%), white (92%), and non-Hispanic (94%). The most reported concerning feature was a "new or changing lesion" (91%). Twenty-two lesions were biopsied, with the most common diagnosis

being seborrheic keratosis ([SK] 36%). Device diagnostic Se was 90% (95% CI: 0.71,1.00); PCP Se was 40% (0.10, 0.70) when compared to the biopsy result or dermatologist panel reference standard. The device NPV was 99% (0.93, 1.00). The overall device PPV was 14% (0.07, 0.25) with a PPV of 60% (0.17, 1.00) for spectral scores 8 to 10. Device Sp was 61% (0.52, 0.68) compared to biopsy or panel consensus. In subgroup analyses, device Sp was 64% for Fitzpatrick skin types IV to VI (0.54, 0.74), 77% for pigmented lesions (0.63, 0.87) and 70% (0.57, 0.81) for seborrheic keratoses (SK). The device recommended patient referral to dermatology with 88% (0.64, 0.97) concordance with the dermatologist panel. Area under the curve was 0.815 for the device and 0.643 for PCP diagnostic performance ($P < .001$).

CONCLUSIONS: The use of the ESS device by PCPs can improve diagnostic and management sensitivity for malignant skin lesions while also ruling out benign lesions of patient concern. This may help increase skin cancer detection while alleviating unnecessary referrals, especially for pigmented lesions and seborrheic keratoses.

MEDICAL DERMATOLOGY

Abstract: MD-01

Clinical Correlation of Nail Change and Hand-Foot-and-Mouth Disease

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BACKGROUND: Hand-foot-and-mouth disease (HFMD) is a contagious disease of childhood that is usually self-limited. HFMD can lead to complications including nail dystrophy, which has received more attention recently.

OBJECTIVES: In this study, we aimed to assess the clinical correlation between HFMD and nail dystrophy in the Iranian patients referred to the dermatology clinics in Yazd, Iran, and to compare our findings with other populations.

Methods: The study included all the patients with HFMD who were referred to dermatology clinics in 2019 in Yazd, Iran. All patients were seen monthly for 3 months. The patients who missed the follow-up visits were excluded from the study. The data were analyzed with IBM SPSS Statistics 22 (IBM, Chicago, USA) and all P values below .05 were considered statistically significant.

RESULTS: Among 50 patients with HFMD, 21 (n = 10 male [47.6%] and n = 11 female [52.4%]) developed nail dystrophy. All patients had a typical presentation of HFMD with low-grade fever, ulcers in the mouth, and rash in their hands, feet, and buttock region. There was no significant difference between the rates of nail dystrophy in males versus females ($P = .65$). The median age of the patients with nail change was 3.4 (range 2.4 to 5.5) and 90.5% of the patients were under 5 years of age. There was no significant difference between the median age of girls and boys (3 and 3.6, respectively, $P = .251$). All 21 patients had fingernail changes, whereas only 10 patients (47.6%) had toenail changes. The number of affected nails on the hands and feet is summarized in Table based on patients' sex. The nail change appeared 3 to 6 weeks after disease onset with a median time of 4 weeks. In our study of the Iranian population, onychomadesis was the most common nail change and was seen in 61.9% of the patients, whereas Beau's lines were found in 38.1%, similar to the study in the Turkish population (Akpolat ND, et al. *Turk J Pediatr* 2016). possibly due to the location (Both Turkey and Iran are located in the Middle East), and less onychomadesis but more beau's line in comparison with the Chinese study (Long et al. *Pediatric dermatology.* 2016).

CONCLUSIONS: Nail dystrophy is seen frequently after the course of HFMD, mostly in fingernails, however, it also can be seen in toenails. The most common type of nail dystrophy was onychomadesis.

Abstract: MD-02

Combination Therapy With Efinaconazole for the Treatment of Toenail Onychomycosis

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BACKGROUND: Successful treatment of onychomycosis is challenged by the rise of antifungal resistance, limited efficacy of some antifungal therapies, and prolonged treatment requirements necessary for appreciable clinical effects to emerge. Combination therapy with topical + oral or topical + laser treatments can potentially improve

clinical outcomes. Efinaconazole 10% solution is one of the latest topical therapies approved by the FDA for the treatment of onychomycosis.

OBJECTIVES/METHODS: Review published data on in vitro and in vivo efficacy of efinaconazole in combination with oral antifungal agents or laser therapy. Therapeutic recommendations/guidelines for the use of efinaconazole as part of combination therapy were also compiled.

Results: In vitro, efinaconazole in combination with either terbinafine or itraconazole demonstrated overall greater synergistic antifungal activity than tavaborole in combination with either drug. These combinations were tested against T. rubrum and T. interdigitale (clonal offshoot of T. mentagrophytes), dermatophytes that are common causes of onychomycosis. In a retrospective case series, 12 patients who failed to achieve high efficacy following ≥ 20 weeks of terbinafine monotherapy were switched to sequential combination therapy with efinaconazole. Prior to combination treatment, 16.7% (n = 2) had shown improvement with terbinafine alone (defined as replacement of 40% to 70% of the affected nail with healthy nail); after sequential combination treatment with efinaconazole, 66.7% (n = 8) of patients achieved improvement or cure (40% to100% replacement). Two studies reported favorable outcomes with combination efinaconazole + laser therapy. In one study (N = 30), significantly greater clinical improvements were observed with combination therapy versus efinaconazole monotherapy as early as week 24, with higher mycological cure rates at week 48 (90% vs 70%). Authors of a second study of 100 great nails treated with efinaconazole + laser therapy (N = 86) concluded that clinical improvements were greater than would be expected with either treatment as monotherapy. Treatment recommendations/guidelines support the use of efinaconazole + oral therapy for severe onychomycosis, older patients, and patients with certain concomitant conditions/medications; efinaconazole + laser therapy has been recommended when oral antifungals are contraindicated.

CONCLUSIONS: Leveraging multiple routes and/or mechanisms of action in the treatment of onychomycosis may improve efficacy and reduce treatment duration. Combination therapy may be of particular use in patients with poor prognostic factors, nonresponsive or recurrent onychomycosis, or more serious disease. Efinaconazole has been recommended as part of combination therapy for certain patient populations.

FUNDING: Ortho Dermatologics

Abstract: MD-03

Integrated Safety Analysis of Baricitinib in Adults With Severe Alopecia Areata From Two Randomized Clinical Trials

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BACKGROUND: We evaluated the safety of baricitinib, a selective oral Janus kinase (JAK)1/JAK2 inhibitor, in adults with severe alopecia areata (AA) from 2 placebo-controlled trials.

METHODS: Integrated data from ongoing randomized, double-blind trials, BRAVE-AA1 (adaptive phase 2/3; NCT03570749) and BRAVE-AA2 (phase 3; NCT03899259), were summarized in three datasets with data through March 2021: "36-week-placebo-controlled" (placebo comparison with baricitinib 2 mg and 4 mg); "ext-bari-AA" (assessed extended dose response); and "all-bari-AA" (included patients who received any baricitinib dose). Frequencies and incidence rates/100 patient-years at risk (PYR) were calculated.

RESULTS: 1244 patients received baricitinib for 1362.2 patient-years (PY) of total exposure (median 393.5 days). Treatment-emergent adverse events were reported in 56.9%, 60.5%, and 63.1% of patients, and serious adverse events in 1.6%, 2.2%, and 2.6%, on placebo, 2 mg, and 4 mg, respectively. Serious infections were low in frequency with no meaningful differences between groups. Herpes zoster frequencies were 0.5%, 1.4%, and 0.9% for placebo, 2 mg, and 4 mg, respectively. Two malignancies were reported during the placebo-controlled period, including 1 prostate cancer (placebo) and 1 B-cell lymphoma (4 mg). One breast cancer (4 mg) and one non-melanoma skin cancer (2 mg) were reported in the ext-bari-AA dataset. One myocardial

infarction was reported during the placebo-controlled period in a patient on 2 mg with multiple risk factors. There were no deaths, venous thromboembolic events, opportunistic infections, tuberculosis infections, or gastrointestinal perforations at the data cut date.

CONCLUSION: This integrated safety analysis in patients with severe AA from 2 ongoing trials revealed no new safety signals compared to the known safety profile of baricitinib.

DISCLOSURE: Study was sponsored by Eli Lilly and Company. Abstract previously presented at 2022 American Academy of Dermatology (AAD) 80th Annual Meeting.

Abstract: MD-04

Therapeutic Recommendations for the Treatment of Toenail Onychomycosis in the United States

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BACKGROUND: Onychomycosis—a fungal infection of the nail bed or plate—affects up to 14% of individuals in North America. It is undertreated and treatment is challenging as toenail growth can take up to 12 months or more, the nail plate may prevent drug penetration, and disease recurrence is common. National guidelines and consensus documents on onychomycosis diagnosis and treatment were last published more than 5 years ago in 2014 (British) and 2015 (Canadian)—around the time that both topical efinaconazole and tavaborole were first approved in the United States in 2014. Since then, more clinical data, post hoc analyses, meta-analyses, and FDA-approved indications have become available for onychomycosis drugs. As such, updated medical guidance is needed.

OBJECTIVES: This document aims to provide recommendations for the diagnosis and pharmaceutical treatment of toenail onychomycosis.

METHODS: A roundtable meeting on the treatment of toenail onychomycosis was convened on March 15, 2021, and included a panel of dermatologists, podiatrists, and a microbiologist specializing in nail disease. Therapeutic recommendations were determined via live discussion and subsequent review.

RESULTS: There was a general consensus on several topics regarding onychomycosis diagnosis, confirmatory laboratory testing, and medications. Onychomycosis should be assessed clinically and confirmed with microscopy, histology, and/or culture. Efinaconazole 10% is the primary choice for topical treatment and terbinafine is the primary choice for oral treatment. For optimal outcomes, patients should be counseled regarding treatment expectations as well as follow-up care and maintenance post-treatment.

CONCLUSIONS: These therapeutic recommendations—based on recent clinical data, including topicals that were FDA-approved within the past decade—provide important updates to previous guidelines/consensus documents to assist healthcare practitioners in the diagnosis and treatment of toenail onychomycosis.

FUNDING: Ortho Dermatologics

PSORIASIS

Abstract: PS-01

Baseline Characteristics and Week 12 Modified Nail Psoriasis Severity Index Results in Patients with Moderate to Severe Plaque Psoriasis Treated With Biologics in the Psoriasis Study of Health Outcomes (PSoHO)

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BACKGROUND: This interim analysis focuses on nail psoriasis (NP) manifestations at baseline and week (W)12 in the 700 patients enrolled in the Psoriasis Study of Health Outcomes (PSoHO), a 3-year, international, prospective, non-interventional cohort study.

METHODS: Adult patients with moderate to severe psoriasis (PsO) for ≥ 6 months duration who initiated/switched biologics or biosimilars during routine care were enrolled. NP was assessed by the modified Nail Psoriasis Severity Index (mNAPSI) and was categorised as present (mNAPSI ≥ 1) or absent (mNAPSI = 0) in 441/700 patients. Baseline data of the subgroup with completed mNAPSI assessments were analyzed by ANOVA or Fisher's exact test. Descriptive statistical analysis only was performed for drugs/drug groups with ≥ 20 patients with NP at W12.
RESULTS: NP was recorded in 62.6% (n = 276) of patients with baseline mNAPSI assessment. The NP cohort had more severe disease as shown by higher baseline mean (standard deviation [SD]) Psoriasis Area and Severity Index scores (16.0 [8.9] vs 13.1 [8.7]; P = .001) and more genital (38.4% [106/276] vs 24.8% [41/165]; P = .004) and palmoplantar (36.6% [101/276] vs 15.2% [25/165]; P < .001) involvement than the no NP cohort. Baseline mean (SD) Dermatology Life Quality Index (DLQI) scores (12.4 [7.4] vs 11.3 [7.6]; P = .164) and comorbid psoriatic arthritis rates (27.9% [77/276] vs 20.6% [34/165]; P = .091) were similar for the NP vs no NP cohorts. For patients with NP at baseline, mean (SD) mNAPSI was 26.0 (23.2), 49.3% (136/276) had moderate to severe NP (mNAPSI ≥ 20) and 23.6% (65/276) had severe NP (mNAPSI ≥ 40). In the NP cohort, the most frequently reported NP features were onycholysis/oil-drop dyschromia (76.1% [210/276]) and pitting (81.5% [225/276]). At baseline, 44.2% (n = 122) of the NP cohort received anti-IL-17A biologics (ixekizumab [IXE], n = 99; secukinumab, n = 23) and 55.8% (n = 154) received other biologics. Among the NP cohort at W12, 62.0% and 32.6% of the anti-IL-17A-treated patients achieved mNAPSI50 and mNAPSI100, respectively, and 41.0% and 18.0% of the other biologics-treated patients reached mNAPSI50 and mNAPSI100, respectively. At W12, 57.3%, 30.8% and 50.0% of IXE-, guselkumab (GUS)-, and adalimumab (ADA)-treated patients with NP achieved mNAPSI50, respectively, while 32.0%, 5.1% and 26.9% of IXE-, GUS-, and ADA-treated patients with NP reached mNAPSI100, respectively.
CONCLUSION: In this interim analysis, skin disease was more severe and genital and palmoplantar involvement was more frequent in patients with NP in the real-world setting. High proportions of anti-IL-17A-treated patients had NP improvements, and almost one-third of IXE-treated patients achieved complete nail clearance as early as W12, consistent with clinical study results.
DISCLOSURES: Sponsored by Eli Lilly and Company. Previously presented at 2021 European Academy of Dermatology and Venereology (EADV) 30th Congress.

Abstract: PS-02

Brodalumab Provides Rapid Onset of Therapeutic Response for Patients With Moderate to Severe Psoriasis

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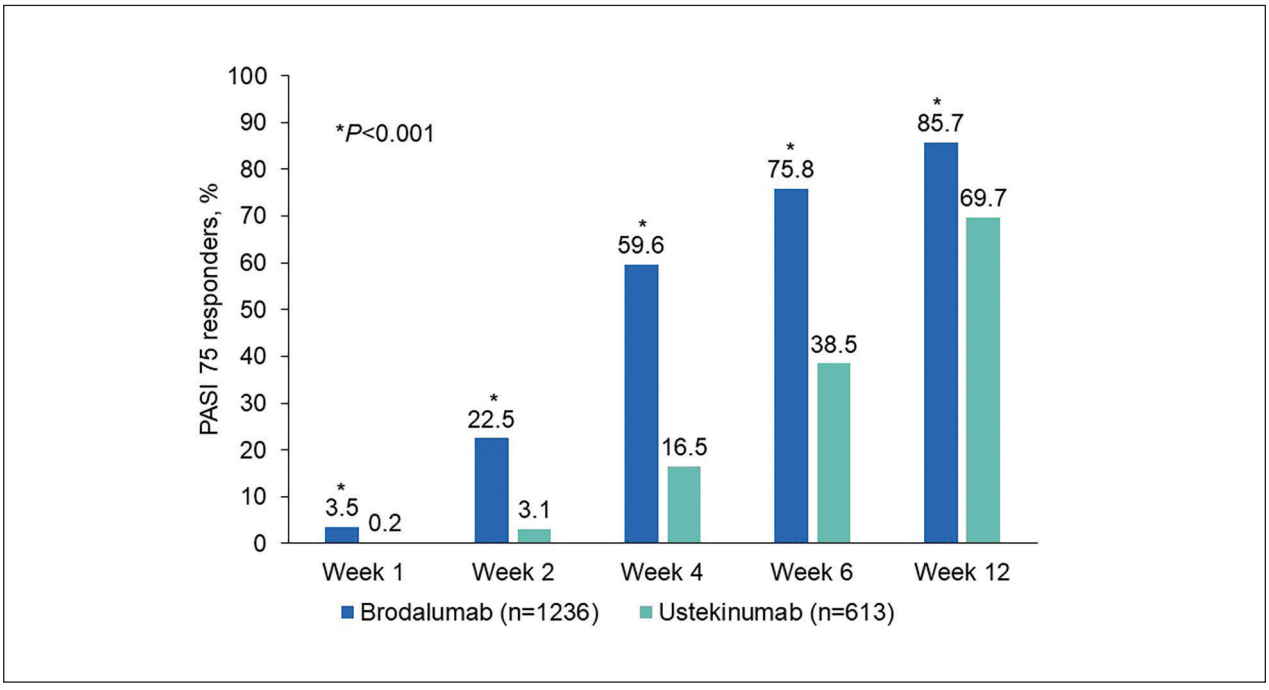
BACKGROUND: Several factors should be considered when selecting the most appropriate treatment of moderate to severe psoriasis, including drug effectiveness, potential adverse events, and time to response. The human anti-interleukin-17-receptor A monoclonal antibody brodalumab has been shown to be safe and effective for moderate to severe psoriasis and improves clinical outcomes more rapidly than do other psoriasis biologic therapies.
OBJECTIVES: To characterize the time to response of brodalumab by directly comparing brodalumab with ustekinumab in clinical studies and by indirectly comparing brodalumab with biologics in the current psoriasis treatment landscape.
METHODS: This post hoc analysis directly compared time to response between brodalumab and ustekinumab in 2 phase 3 studies (AMAGINE-2/-3) as measured by psoriasis area and severity index (PASI) responses from baseline (Blauvelt A, et al. *J Am Acad Dermatol* 2017). Psoriasis symptom improvement was assessed with the psoriasis symptom inventory (PSI) (Gordon KB, et al. *Br J Dermatol* 2014), and changes in patient-reported quality of life were determined with the dermatology life quality index (DLQI) (Wu JJ. *Am J Manag Care* 2017). To assess time to response of brodalumab compared with that of other current biologics, indirect comparisons from previously published studies were used (Egeberg A, et al. *J Eur Acad Dermatol Venereo*l 2020).
RESULTS: In clinical studies, significant differences in speed of efficacy between brodalumab and ustekinumab were seen as early as week 1, in which 3.5% of brodalumab-treated patients achieved ≥ 75% reduction from baseline in PASI (PASI 75), vs 0.2% of ustekinumab-treated patients (P < .001; Figure). By week 12, 85.7% and 69.7% of patients treated with brodalumab or ustekinumab, respectively, achieved PASI 75 (P < .001). Median times to achieve PASI 25, PASI 50, or PASI 75 and median times for 50% of patients to achieve PASI 75, PASI 90, or PASI 100 were significantly shorter with brodalumab compared with ustekinumab (P < .001 for all analyses) (Blauvelt A, et al. *J Am Acad Dermatol* 2017). Similarly, a significantly greater proportion of patients treated with brodalumab achieved a PSI score of 0 compared with patients treated with ustekinumab at week 12 (22.7% vs 13.4%; P < .001) (Gottlieb AB, et al. *J Eur Acad Dermatol Venereol* 2018). Complete skin clearance by brodalumab was associated with greater improvements in DLQI (Wu JJ. *Am J Manag Care* 2017). In an indirect comparison, brodalumab treatment resulted in faster time to



response (mean time for 50% of patients to achieve PASI 90) than other psoriasis biologics, including ixekizumab and secukinumab (6.2 vs 7.4 and 16.3 weeks, respectively) (Egeberg A, et al. *J Eur Acad Dermatol Venereol* 2020).

CONCLUSIONS: Brodalumab provides a safe and effective treatment option with rapid onset of response for patients with moderate-to-severe psoriasis.

FUNDING: This study was sponsored by Ortho Dermatologics. Medical writing support was provided by MedThink SciCom and funded by Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

Abstract: PS-03

Brodalumab: 4-Year US Pharmacovigilance Report

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BACKGROUND: Brodalumab is an interleukin-17 receptor A (IL- 17RA) antagonist indicated for moderate to severe plaque psoriasis in adult patients with loss of or no response to alternative systemic therapies. Brodalumab has a boxed warning for suicidal ideation and behavior in the United States, even though pivotal clinical trials and recent pharmacovigilance data do not confirm a causal relationship. No completed suicides and 1 suicide attempt by a patient with a history of depression occurred during the initial 3-year pharmacovigilance reporting period. Arthralgia was the most common treatment-specific adverse event (AE) in the 2- and 3-year pharmacovigilance reports.

OBJECTIVES: To review the pharmacovigilance data over a 4-year reporting period to provide insight into the safety of brodalumab for the treatment of moderate to severe psoriasis in adults.

METHODS: Pharmacovigilance data for brodalumab were compiled from August 15, 2017, to August 14, 2021, from US patients and healthcare providers. The most common AEs listed in the brodalumab package insert (incidence ≥ 1%; arthralgia, headache, myalgia, influenza, diarrhea, oropharyngeal pain, nausea, injection site reactions, fatigue, neutropenia, and Tinea infections) and AEs of special interest were assessed as exposure-adjusted rates per 100 patient-years (PYs). Exposure was estimated as the time between first and last prescription-dispensing authorization date. Patients with the same initial and last prescription-dispensing authorization date were excluded.

RESULTS: Data were collected from 4019 US patients and exposure was estimated as 4563 PYs. There were 2118 unique AE cases reported, of which 22% were reported by healthcare providers and 78% by patients. The most common AE was arthralgia (115 reports, 2.52 events/100 PYs). Since the 3-year report, 2 new cases of headache, 3 new cases of myalgia, 1 new case of influenza, 1 new case of diarrhea, and 1 new case of oropharyngeal pain were reported; no new cases of fatigue, injection-site reactions, neutropenia, or Tinea infections were reported. No new suicide attempts or completed suicides were reported. Within the 4-year reporting period, 102 serious infections occurred, of which 3 were considered to be related

Table. US Pharmacovigilance Monitoring of Brodalumab Through 4 Years (August 15, 2017–August 14, 2021)

AE	Event, n (r)[a]	Event drug related, n[b]	Discontinued, n (%)[c]	Maintained, n (%)[c]	Action unknown/NA, n (%)[c]
Arthralgia	115 (2.52)	1	25 (22)	53 (46)	37 (32)
Headache	45 (0.99)	0	6 (13)	25 (56)	14 (31)
Fatigue	44 (0.96)	1	6 (14)	20 (45)	18 (41)
Injection-site reaction	35 (0.77)	3	1 (3)	18 (51)	16 (46)
Diarrhea	33 (0.72)	0	6 (18)	19 (58)	8 (24)
Myalgia	31 (0.68)	0	6 (19)	18 (58)[d]	7 (23)
Nausea	29 (0.64)	0	5 (17)	17 (59)	7 (24)
Influenza	23 (0.50)	1	9 (39)	7 (30)	7 (30)
Oropharyngeal pain	21 (0.46)	0	2 (10)	11 (52)[e]	8 (38)
Neutropenia	1 (0.02)	0	0	1 (100)	0
Tinea infection	0	—	—	—	—

AE, adverse event; NA, not applicable; r, exposure-adjusted rate per 100 patient-years. [a]Number of patients experiencing AE, not total number of AEs. [b]Relatedness to brodalumab was based on company-determined causality. [c]Treatment action taken upon AE occurrence. Percentage is event divided by total number of patients experiencing event. [d]One patient increased brodalumab dose. [e]One patient temporarily stopped taking the drug but planned to resume brodalumab treatment.

to brodalumab. There were 24 patients with confirmed COVID-19. No new cases of Crohn's disease were reported since the 2-year report (1 case), and there was 1 new case of ulcerative colitis (most likely unrelated to brodalumab). Of 37 malignancies reported in 32 patients (0.81 events/100 PYs), including 30 cases previously reported in the 3-year analysis, none were related to brodalumab.

CONCLUSIONS: These pharmacovigilance data are consistent with previous pharmacovigilance data and the safety profile of brodalumab established in pivotal clinical trials.

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Abstract: PS-04

Changes in Disease Activity and Patient-Reported Outcomes in Psoriatic Arthritis Patients Treated With Ixekizumab in a Real-World US Cohort

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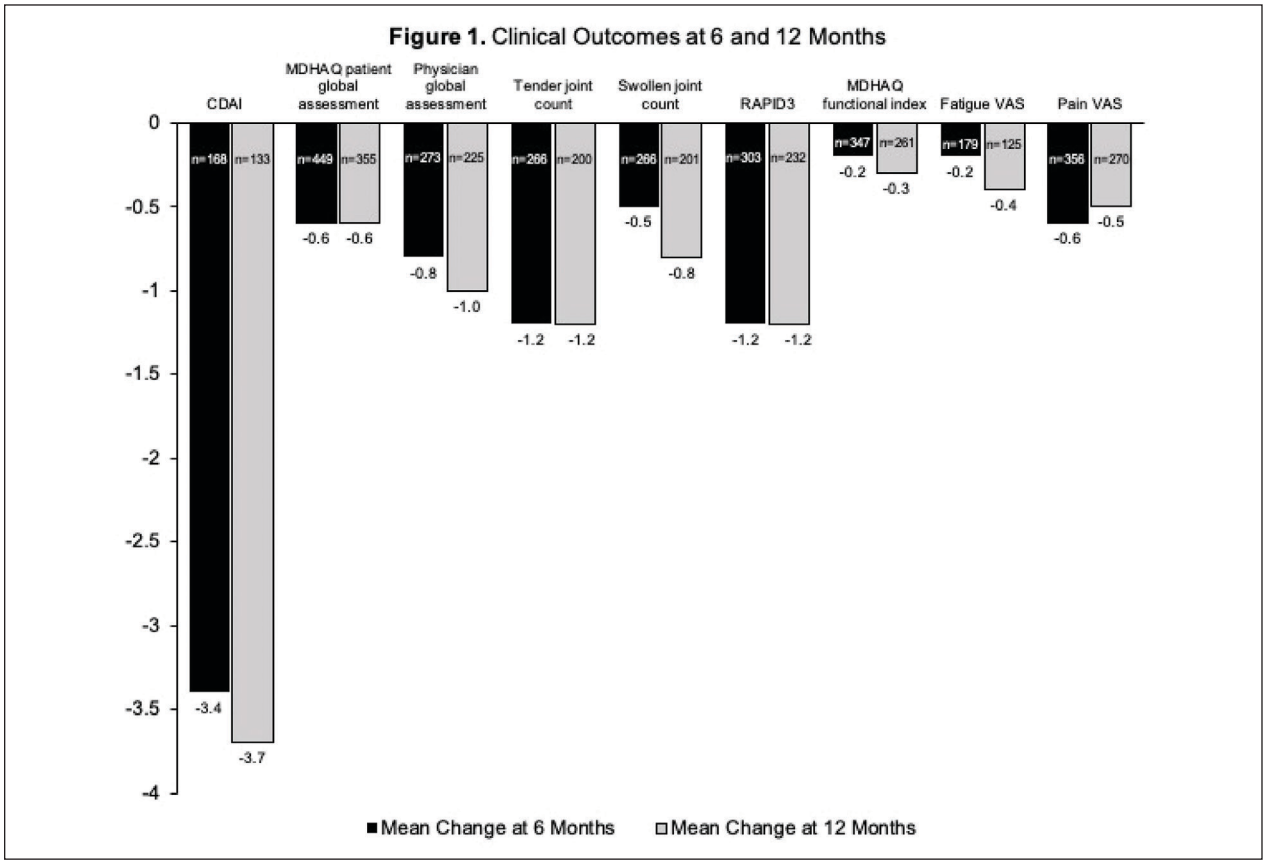
BACKGROUND: Ixekizumab (IXE), an interleukin-17 receptor A (IL-17A) inhibitor, has demonstrated efficacy in clinical trials, but real-world effectiveness data are limited.
OBJECTIVES: To describe changes in disease activity and patient-reported outcomes (PROs) at 6- and 12-month follow-up among psoriatic arthritis (PsA) patients (pts) initiating IXE in a real-world setting.
METHODS: This retrospective cohort study included pts from the OM1 PsA Registry (OM1, Boston, MA), a linked electronic medical record and administrative claims dataset with over 50,000 patients. Eligible pts had ≥ 1 prescription for IXE (first considered index), were ≥ 18 years old at index, had ≥ 1 diagnosis code for PsA in the 12 months before or on index, and had ≥ 12 months of baseline and ≥ 6 months of follow-up data as of June 2021. For pts with baseline and follow-up measures available, changes in Clinical Disease Activity Index (CDAI), PROs, and other clinical outcomes from baseline to 6 and 12 months were described. For pts on IXE monotherapy, change in CDAI score from baseline to 6 and 12 months was assessed using mixed effects linear models adjusted for age, sex, and baseline CDAI score.
RESULTS: The study population included 1812 pts with a mean age of 53.7 years (Table 1). For all pts, domains of PsA included psoriasis (82%) and enthesitis (28%). Over 60% of pts were obese, and the mean Charlson Comorbidity Index was 1.3. Of 291 pts with a baseline CDAI score, 61% had moderate or severe disease activity. Most pts (84%) had prior treatment with a biologic disease-modifying antirheumatic drug (bDMARD) and 40% with a targeted synthetic DMARD (tsDMARD). The mean number of prior bDMARDs and tsDMARDs used during all available prior history was 2.3 and 1.1, respectively. The most common prior b/tsDMARDs were secukinumab (n = 428, 24%) and adalimumab (n = 245, 14%).

For all pts, CDAI scores improved (decreased) by an average of 3.4 and 3.7 points at 6 and 12 months, respectively, from a baseline mean of 15.4. All disease activity measures and PROs improved from baseline to 6 and 12 months (Figure 1). In pts persistent with IXE, 35.3% and 33.7% were in CDAI remission or low disease activity at 6 and 12 months after initiation, respectively. For IXE monotherapy users (82% of pts), at baseline, pts had a mean CDAI of 14.3 (n = 131) and 15.1 (n = 105) for the 6- and 12-month analyses, respectively. Adjusted mean changes in CDAI from baseline to 6 months (-3.6 points, $P < .0001$) and 12 months (-4.9 points, $P < .0001$) were statistically significant.
CONCLUSIONS: In this cohort of biologic-experienced, difficult-to-treat PsA pts with high comorbidity burden, improvements in disease activity and PROs were observed at 6 and 12 months after initiating treatment with IXE. Improvements were observed in pts overall and in the monotherapy subgroup. More real-world research on IXE

Table 1. Demographic and Clinical Characteristics by Therapy Status

		All Patients (N=1,812)	*Monotherapy (N=1,485)*	*Combination Therapy (N=327)*
Age (years)	Mean (s.d.)	53.7 (12.2)	53.9 (12.3)	52.9 (11.7)
	Median (Q1-Q3)	55 (46-62)	55 (46-62)	54 (45-61)
Sex	Female	1,108 (61.1%)	909 (61.2%)	199 (60.9%)
	Male	704 (38.9%)	576 (38.8%)	128 (39.1%)
Charlson Comorbidity Index	Mean (s.d.)	1.3 (1.6)	1.3 (1.6)	1.5 (1.7)
	Median (Q1-Q3)	1 (0-2)	1 (0-2)	1 (0-2)
BMI	Underweight: <18.5	10 (0.6%)	10 (0.7%)	0 (0.0%)
	Normal weight: 18.5-24.9	210 (12.2%)	172 (12.2%)	38 (12.1%)
	Overweight: 25-29.9	455 (26.5%)	379 (27.0%)	76 (24.2%)
	Obese: >= 30	1,045 (60.8%)	845 (60.1%)	200 (63.7%)
	Missing	92	79	13
Domains of PsA: Psoriasis	Yes	1,490 (82.2%)	1,222 (82.3%)	268 (82.0%)
	No	322 (17.8%)	263 (17.7%)	59 (18.0%)
Domains of PsA: Enthesitis	Yes	510 (28.1%)	409 (27.5%)	101 (30.9%)
	No	1,302 (71.9%)	1,076 (72.5%)	226 (69.1%)



and other bDMARDs may inform the effect of treatment choices on clinical and PROs in both bDMARD-naive and experienced PsA pts.

FUNDING: Lilly

Abstract: PS-05

COVID-19–Related Adverse Events in the Phase 3 POETYK Trials of the Allosteric Tyrosine Kinase 2 Inhibitor, Deucravacitinib, in Patients With Moderate to Severe Plaque Psoriasis

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BACKGROUND: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, suppresses signaling of cytokines involved in psoriasis. In 2 global phase 3 trials in patients with moderate to severe plaque psoriasis (POETYK PSO-1 [NCT03624127], PSO-2 [NCT03611751]), deucravacitinib showed superior efficacy versus placebo and apremilast. Upon completion of either trial, patients could enroll in the POETYK long-term extension (LTE) trial (NCT04036435).

OBJECTIVES: To evaluate the incidence rate and severity of adverse events (AEs) due to COVID-19 with deucravacitinib.

METHODS: In PSO-1 (N = 666) and PSO-2 (N = 1020), adult patients with moderate to severe plaque psoriasis were randomized 2:1:1 to deucravacitinib 6 mg once daily,placebo, or apremilast 30 mg twice daily. At week 16, placebo patients in both trials switched to deucravacitinib. Based on their week 24 Psoriasis Area Severity Index (PASI) response, apremilast patients continued with apremilast or switched to placebo or deucravacitinib. Deucravacitinib patients continued treatment for 52 weeks or had withdrawn treatment at week 24 in 1 trial. At week 52, all patients could enroll in the open-label LTE and receive deucravacitinib. Incidence rates and severity of COVID-19-related AEs in the POETYK trials (n = 1364; 2076.7 person-years [PY] of follow-up) were compared with the Janssen/Johnson & Johnson COVID-19 vaccine trial placebo group (n = 19,544; 3096.1 PY of follow-up). This reference population was selected due to the study design and timing of the trial, which occurred when variants were in circulation.

RESULTS: As of October 1, 2021, 1519 patients received ≥ 1 dose of deucravacitinib over a 2-year follow-up period; 1364 met criteria for analysis since the pandemic onset. In total, 153 deucravacitinib patients reported a

COVID-19-related AE, for an overall exposure-adjusted incidence rate (EAIR) of 7.4/100 PY (95% CI, 6.2, 8.6). Serious COVID-19-related AEs occurred in 43 patients (EAIR, 2.1/100 PY; 95% CI, 1.5, 2.8), including 30 with COVID-19 and 13 with COVID-19 pneumonia; this rate was within those for moderate to severe COVID-19 reported in the reference population (EAIR, 16.5/100 PY; 95% CI, 15.0,17.9). Deaths due to COVID-19 occurred in 6 patients (EAIR, 0.3/100 PY; 95% CI, 0.1, 0.6), with the COVID-19-related mortality rate being consistent with the reference population (EAIR, 0.23/100 PY; 95% CI, 0.1,0.5). Treatment was discontinued due to COVID-19 or COVID-19 pneumonia in 7 patients, including the 6 patients who died due to COVID-19.

CONCLUSIONS: COVID-19 was among the most frequently reported AEs during the 2-year period of the pooled PSO-1, PSO-2, and LTE trials due to the temporal overlap of the pandemic with the trials. However, COVID-19 infection and death rates did not differ from the reference population; most infections were not serious and did not lead to treatment discontinuation. Based on this analysis, deucravacitinib did not appear to increase the risk of COVID-19 nor its progression to severe outcomes.

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MG: Advisory board, principal investigator, and lecture fees: AbbVie, Galderma, Leo Pharma, Pfizer, and Regeneron; Advisory board and lecture fees: Actelion; Principal investigator and consulting fees: Akros Pharma; Advisory board, principal investigator, lecture fees, and consulting fees: Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Novartis, Sanofi Genzyme, and Valeant; Principal investigator: Arcutis, Bristol Myers Squibb, Dermira, GlaxoSmithKline, MedImmune, Merck, Roche Laboratories, and UCB; Principal investigator and lecture fees: Glenmark

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Abstract: PS-06

Deucravacitinib Long-term Efficacy and Safety in Plaque Psoriasis: 2-Year Results From the Phase 3 POETYK PSO Program

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BACKGROUND: Deucravacitinib is an oral, selective, allosteric tyrosine kinase 2 inhibitor.

Objectives: The efficacy and safety of deucravacitinib were assessed in patients enrolled in the phase 3, double-blind POETYK PSO-1 and PSO-2 trials and the open-label long-term extension (LTE) trial.

METHODS: The 52-week PSO-1 and PSO-2 trials randomized patients with moderate to severe plaque psoriasis 2:1:1 to receive deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily. Patients could then enroll in the LTE trial and receive open-label deucravacitinib 6 mg once daily.

RESULTS: A total of 1221 patients were enrolled in the LTE trial and received ≥ 1 dose of deucravacitinib. Cumulative exposures in person-years from randomization in PSO-1 or PSO-2 and the LTE trial were 2166.9 and 2482.0 for efficacy and safety analyses, respectively. At enrollment in the LTE trial, response rates for ≥ 75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) (sPGA 0/1) were 65.1% and 50.9%, respectively, and were maintained for up to 2 years after initial randomization (week 48 of LTE; PASI 75: 75.7%; sPGA 0/1: 56.4% [as observed]). Exposure-adjusted incidence rates per 100 person-years for adverse events were similar in the controlled period (weeks 0 to 52) of PSO-1 and PSO-2 and during the cumulative PSO-1, PSO-2, and LTE trial period (229.2 [controlled period] vs 154.4 [cumulative period]), serious adverse events (5.7 vs 6.1), discontinuations (4.4 vs 2.8), deaths (0.2 vs 0.4), herpes zoster (0.9 vs 0.7), malignancies (1.0 vs 0.9), major adverse cardiovascular events (0.3 vs 0.4), and venous thromboembolism (0.1 vs 0.1).

CONCLUSIONS: Deucravacitinib demonstrated persistent efficacy and consistent safety profiles for up to 2 years after initial randomization in the POETYK PSO-1, PSO-2, and LTE trials.

Abstract: PS-07

Deucravacitinib, an Oral, Selective Tyrosine Kinase 2 Inhibitor, Versus Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Analysis of Body Surface Area Involvement in the Phase 3 POETYK PSO-1 and PSO-2 Trials

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BACKGROUND: Tyrosine kinase 2 (TYK2), an intracellular kinase, mediates cytokine (eg, interleukin [IL]-23, Type I interferons) signaling in psoriasis pathogenesis. Deucravacitinib is an oral, selective TYK2 inhibitor that binds to the regulatory domain of TYK2. Two phase 3 trials (POETYK PSO-1 and PSO-2) demonstrated the superior efficacy of deucravacitinib versus placebo and apremilast in patients with moderate to severe psoriasis at week 16.

OBJECTIVES: To evaluate the efficacy of deucravacitinib over 24 weeks based on body surface area (BSA) involvement.

METHODS: PSO-1 (NCT03624127) and PSO-2 (NCT03611751) were 52-week, double-blinded trials that randomized patients with moderate to severe plaque psoriasis 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily. Patients receiving placebo were switched to deucravacitinib at week 16. Mean change from baseline in BSA and BSA×static Physician's Global Assessment (sPGA), and the proportions of patients achieving ≥ 75% reduction from baseline in BSA×sPGA (BSA×sPGA 75), are presented for both POETYK trials.

RESULTS: Mean baseline scores in the 666 patients randomized in PSO-1 (BSA: deucravacitinib 26.6, placebo 25.3, apremilast 26.6; BSA×sPGA: deucravacitinib 86.9 placebo 82.1, apremilast, 85.4) and 1020 randomized in PSO-2 (BSA: deucravacitinib 26.3, placebo 25.3, apremilast 28.3; BSA×sPGA: deucravacitinib 85.0, placebo 81.1, apremilast 92.4) were similar across treatment groups. Significantly greater improvements from baseline in BSA and BSA×sPGA scores were observed at week 16 for deucravacitinib versus placebo and apremilast (Table) and were maintained through week 24 ($P < .0001$). Similar results for deucravacitinib were observed for BSA×sPGA 75 at week 16 ($P < .0001$ vs placebo and apremilast in both trials) and week 24 ($P < .0001$ vs apremilast).

CONCLUSIONS: In the POETYK PSO-1 and PSO-2 trials, deucravacitinib treatment was associated with greater improvements in BSA and BSA×sPGA over time compared with placebo and apremilast in patients with moderate to severe plaque psoriasis.

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Abstract: PS-08

Deucravacitinib, an Oral, Selective, Tyrosine Kinase 2 Inhibitor in Patients With Moderate to Severe Plaque Psoriasis: 52-Week Efficacy by Prior Treatment in the Phase 3 POETYK PSO-1 Trial

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BACKGROUND: Deucravacitinib, an oral, selective tyrosine kinase 2 inhibitor, was significantly more effective than placebo or apremilast for plaque psoriasis in the global, 52-week, phase 3 POETYK PSO-1 trial (NCT03624127). Response rates for the coprimary endpoints, Psoriasis Area and Severity Index (PASI) 75 and static Physician Global Assessment (sPGA) 0/1 at week 16, were superior with deucravacitinib regardless of prior biologic, systemic nonbiologic, and/or phototherapy exposure.

OBJECTIVES: To examine response rates through week 52 in patient subgroups defined by previous biologic, systemic (biologic or nonbiologic), and/or oral systemic treatment.

METHODS: POETYK PSO-1, a multicenter, double-blind trial, enrolled adult patients with moderate to severe plaque psoriasis. Patients who previously received phototherapy, systemics, and/or biologics completed washout periods ranging from 4 weeks to 6 months before study entry, depending on the treatment. Patients were randomized 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily; this analysis focuses on patients randomized to deucravacitinib or placebo. Placebo patients switched to deucravacitinib at week 16. PASI 75 and sPGA 0/1 outcomes were evaluated through week 52 by prior treatment, including patients who received biologics, systemics (biologic and nonbiologic), and oral systemics, as well as biologic- and systemic-naive patients. Nonresponder imputation analyses were used for all reported endpoints.

RESULTS: In total, 332 patients were randomized to deucravacitinib and 166 to placebo. At baseline, 34.3% of deucravacitinib patients and 44.0% of placebo patients had received prior oral systemic; 60.2% and 65.7% had received prior systemic (biologic and nonbiologic) and 39.2% and 38.0% had received prior biologic treatments, respectively. At week 52, PASI 75 response rates were similar in patients randomized to deucravacitinib at baseline and those originally randomized to placebo who switched to deucravacitinib at week 16 (65.1% and 68.3%, respectively). Findings in patients randomized to deucravacitinib were similar to those originally randomized to placebo regardless of prior systemic (65.5% and 68.1%), oral (70.2% and 69.2%), or biologic treatment (61.5% and 61.8%), and in patients with no prior systemics (64.4% and 68.6%) or biologics (67.3% and 72.2%). sPGA 0/1 response rates were comparable in patients randomized to deucravacitinib and those randomized to placebo in the overall population (52.7% vs 53.8%) and in the prior systemic (53.0% vs 55.3%), prior oral systemic (57.0% vs 53.8%), prior biologic (47.7% vs 45.5%), systemic-naive (52.3% vs 51.0%), and biologic-naive (55.9% vs 58.9%) cohorts.

CONCLUSIONS: Deucravacitinib was effective through 52 weeks in patients with moderate to severe plaque psoriasis regardless of previous systemic treatment history. Patients switching from placebo to deucravacitinib at week 16 achieved PASI 75 and sPGA 0/1 response rates similar to those continuously treated with deucravacitinib.

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Abstract: PS-09

Early Detection of Axial Psoriatic Arthritis in Patients With Psoriasis: A Prospective, Multicenter Study

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BACKGROUND: In the absence of reliable serological and/or imaging biomarkers that can support an early diagnosis of psoriatic arthritis (PsA) in patients with psoriasis (PsO),

Table 1. Clinical characteristics of all referred patients with PsO and suspicion of axSpA.

Patient characteristic	pPsA (N=5)	axPsA (N=14)	No PsA (N=81)	p-value[1]
Age (years) – Mean (SD)	42.8 (9.0)	46.2 (13.6)	45.7 (13.3)	0.883
Female – n (%)	2 (40.0)	9 (64.3)	45 (55.6)	0.543
PASI – Mean (SD)	3.3 (2.1)	4.3 (4.9)	4.0 (4.5)	0.971
Inflammatory back pain – n (%)	5 (100.0)	8 (57.1)	36 (44.4)	0.379
HLA-B27 positive – n (%)	0	4 (28.6)	12 (14.8)	0.204
Elevated CRP (>5 mg/L) – n (%)	1 (20.0)	5 (35.7)	11 (13.6)	0.041
Peripheral arthritis, current (last 7 days) – n (%)	5 (100.0)	3 (21.4)	3 (3.7)	0.012
Radiographic sacroiliitis as per mNY criteria – n (%)	0	4 (28.6)	1 (1.2)	<0.001
Active inflammation, sacroiliac joint (MRI) – n (%)	0	8 (57.1)	0	<0.001
Structural (post)inflammatory changes, sacroiliac joint (MRI) – n (%)	0	8 (57.1)	0	<0.001
Active inflammation, spine (MRI) – n (%)	0	13 (92.9)	0	<0.001
Structural (post)inflammatory changes, spine (MRI) – n (%)	0	8 (57.1)	0	<0.001

[1]Statistically significant differences between the axPsA and No PsA groups of patients were determined by using Mann–Whitney U test for continuous data and Chi-square test for categorical data

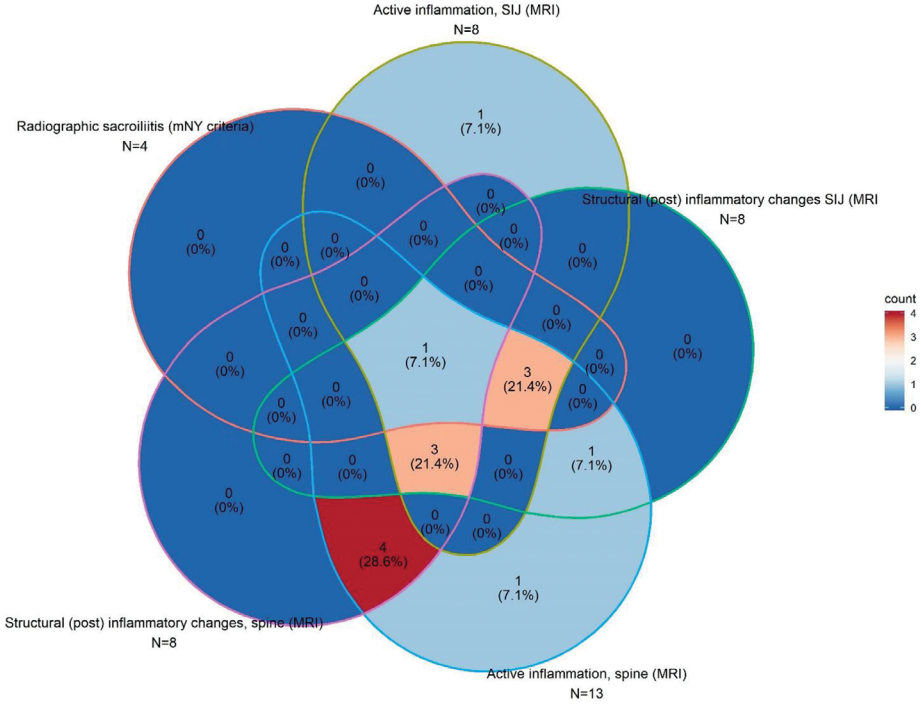

Figure . Imaging features of axial involvement in PsO patients diagnosed with axPsA

and considering the known diagnostic delay, there is a need for screening tools for detection of early PsA. While different validated screening/referral tools focusing on peripheral manifestations of PsA exist, validated referral algorithms for PsA with axial involvement (also referred to as axial PsA - axPsA) are still missing.

OBJECTIVES: In this prospective, multicenter study we applied a dermatologist-centered screening tool and a structured rheumatologic examination including magnetic resonance imaging (MRI) of sacroiliac joints (SIJs) and spine to detect axPsA in patients with psoriasis (PsO).

METHODS: Patients with PsO were systematically screened by their dermatologist for eligibility for referral to a rheumatology clinic. Eligible patients were ≥ 18 years with a confirmed diagnosis of PsO who reported having chronic back pain (≥ 3 months) with onset prior to 45 years of age and who had not been treated with any biologic or targeted synthetic DMARD 12 weeks prior to screening. For those patients who qualified for referral, a rheumatologic investigation including clinical, laboratory, and genetic assessments, as well as imaging with conventional radiography and MRI of sacroiliac joints and spine, was performed. The primary outcome of the study was the proportion of patients diagnosed with axPsA among all referred PsO patients.

RESULTS: In total, 355 patients were screened at 14 dermatology sites, of whom 151 (42.5%) qualified for referral to rheumatology clinic and 100 (28.2%) were seen by a rheumatologist. The diagnosis of axPsA was confirmed in 14 patients (3/14 with both axial and peripheral involvement) and the diagnosis of peripheral PsA (pPsA) without axial involvement was made in 5 patients. The Assessment of SpondyloArthritis international Society (ASAS) classification criteria for axSpA were fulfilled in nine (64.3%) of the patients diagnosed with axPsA. All but 1 patient diagnosed with PsA (13/14 with axPsA and 5/5 with pPsA) fulfilled the ClASsification criteria for Psoriatic ARthritis (CASPAR) criteria for PsA. Patient characteristics are presented in Table. All patients diagnosed with axPsA had active inflammatory and/or structural (post)inflammatory changes in the sacroiliac joints and/or spine on imaging. In 5 patients (35.7%), MRI changes indicative of axial involvement were found only in the spine as illustrated in Figure.

CONCLUSIONS: Our study revealed that applying a dermatologist-centered screening tool may be useful for the early detection of patients with a high probability of PsA (and specifically axPsA) in PsO patients. Given the high prevalence of isolated spinal involvement (without SIJs), imaging of the entire axial skeleton may be required as a part of diagnostic procedure in patients with suspected axPsA.

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Abstract: PS-10

Efficacy of Deucravacitinib Treatment in Patients With Moderate to Severe Plaque Psoriasis Who Relapsed During the Randomized Withdrawal and Maintenance Period in POETYK PSO-2: 48-Week Findings From the POETYK Long-term Extension Trial

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BACKGROUND: Deucravacitinib, an oral agent, selectively inhibits tyrosine kinase 2 (TYK2) via an allosteric mechanism. The phase 3, 52-week POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials demonstrated that deucravacitinib was significantly more efficacious than placebo and apremilast based on the coprimary endpoints of ≥ 75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and static Physician's Global Assessment (sPGA) score of 0 (clear) or 1 (almost clear; sPGA 0/1) at week 16. At week 52, patients completing the phase 3 trials could enroll in the POETYK long-term extension (LTE) trial and receive deucravacitinib treatment.

OBJECTIVES: The current analysis evaluated clinical response with deucravacitinib in the LTE trial among patients who relapsed after rerandomization from deucravacitinib to placebo or switching from apremilast to placebo in PSO-2.

METHODS: The POETYK PSO-2 trial randomized 1020 patients with moderate to severe plaque psoriasis 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily. At week 16, patients in the placebo group switched to deucravacitinib, and at week 24, patients who achieved PASI 75 on deucravacitinib were rerandomized (1:1) to continue deucravacitinib or switch to placebo, and patients who achieved PASI 75 on apremilast were switched to placebo. Upon completion of the PSO-2 trial at week 52, patients could enroll in the single-arm LTE trial where they received open-label deucravacitinib 6 mg once daily. PASI 75 and sPGA 0/1 responses were assessed through LTE week 48 (cumulative week 100) in patients who had relapsed (defined as a loss of ≥ 50% from week 24 PASI percentage improvement from baseline) after transitioning to placebo at week 24 in PSO-2 and were subsequently treated with deucravacitinib in the LTE trial.

RESULTS: A total of 150 patients were rerandomized from deucravacitinib to placebo and 97 patients were switched from apremilast to placebo at week 24 in PSO-2. This analysis included 54 and 37 patients who relapsed between weeks 24 and 52 after withdrawal from deucravacitinib and apremilast, respectively, and entered the LTE. Among patients who had reached week 48 in the LTE, PASI 75 and sPGA 0/1 response rates (as observed) increased progressively in both groups, with 87.5% (n = 28/32) and 73.3% (n = 11/15) achieving PASI 75 in the deucravacitinib and apremilast withdrawal groups, respectively, and 56.3% (n = 18/32) and 66.7% (n = 10/15) achieving sPGA 0/1, respectively, at week 48.

CONCLUSIONS: Progressively increasing PASI 75 and sPGA 0/1 responses were observed over 48 weeks in the LTE trial among patients with moderate to severe plaque psoriasis who had relapsed after treatment withdrawal in PSO-2.

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Abstract: PS-11

Efficacy of Spesolimab for Generalized Pustular Psoriasis (GPP) Flare Treatment According to GPP Area and Severity Index (GPPASI) Score at Baseline

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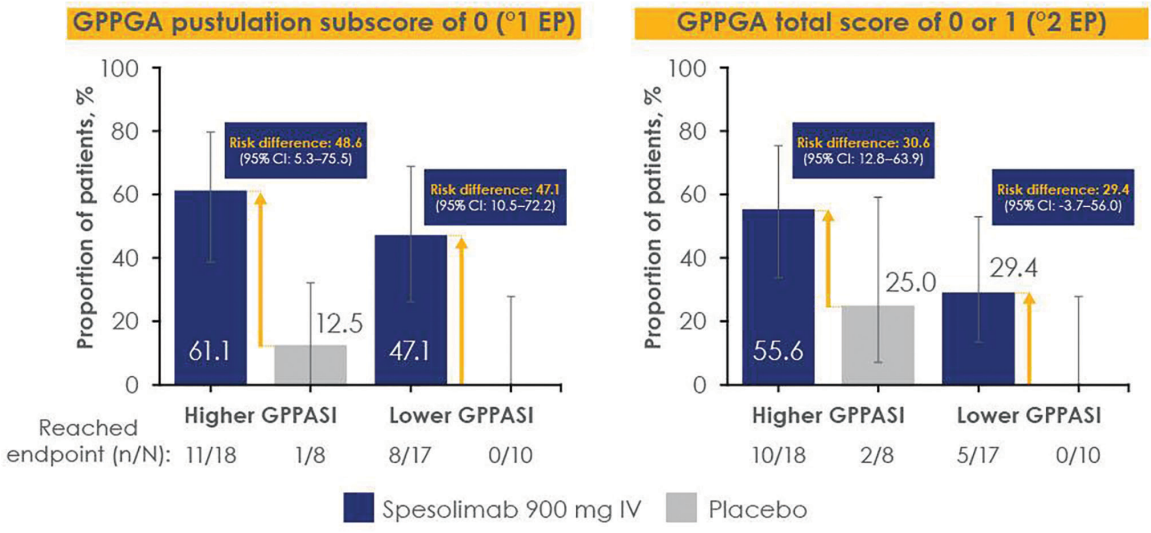
Figure. Primary and key secondary endpoints at Week 1 in patients with higher or lower GPPASI at baseline



Two patients in the spesolimab arm and one patient in the placebo arm received another medication for GPP within the first week; one patient in the spesolimab arm discontinued before completing Week 1. Missing values or use of another medication for GPP within the first week of the trial were regarded as non-response for the analysis of these endpoints. °1 EP, primary endpoint; °2 EP, key secondary endpoint; GPP, generalized pustular psoriasis; GPPASI, Generalized Pustular Psoriasis Area and Severity Index; GPPGA, Generalized Pustular Psoriasis Physician Global Assessment; IV, intravenous.

BACKGROUND: Generalized pustular psoriasis (GPP) is a rare, life-threatening neutrophilic skin disease characterized by widespread eruption of sterile pustules with or without systemic inflammation and symptoms. Effisayil 1, a global, multicenter, randomized, double-blind, placebo-controlled trial, studied spesolimab, an anti-interleukin-36 receptor antibody, in patients with GPP flares.
OBJECTIVE: To report the efficacy of spesolimab according to the severity of GPP at baseline, assessed by GPP Area and Severity Index (GPPASI) score.
METHODS: In Effisayil 1 (NCT03782792), 53 patients with GPP flares were randomized 2:1 to receive one 900 mg intravenous dose of spesolimab or placebo. Patients were assigned to 2 subgroups based on GPPASI scores above or below the median (27.2) for the overall population at baseline. Subgroup analyses included the proportion of patients achieving a GPP Physician Global Assessment (GPPGA) pustulation subscore of 0 or a GPPGA total score of 0 or 1 at week 1 and over the 12-week study. We also evaluated the proportion of patients treated with spesolimab who achieved a 50% improvement in GPPASI score from baseline (GPPASI 50) according to GPPASI subgroup. Results include patients who received up to 2 doses of spesolimab: on day 1 plus optional open-label spesolimab on Day 8 for persistent flares; missing GPPGA values, any use of other medication to treat GPP, or use of spesolimab to treat a new GPP flare were considered non-response.
RESULTS: Patients with a higher GPPASI at baseline had higher GPPGA scores and were more likely to have higher C-reactive protein and leukocytosis at baseline. Patients with a higher GPPASI (73.1%, 19/26) were more likely to be hospitalized for current GPP flare than those with a lower GPPASI (22.2%, 6/25) and had poorer patient-reported outcomes (mean [SD] Dermatology Life Quality Index scores 22.2 [5.3] vs 16.8 [7.5], respectively). The primary and key secondary endpoints were achieved by a similar proportion of patients in the spesolimab arm, regardless of GPPASI subgroup, and the treatment effect vs placebo was consistent in each subgroup (Figure). Improvements observed with spesolimab treatment in both subgroups were sustained at week 12: a GPPGA pustulation subscore of 0 was achieved by 72.2% of patients in the higher GPPASI group and 47.1% in the lower GPPASI group; a GPPGA total score of 0 or 1 was achieved by 66.7% and 52.9% of patients, respectively. GPPASI 50 was achieved by 23.5% of patients in the higher GPPASI group and 61.1% in the lower GPPASI group at week 1, and by 70.6% and 72.2% of patients at week 12, respectively.
DISCUSSION: Patients with a higher baseline GPPASI experienced a greater impact on symptom burden and quality of life, and were more likely to be hospitalized than patients with a lower GPPASI. Pustular and skin clearance following spesolimab treatment were consistently superior to placebo in each subgroup and independent of the severity of GPP at baseline assessed by GPPASI score.
DISCLOSURES: This encore was originally accepted to the European Academy of Dermatology and Venereology (EADV), 07 Sept to 10 Sept 2022.

Abstract: PS-12

Fixed-Combination Halobetasol Propionate and Tazarotene Lotion for the Treatment of Plaque Psoriasis in Patients With Affected Body Surface Area of 3% to 5% and Poor Quality of Life

Linda Stein Gold,[1] Edward Lain,[2] Jerry Bagel,[3] Abby Jacobson[4]

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

BACKGROUND: Use of tazarotene with topical steroids, such as superpotent halobetasol propionate, is recommended for mild to moderate psoriasis, as the combination may provide efficacy while increasing duration of treatment effect and remission. However, objective measures of psoriasis, such as body surface area (BSA) involvement, may underestimate disease severity. Patients with low BSA involvement may face challenges in controlling their psoriasis, including their providers' perceptions of disease impact and insurance coverage for systemic therapy.
OBJECTIVE: To investigate fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) in patients with relatively low BSA involvement and poor quality of life (QOL).
METHODS: Two phase 3, multicenter, double-blind studies enrolled 418 adults with BSA involvement of 3% to 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 posttreatment follow-up. Pooled, post hoc analyses were conducted in a subset of 65 participants with baseline BSA involvement of 3% to 5% and dermatology life quality index (DLQI) of ≥ 11.
RESULTS: At week 8, 50.3% of HP/TAZ–treated participants achieved treatment success (≥ 2-grade reduction from baseline in IGA and score of 0 [clear] or 1 [almost clear]) versus 14.6% of vehicle-treated participants ($P < .05$). BSA involvement was significantly reduced with HP/TAZ (39.2%) versus that with vehicle lotion (+15.9%; $P < .05$). The percentage of participants experiencing a clinically meaningful ≥ 4-point reduction in DLQI was greater for HP/TAZ (85.3%) than for vehicle (55.6%). Numerical improvements with HP/TAZ were maintained 4 weeks posttreatment for efficacy measures and DLQI, consistent with the overall population.
CONCLUSIONS: Though analyses were limited by the small population, HP/TAZ provided significantly greater efficacy than did vehicle in participants with low BSA involvement and poor QOL, with clinically relevant improvements in QOL. Considering treatment and QOL challenges faced by patients with low BSA involvement, HP/TAZ presents an effective therapeutic option for psoriasis patients with limited skin involvement.

FUNDING: This study was sponsored by Ortho Dermatologics. Medical writing support was provided by MedThink SciCom and funded by Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

DISCLOSURE: Data included in this abstract have been previously presented in full at American Academy of Dermatology (AAD) Virtual Meeting Experience 2021, April 23-25, 2021; and at Maui Derm 2022, January 24-28, 2022.

Abstract: PS-13

Importance of Topical Vehicle Design for the Treatment of Psoriasis: A Review of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion

Linda Stein Gold,[1] Zoe Draelos,[2] Emil Tanghetti,[3] Ted Lain,[4] Andrea Murina,[5] Abby Jacobson[6]

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BACKGROUND: Fixed-dose combination halobetasol propionate 0.01%/tazarotene 0.045% (HP/TAZ) lotion is an effective topical treatment for psoriasis that is formulated with a polymeric matrix that promotes uniform drug distribution and absorption, which is important for achieving consistent results and avoiding localized irritation. HP and TAZ are encapsulated within the same oil droplet along with moisturizing excipients. These oil droplets are uniformly distributed in the matrix, which contains additional moisturizing components. When in contact with salts on the skin, the mesh breaks and uniformly releases HP/TAZ. In a phase 2 study of HP/TAZ, rates of adherence were high (95%) among participants, possibly because the drug was easy to use and met expectations regarding cosmetic qualities.

OBJECTIVE: To describe the vehicle properties of HP/TAZ in the context of recent patient satisfaction surveys.

METHODS: Preferences to several vehicle features of HP/TAZ lotion were assessed through a questionnaire (18 questions) administered to 15 participants with plaque psoriasis. Additionally, female participants in phase 3 trials of HP/TAZ were given a questionnaire to assess satisfaction with the formulation.

RESULTS: Most survey respondents (> 90%) rated the hydration, moisturization, and absorption properties of HP/TAZ lotion positively. Additionally, in a formulation satisfaction survey of study participants treated with HP/TAZ lotion, 100% reported that the vehicle was nongreasy, moisturizing, and quickly absorbed.

CONCLUSIONS: By meeting patient expectations regarding topical characteristics, HP/TAZ may enhance adherence to treatment.

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Abstract: PS-14

Improvement in Touch Avoidance in Patients with Genital Psoriasis Treated With Ixekizumab: 52-Week Results of a Phase 3 Clinical Trial in Patients With Moderate to Severe Genital Psoriasis (IXORA-Q)

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INTRODUCTION: Genital psoriasis can have a significant impact on quality of life, where people may avoid close social interactions such as touching others or being touched. Ixekizumab, an interleukin-17A antagonist, demonstrated rapid and persistent improvement in genital psoriasis up to 52 weeks and touch avoidance (TA) up to 12 weeks. Here, we report TA up to 52 weeks with ixekizumab.

METHODS: IXORA-Q (NCT02718898) was a phase 3 trial among patients with moderate to severe genital psoriasis. Patients received 80 mg ixekizumab every 2 weeks (IXE Q2W, n = 75) or placebo (PBO, n = 74) for 12 weeks. At week 12, open-label treatment began, where all patients received 80 mg ixekizumab every 4 weeks (IXE Q4W) up to week 52. Patients used a numeric rating scale (NRS) to self-report the degree of TA over the past 2 weeks (0 = not at all, 10 = very much). TA NRS change from baseline was

imputed by modified baseline observation carried forward and TA NRS = 0 by nonresponder imputation.
RESULTS: Mean (SD) baseline score was 2.7 (3.3) for IXE Q2W. Mean (SD) change from baseline at week 52 was -2.2 (3.5) for patients treated continuously with ixekizumab (Q2W then Q4W) and -2.2 (3.3) for PBO/IXE Q4W. The proportion of patients with TA NRS > 0 at baseline who achieved TA NRS = 0 at week 52 was 78.0% (32/41) for patients treated continuously with ixekizumab and 62.5% (25/40) for PBO/IXE Q4W.
Conclusion: Among patients with moderate to severe genital psoriasis, ixekizumab treatment achieves continued sustained improvement in touch avoidance to 52 weeks.
DISCLOSURE: This study was previously presented at the 2022 American Academy of Dermatology (AAD) 80th Annual Meeting. Sponsored by Eli Lilly and Company.

Abstract: PS-15

Long-Term Efficacy and Safety of Ixekizumab in a Phase III, Randomized, Double-Blind, Placebo-Controlled Study in Pediatric Patients with Moderate To Severe Plaque Psoriasis (IXORA-PEDS) Up to 108 Weeks

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BACKGROUND: About 1% of children and adolescents worldwide are affected by plaque psoriasis (PsO).
OBJECTIVE: To report the long-term efficacy and safety of ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, for moderate to severe pediatric PsO from a randomized, double-blind phase 3 study (IXORA-PEDS [NCT03073200]) up to 108 weeks.
METHODS: Full study methods for IXORA-PEDS have been published previously. Patients aged 6 to < 18 years were randomized 2:1 to weight-based dosing of IXE every 4 weeks (IXE Q4W, n = 115) or placebo (n = 56). After a 12-week placebo-controlled period all patients entered a 48-week open-label IXE Q4W maintenance period (weeks 12 to 60) followed by an extension period through 108 weeks. A substudy evaluated randomized withdrawal of IXE after week 60. This analysis focuses on treatment response rates (modified nonresponder imputation) through 108 weeks.
RESULTS: The completion rate at week 108 was 83.7% (N = 139). Primary and gated secondary endpoints achieved by week 12 were sustained through week 108 with 91.7%/79.0%/55.1% of patients achieving or maintaining PASI 75/90/100, respectively. sPGA (0) and sPGA (0,1) responses were also sustained at week 108 in 52.4% and 78.3% of patients, respectively. A total of 78.5% of patients also reported an Itch NRS ≥ 4-point reduction at week 108. There were no new safety events during the 48-to-108 week period, including no new cases of inflammatory bowel disease or candida infection.
CONCLUSION: In IXE-treated pediatric patients, efficacy response rates were sustained through week 108. Safety findings were as expected for this population and the known safety profile of IXE.
DISCLOSURES: Study was sponsored by Eli Lilly and Company. Abstract previously presented at 2022 American Academy of Dermatology (AAD) 80th Annual Meeting.

Abstract: PS-16

Long-Term Skin Clearance Achieved in Moderate to Severe Psoriasis Through Interleukin-17 Receptor A Blockade

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BACKGROUND: Most biologics available for treatment of moderate to severe psoriasis target individual cytokines. However, numerous inflammatory mediators have been implicated in the pathogenesis of psoriasis, including interleukin (IL)-17 family members. Brodalumab is a human monoclonal antibody that targets the IL-17 receptor A, thereby blocking the signaling of multiple IL-17 cytokines (ie, IL-17A, IL-17C, IL-17E, and IL-17F; Figure 1). This unique mechanism of action potentially contributes to complete, long-term skin clearance in patients with psoriasis.

Figure 1. Brodalumab inhibits multiple IL-17 cytokines by blocking IL-17RA. IL, interleukin; IL-17RA, IL-17 receptor A; T_H17, helper T cell, subtype 17.

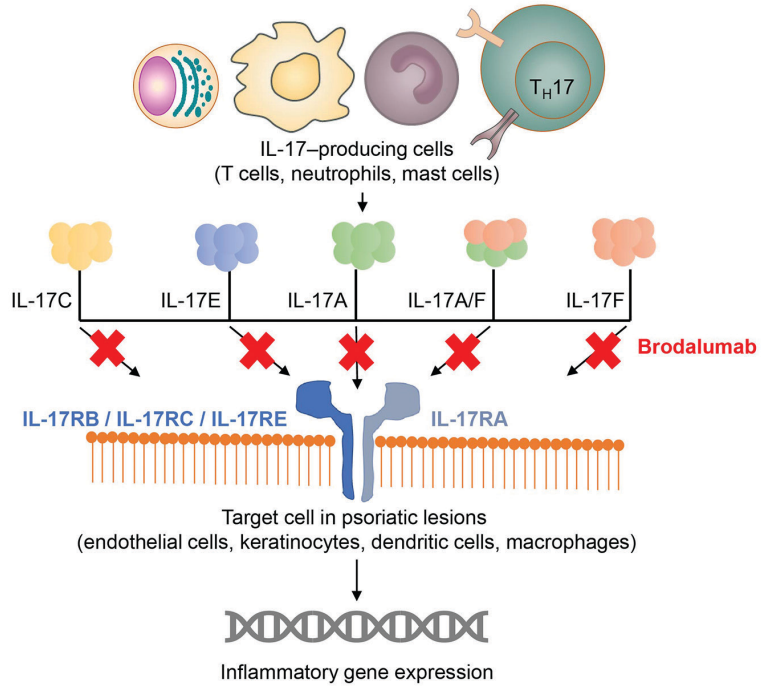
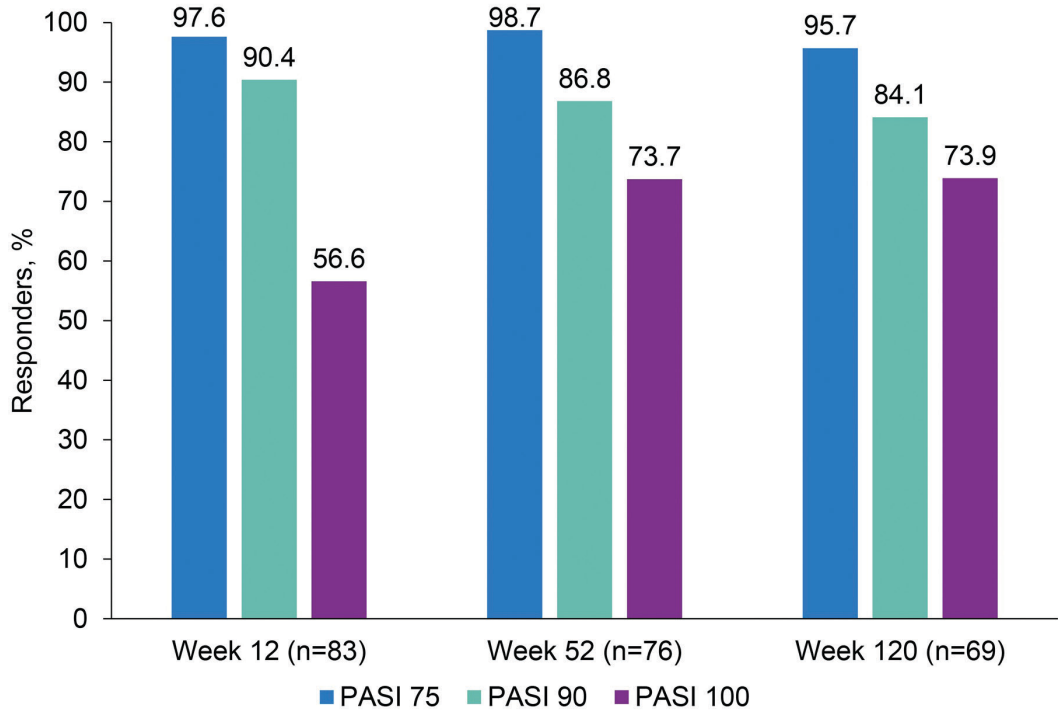


Figure 2. PASI scores following continuous brodalumab 210 mg Q2W. PASI 75, 90, and 100, psoriasis area and severity index 75%, 90%, and 100% improvement; Q2W, every 2 weeks.



OBJECTIVES: To evaluate the long-term efficacy and safety of brodalumab in treating moderate to severe psoriasis in the phase 3 AMAGINE-1 trial (NCT01708590).

METHODS: Patients were randomized to brodalumab 210 mg or placebo every 2 weeks (Q2W) for 12 weeks. At week 12, patients treated with brodalumab who achieved static physician's global assessment of 0 or 1 (sPGA 0/1) were rerandomized to brodalumab 210 mg Q2W or placebo for up to 120 weeks. Patients rerandomized to placebo who had return of disease (sPGA ≥ 3) qualified for retreatment beginning at week 16. Observed Psoriasis Area and Severity Index (PASI) 75%, 90%, and 100% response rates (PASI 75, PASI 90, and PASI 100) were used to monitor skin clearance, and safety was summarized by exposure-adjusted treatment-emergent adverse events.

RESULTS: Observed PASI 75, PASI 90, and PASI 100 in patients receiving continuous brodalumab 210 mg Q2W (n = 83) at week 120 were 95.7%, 84.1%, and 73.9%, respectively (Figure 2). Of patients who switched from brodalumab 210 mg Q2W to placebo at week 12 (n = 84), 94.0% (n = 79) experienced return of disease (sPGA ≥ 3) at or after study week 16 through 52. Return of disease occurred after a mean of 74.7 days from starting placebo. Among patients who switched to placebo, observed PASI 75 was 100.0% at week 12, 55.1% at week 20 (8 weeks after switch to placebo), and 94.0% at week 120 (retreatment with brodalumab started on or after week 16). Similarly, observed PASI 100 for patients who switched to placebo was 54.8% at week 12, 12.8% at week 20, and 74.6% at week 120. Of patients who achieved PASI 75, PASI 90, and PASI 100 before brodalumab withdrawal, 92.1%, 91.2%, and 90.5%, respectively, recaptured their prior response after 16 weeks of retreatment. There were no new safety signals during long-term analysis.

CONCLUSIONS: Brodalumab is efficacious and well tolerated for long-term treatment of moderate to severe psoriasis. The unique mechanism of action of brodalumab may allow for long-term, durable efficacy and high rates of response recapture.

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Abstract: PS-17

PASI Regional Component Speed of Response and Cumulative Response in Patients With Moderate to Severe Plaque Psoriasis Treated With Ixekizumab vs Guselkumab in the IXORA-R Trial

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INTRODUCTION: This post hoc analysis compares speed of response and cumulative response over time for ixekizumab (IXE) vs guselkumab (GUS) in different body regions (head = head/scalp/neck; trunk = chest/abdomen/back/axillae/genitalia; upper extremities = arms/hands/palms; lower extremities = legs/buttocks/feet/soles) in moderate to severe plaque psoriasis (PsO) patients participating in IXORA-R study, up to week (Wk) 24.

METHODS: Patients received the respective on-label dosing of IXE and GUS. Median time-to-first Psoriasis Area and Severity Index (PASI) 50/75/90/100 response was calculated based on Kaplan-Meier analysis and statistical difference between IXE and GUS was assessed using log-rank test. Cumulative skin clearance days were assessed for PASI response rates in each body region by the average number of days with PASI response up to the applicable time point and estimated by the percentage of maximum area under the curve (AUC) over the total duration at that time point. Treatment comparisons were done based on analysis of covariance adjusting for baseline PASI and pooled sites. Missing data were imputed with nonresponder imputation for categorical variables, modified baseline observation carried forward for continuous variables, and between visits extrapolation for patient level AUC.

RESULTS: 1027 patients (IXE = 520; GUS = 507) enrolled in the trial. Median time-to-first PASI 50/75/90/100 response was shortest in the head, followed by trunk and upper extremities, and lastly by lower extremities in both IXE and GUS treatment arms (Figure 1). In each region, IXE was significantly faster ($P < .001$) than GUS in achieving PASI 50/75/90/100. Median time-to-first PASI 100 in IXE-treated patients was 4.1 Wk (vs 8.1 Wk with GUS) in the head, 6.4 Wk (vs 10.1 Wk) in the trunk, 8.1 Wk (vs 10.1 Wk) in the upper extremities, and 10.1 Wk (vs 16.1 Wk) in the lower extremities. Number of days with clear skin for IXE at Wk 24, PASI 75/90/100, was greater in the head, followed by trunk, upper extremities, and lastly by lower extremities (Table). Patients on IXE experienced a significantly higher number of

Figure 1. Median time-to-first PASI 50, 75, 90, and 100 response by body regions (head, trunk, upper extremities, lower extremities) in patients on IXE (N=520) or GUS (N=507). Data are presented as median number of weeks with 95% confidence interval. ***Log-Rank Test p-value <0.001. IXE=ixekizumab; GUS=guselkumab; PASI=Psoriasis Area and Severity Index.

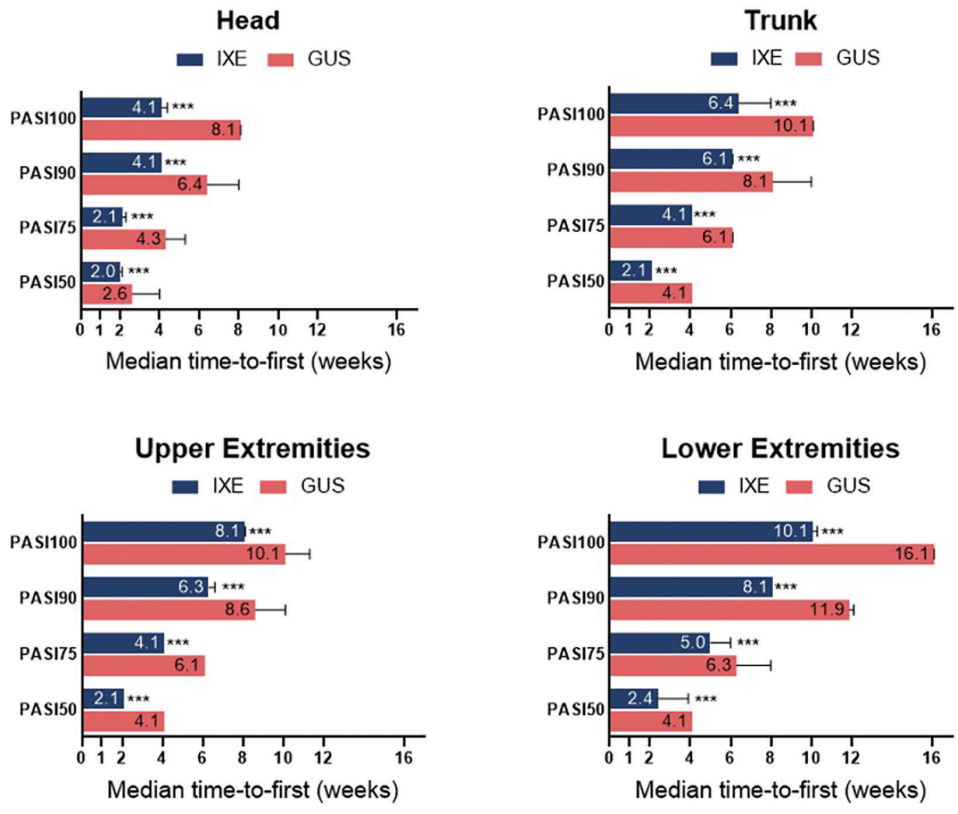

Table 1. Days of clear skin for PASI 50, 75, 90, and 100 response by body regions (head, trunk, upper extremities, lower extremities) in patients on IXE (N=514) or GUS (N=506) at week 24. Least-squares means and the p-values based on ANCOVA for the treatment comparisons are reported. IXE=ixekizumab; GUS=guselkumab; PASI=Psoriasis Area and Severity Index.

	Head			Trunk			Upper Extremities			Lower Extremities		
	IXE	GUS	p-value	IXE	GUS	p-value	IXE	GUS	p-value	IXE	GUS	p-value
PASI 50	136.2	127.6	0.003	137.4	130.1	0.004	139.8	133.0	0.002	137.4	129.4	<0.0001
PASI 75	125.2	112.2	<0.0001	122.9	111.1	<0.0001	121.7	113.6	0.002	117.7	106.9	<0.0001
PASI 90	113.0	97.1	<0.0001	106.9	91.3	<0.0001	93.6	85.3	0.007	89.7	72.3	<0.0001
PASI 100	107.5	90.6	<0.0001	97.7	83.9	<0.0001	85.0	75.6	0.002	75.7	59.8	<0.0001

days of response for PASI 50/75/90/100 in each body region than patients on GUS.

DISCUSSION: IXE is significantly faster than GUS in achieving PASI 50/75/90/100 in all body regions of patients with moderate to severe plaque PsO. IXE-treated patients experienced a significantly higher cumulative response with more days of clear skin for PASI 50/75/90/100 in all body regions at Wk 24 than GUS.

DISCLOSURES: Study was sponsored by Eli Lilly and Company. Previously presented at 2022 European Academy of Dermatology and Venereology (EADV) 31st Congress.

Abstract: PS-18

Patient-Reported Symptom Relief in a Phase 4 Real-World Study of Tildrakizumab in Patients With Moderate to Severe Plaque Psoriasis

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BACKGROUND: Tildrakizumab is an anti-interleukin-23 p19 monoclonal antibody approved for the treatment of moderate to severe plaque psoriasis.

OBJECTIVES: To evaluate improvements in patient-reported relief from itching, skin pain, and scaling—common symptoms in patients with psoriasis (Ljosaa TM, et al. Acta Derm Venereol 2013)—through 64 weeks in a real-world study of tildrakizumab in patients with moderate to severe plaque psoriasis.

METHODS: In this phase 4, uncontrolled, open-label, real-world study (NCT03718299), patients with moderate to severe plaque psoriasis received tildrakizumab 100 mg at weeks 0, 4, and every 12 weeks thereafter up to week 52. Patient-reported Numerical Rating Scale (NRS) scores for itching, pain, and scaling (measured on a scale ranging from 0 [none] to 10 [worst imaginable]) were assessed through week 64. The change from baseline in Itch-NRS, Pain-NRS, and Scaling-NRS and proportion of patients with scores of zero are reported. Missing data were not imputed.

RESULTS: Of 55 patients enrolled, 45 were assessed at week 64; 50.9% were male and 94.5% were White, with mean ± standard deviation (SD) age 48.6 ± 15.3 years. Patients receiving tildrakizumab had significant and consistent improvements in patient-reported symptoms beginning as early as week 4. The mean ± SD Itch-NRS score improved from 6.6 ± 2.6 at baseline to 4.9 ± 2.6 at week 4 and 2.4 ± 2.4 at week 64 (both $P < .001$). The mean ± SD Pain-NRS score was 3.8 ± 3.2 at baseline and decreased to 2.6 ± 2.5 at week 4 ($P = .001$) and 1.1 ± 1.9 at week 64 ($P < .001$). Mean ± SD Scaling-NRS score improved from 7.0 ± 2.3 at baseline to 4.4 ± 2.5 at week 4 and 2.4 ± 2.6 at week 64 (both $P < .001$). At week 64, 24.4%, 48.9%, and 17.8% of patients reported an Itch-, Pain-, and Scaling-NRS score of zero, respectively. Generally, improvements from baseline were observed at each postbaseline visit.

CONCLUSIONS: Tildrakizumab treatment rapidly and significantly improved patient-reported itching, pain, and scaling, with meaningful effects observed after 1 dose and mantained for up to 64 weeks, in patients with moderate to severe plaque psoriasis in a real-world setting.

DISCLOSURES: This study was funded by Sun Pharma. Analyses were funded by Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA.

Abstract: PS-19

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

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

OBJECTIVES: Describe pooled efficacy and safety results from 2 identical phase 3 randomized controlled trials of roflumilast cream (DERMIS-1: NCT04211363 and DERMIS-2: NCT04211389).

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

RESULTS: Significantly greater percentages of roflumilast-treated versus vehicle-treated patients achieved the primary efficacy endpoint, Investigator Global Assessment (IGA) Success (Clear or Almost Clear IGA plus ≥ 2-grade improvement from baseline) at week 8 (39.9% vs 6.5%; $P < .0001$), and had IGA of Clear/Almost Clear at week 8 (48.0% vs 9.5%; $P < .0001$). Statistically significant differences favoring roflumilast were observed for multiple secondary endpoints at week 8: percentages of patients achieving intertriginous-IGA Success (69.7% vs 16.1%; $P = .0025$), percentages achieving 75% reduction in Psoriasis Area Severity Index (40.3% vs 6.5%; $P < .0001$), and percentages with baseline Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 4 achieving a 4-point reduction (68.5% vs 31.3%; $P < .0001$). Differences in WI-NRS for roflumilast- vs vehicle-treated patients were significant as early as 2 weeks (38.4% vs 21.6%; $P < .001$).

Overall incidence of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation were low and similar between roflumilast and vehicle. Local tolerability was highly favorable on patient and investigator assessments.

CONCLUSIONS: Once-daily roflumilast cream 0.3% provided superior improvement across multiple efficacy endpoints by week 8, and favorable safety and tolerability in patients with psoriasis in 2 phase 3 trials.

Abstract: PS-20

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

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

OBJECTIVE: To explore the effects of spesolimab over the 12-week study duration based on observed case analysis.

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

RESULTS: Of patients initially randomized to spesolimab, 61.8% and 84.4% achieved a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of 0, and 50.0% and 81.3% a GPPGA total score of 0/1 by weeks 1 and 12, respectively. Of patients initially randomized to placebo who received open-label spesolimab at day 8, 83.3% and 80.0% had a GPPGA pustulation subscore of 0, and 72.2% and 93.3% had a GPPGA total score of 0/1 by weeks 2 (1 week post-spesolimab) and 12, respectively. After day 8, 32 and 17 patients randomized to spesolimab and placebo, respectively, completed the 12-week follow-up period, during which 4 and 2 patients, required rescue treatment with spesolimab for a new flare episode.

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

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