Supported by independent education grants from AbbVie, Arcutis Biotherapeutics, Chiesi USA, Galderma, Janssen, Novartis, and UCB Pharma.

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REFERENCED IN *INDEX MEDICUS* | VOL. 113 | NO. 4S | APRIL 2024 | mdedge.com/dermatology

# *Spring* ABSTRACT COMPENDIUM

## 46TH ANNUAL HAWAII DERMATOLOGY SEMINAR

### FEBRUARY 18-24, 2024; WAIKOLOA, HAWAII

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Spring
ABSTRACT COMPENDIUM
46TH ANNUAL HAWAII DERMATOLOGY SEMINAR
FEBRUARY 18-24, 2024; WAIKOLOA, HAWAII

## Acne, Rosacea, & Pigmentation

### Abstract AR-01

### Early Acne Improvements With Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel: What to Expect in the First 4 Weeks of Treatment

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

**BACKGROUND:** Treatments with fast and substantial acne clearance are highly desirable. While a three-pronged approach may increase treatment efficacy versus monotherapy or dual-combination therapy, it is unknown if triple-combination provides more rapid improvement. CAB gel—clindamycin phosphate (clin) 1.2%/adapalene 0.15%/benzoyl peroxide (BPO) 3.1%—is the first fixed-dose, triple-combination acne topical. Since rapid/substantial acne improvements and fewer side effects can increase adherence, the efficacy and safety of CAB in the first 4 weeks of treatment was evaluated.

**METHODS:** In a phase 2 (N=741; NCT03170388) and two phase 3 (N=183; N=180; NCT04214639; NCT04214652), double-blind, 12-week studies, participants aged ≥9 years with moderate-to-severe acne were randomized to once-daily CAB or vehicle gel; the phase 2 study included 3 additional dyad arms: BPO/adapalene; clin/BPO; and clin/adapalene. Efficacy assessments included least-squares mean percent change from baseline in inflammatory and noninflammatory lesions. Cutaneous safety/tolerability assessments were graded from 0=none to 3=severe. Post hoc analyses included percentages of participants with one-third and one-half acne lesion reductions.

**RESULTS:** At week 4, CAB led to ~55% reductions from baseline in inflammatory acne lesions in the ph2 and pooled ph3 studies, significantly greater than vehicle (~40%) and its 3 dyads (ph2 range: 44.2-47.6%; $P<0.05$, all). The percentages of participants with one-third and one-half reductions of inflammatory lesions were significantly greater with CAB than vehicle and dyads ($P<0.05$, all). Similar trends were observed for noninflammatory lesions, though reductions were less pronounced. As expected for retinoids, transient increases from baseline to week 2 in scaling, erythema, itching, burning, and stinging were observed for CAB, BPO/adapalene, and clin/adapalene, with mean scores ≤0.6 (1=mild); no trends in dyspigmentation were observed. Mean scores for all cutaneous assessments were highest for BPO/adapalene, indicating that adding a third product in the fixed-dose CAB gel formulation did not worsen tolerability.

**CONCLUSIONS:** Acne lesion reductions were significantly greater with clin 1.2%/adapalene 0.15%/BPO 3.1% gel versus its dyads and vehicle gel as early as week 4. More rapid efficacy with this first fixed-dose triple-combination acne product—coupled with its optimized formulation, once-daily dosing, and tolerability—may positively impact treatment adherence.

**FUNDING:** Ortho Dermatologics.

**DISCLOSURES:** JCH has received honoraria from: Aclaris, Almirall, BioPharmX, Cassiopea, Cutanea, Dermira, Foamix, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun Pharma. LHK has acted as an investigator, advisor, speaker, and consultant for: Ortho Dermatologics. MG has acted as an investigator, advisor, speaker, and consultant for: Ortho Dermatologics. AAH has received honoraria from: Amirall, Cassiopea, Cutanea, Demira, Ferrer, Galderma, LEO Pharma, Ortho Dermatologics, Pfizer; the UTHealth McGovern Medical School had received research grants from: Cassiopea, Demira, Ortho Dermatologics. LG has served as an investigator, consultant, or speaker for: Almirall, Cassiopea, Galderma, Ortho Dermatologics, Sol-Gel, Sun Pharma, and Vyne. LSG has served as an investigator/consultant or speaker for: AbbVie, Arcutis, Dermavant, Incyte, LEO Pharma, Lilly, Novartis, Ortho Dermatologics, Pfizer, Sun Pharma, and UCB. JLS is a consultant for: Bausch Health, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, and Verrica. HB has served as advisor, investigator, and on speakers' bureaus for: Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol-Gel, and Sun Pharma.

JQDS has served as a consultant, investigator, and/or speaker for: AbbVie, Amgen, Arcutis, Dermavant, EPI Heath, Galderma, Incyte, LEO Pharma, Lilly, MC2 Therapeutics, Ortho Dermatologics, Pfizer, Sun Pharma, and UCB. TL and EG are employees of: Ortho Dermatologics and may hold stock and/or stock options in its parent company.

## Atopic Dermatitis

### Abstract AD-01

### Conjunctivitis Does Not Increase With Longer Duration of Lebrikizumab Exposure in Patients With Moderate-to-Severe Atopic Dermatitis

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**BACKGROUND:** Integrated safety data for lebrikizumab (LEB) treatment in moderate-to-severe atopic dermatitis (AD) has been previously published. Conjunctivitis and keratitis were identified as adverse events (AEs) of special interest in the AD program.

**OBJECTIVE:** Further characterize patient-reported conjunctivitis and keratitis AEs in LEB clinical trials for AD.

**METHODS:** Data from adult and adolescent patients were analyzed in 2 groups: a) LEB 250 mg every 2 weeks (LEBQ2W, N=783) vs placebo (PBO, N=404), weeks 0-16 (PC 0-16wk) from 4 clinical trials (ADvocate1, ADvocate2, ADhere, Phase 2b study); and b) patients who received at least one dose of LEB (ALL-LEB, N=1720) from 8 clinical trials (ADvocate1, ADvocate2, ADhere, ADore, ADjoin (ongoing), ARBAN, TREBLE, Phase 2b study). Conjunctivitis and keratitis refer to cluster definitions defined by MedDRA preferred terms conjunctivitis, allergic conjunctivitis, bacterial conjunctivitis, viral conjunctivitis, giant papillary conjunctivitis; and keratitis, atopic keratoconjunctivitis, allergic keratitis, ulcerative keratitis, vernal keratoconjunctivitis, respectively. Exposure adjusted incidence rates (IR) are provided as per 100 patient-years.

**RESULTS:** In PC 0-16wk, at baseline, similar proportions of LEB (21.5%) and PBO (19.3%) patients had medical history (MH) of conjunctivitis. Of ALL-LEB, 22.2% had MH of conjunctivitis; of those with conjunctivitis or keratitis AE, 40% had MH of conjunctivitis. In PC 0-16wk, conjunctivitis cluster was reported by 8.5% (IR:30.6) LEBQ2W vs 2.5% (IR:8.9) PBO; keratitis cluster was reported by 0.6% (IR:2.2) and 0.3% (IR:0.9) of patients, respectively. All conjunctivitis and keratitis events in PC 0-16wk were mild or moderate in severity; 5 events (3 conjunctivitis, 2 keratitis) led to treatment discontinuation (LEBQ2W) vs 1 conjunctivitis event (PBO). ALL-LEB treatment duration ranged from 1 dose to 100 weeks. In ALL-LEB, conjunctivitis cluster was reported by 10.6% (IR:12.2), with the majority being mild or moderate (10.3%) and 0.3% severe. Keratitis was reported by 0.5% (IR:0.6), with 1 severe event of vernal keratoconjunctivitis. Conjunctivitis and keratitis events resulted in 17 (1.0%) and 3 (0.2%) treatment discontinuations, respectively. Similar proportions of adult (11.3%; 0.6%) and adolescent (8.3%; 0.3%) patients reported conjunctivitis and keratitis events. The majority were reported within first 16 weeks of treatment.

**CONCLUSION:** Conjunctivitis is an AE reported by LEB-treated patients. Patients with MH of conjunctivitis may have higher risk of developing treatment-emergent conjunctivitis or keratitis. Most events were mild or moderate in severity, did not lead to treatment discontinuation, were reported within the first 16 weeks of treatment, and IR did not increase with longer duration of exposure.

**ACKNOWLEDGMENTS AND FUNDING:** These studies were funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications including atopic dermatitis in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe. Abstract previously presented at Fall Clinical Dermatology Conference, Oct 19-22, 2023, Las Vegas, NV.

**DISCLOSURES:** AA has served as a consultant, speaker, and/or investigator for: AbbVie, Almirall, Arcutis, ASLAN Pharmaceuticals, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI Health, Incyte Corporation, Janssen, LEO Pharma, Modernizing Medicine, Nimbus Therapeutics, Novartis, Ortho Dermatologics, PAREXEL, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. AW has served as an advisor and/or paid speaker for and/or participated in clinical trials sponsored by: AbbVie, Aileens Pharma, Almirall, Amgen, Beiersdorf, Bioderma, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai Pharmaceutical, Eli Lilly and Company, Galapagos NV, Galderma, GlaxoSmithKline, Janssen, LEO Pharma, L'Oréal, Novartis, Pfizer, Pierre Fabre, Regeneron, and Sanofi. MBW has served as a consultant, speaker, advisor, and/or advisory board member for: AbbVie, Almirall, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Pfizer, Regeneron, and Sanofi Genzyme. PAL reports research grants and/or funding from: AbbVie, AOBiome, Eczema Foundation; has been on speaker's bureaus for: AbbVie, Eli Lilly and Company, Galderma, Hyphens Pharma, Incyte Corporation, La Roche-Posay/L'Oréal, MyOR Diagnostics, ParentMD, Pfizer, Pierre Fabre, and Regeneron/Sanofi Genzyme; has received

consulting fees from and/or been on advisory boards for: AbbVie, Almirall, Amyris, Arbonne, Arcutis, ASLAN Pharmaceuticals, Bodewell, Boston Skin Science, Bristol Myers Squibb, Burt's Bees, Castle Biosciences, Codex Labs, Concerto Biosciences, Dermavant, Dermira, Dermveda, Eli Lilly and Company, Galderma, IntraDerm, Janssen, Johnson & Johnson, Kaleido Biosciences, Kimberly-Clark, L'Oréal, LEO Pharma, Lipidor, Menlo Therapeutics, Merck, Micreos, MyOR Diagnostics, Regeneron/Sanofi Genzyme, Sibel Health, Skinfix, Sonica, Theraplex, UCB Pharma, Unilever, Verrica Pharmaceuticals, and Yobee Care; has stock options with: LearnSkin/Learn Health, Medable, Micreos, Modernizing Medicine, and Yobee Care; has a patent pending for: Theraplex product with royalties paid; and is a board member and scientific advisory committee member of: the National Eczema Association. CRN, FZ, ARA, and BRM are employees and shareholders of: Eli Lilly and Company. GJ is an employee of: Almirall. C-YC is an investigator, consultant, speaker, and/or advisory board member for: AbbVie, Dermira, Eli Lilly and Company, Janssen, Mylan, Novartis, Oneness Biotech, Pfizer, Regeneron, Roche, Sanofi, United BioPharma, and Viatris. CV has served as an advisor and/or speaker and/or has received fees or grant and/or research support for and/or has participated in clinical trials sponsored by: AbbVie, Almirall, AstraZeneca, Eli Lilly and Company, Galderma, LEO Pharma, Novartis, OM Pharma, Pfizer, Pierre Fabre, and Sanofi Genzyme.

## Abstract AD-02

### Dupilumab Improves Disease Severity in Children <12 Years of Age With Moderate-Severe Atopic Dermatitis: Interim Results From PEDISTAD Real-World Registry

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**BACKGROUND:** Effective treatments for children with moderate to severe atopic dermatitis (AD) are limited. Immunosuppressants, e.g. methotrexate (MTX) and cyclosporine (CsA), are commonly used off label, and dupilumab has improved AD severity in phase 3 studies. Further data on these treatments in real-word settings are needed.

**OBJECTIVE:** To study the efficacy of dupilumab in treating AD in comparison to MTX and CsA in real-world settings.

**METHODS:** PEDISTAD (NCT03687359) is an ongoing study in patients aged <12 years with moderate-to-severe AD. Effects of dupilumab, MTX, and CsA on Eczema Area and Severity Index (EASI) total score and % affected body surface area (BSA) were assessed.

**RESULTS:** 129 patients received dupilumab (median treatment observation period: 17.0 months; 3-year discontinuation rate: 10.1%), 70 CsA (12.2 months; 40.0%), and 77 MTX (21.3 months; 22.1%). At first treatment, prevalence of atopic comorbidities was high (dupilumab: 79.8%; CsA: 72.9%; MTX: 58.4%), including food allergies (48.8%; 35.7%; 31.2%), allergic rhinitis (44.2%; 40.0%; 33.8%), and asthma (34.9%; 27.1%; 28.6%). Proportion of patients with clear/mild AD (EASI <7 [range 0–72]) increased for dupilumab (treatment start: 27.0%; last observation: 78.8%), CsA (18.8%; 54.6%), and MTX (13.3%; 58.7%). Mean (± SE) EASI scores improved with dupilumab (treatment start: 18.4 ± 1.3; last observation: 5.0 ± 0.7), CsA (16.9 ± 1.4; 10.0 ± 1.4), and MTX (16.6 ± 1.3; 8.4 ± 1.1). Mean (± SE) BSA affected decreased for dupilumab (37.5 ± 2.2; 15.6 ± 2.3), CsA (36.9 ± 2.8; 24.0 ± 2.8), and MTX (34.3 ± 2.3; 20.3 ± 2.5). Exposure-adjusted AE/serious AE rate per 100 patient-years was 29.2/1.5 for dupilumab; 43.5/0.9 for CsA; and 30.7/0.6 for MTX.

**CONCLUSION:** Atopic comorbidities were high in this cohort of patients. Dupilumab treatment led to numerically greater improvement in disease severity and extent was also associated with lower treatment discontinuation and fewer AEs compared with MTX and CsA.

**ACKNOWLEDGMENTS AND FUNDING:** Data first presented at the 13th Symposium of the International Society of Atopic Dermatitis (ISAD); Gdansk, Poland (August 31st–September 2nd, 2023). Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT03687359. Medical writing/editorial assistance was provided by Eleanor Ewins, PhD, of Excerpta Medica and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guideline.

**DISCLOSURES:** ASP has served as an investigator for: AbbVie, AnaptysBio, Eli Lilly and Company, Incyte, Janssen, KrystalBio, Regeneron, and UCB; has served as a consultant with honorarium from: AbbVie, Acrotech, Almirall, Amgen, Amryt, Arcutis, Arena, Azitra, BioCryst, BiomX, Bridgebio, Bristol Myers Squibb, Castle Biosciences, Catawba, Eli Lilly and Company, Exicure, Gilead, Incyte, Janssen, Johnson & Johnson, Kamari, LEO Pharma, Novartis, OM Pharma, Pfizer, Pierre Fabre, RAPT, Regeneron, Sanofi, Seanergy, and UCB; has served on the Data Safety Monitoring Board for: AbbVie, Abeona, Bausch, Galderma, and Novan. EB has served as an investigator for: AbbVie, LEO Pharma, Novartis, Pfizer, and Pierre Fabre Dermo-Cosmetics; has served as a consultant for: Pierre Fabre Dermo-Cosmetics, Regeneron Pharmaceuticals Inc., and Sanofi. MR has served as a consultant for: AbbVie, LEO Pharma, Pfizer, and Sanofi; has served on a registry study for: Sanofi. DM has served as an advisory board member for: AbbVie, Arcutis, Eli Lilly and Company, LEO Pharma, Pfizer, Regeneron Pharmaceuticals Inc., and Sanofi; has served as a consultant for: AbbVie, LEO Pharma, Regeneron

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## Abstract AD-03

### Dupilumab Treatment Normalizes Skin Barrier Function and Improves Patient-Reported Outcomes in Patients Aged 6 to 11 Years With Moderate-to-Severe Atopic Dermatitis

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**BACKGROUND:** Atopic dermatitis (AD) is associated with significant disruption in skin barrier function, mediated by type 2 inflammatory cytokines interleukin (IL)-4 and IL-13. Previous studies show that dupilumab treatment in patients over 12 years of age with moderate-to-severe AD improves skin barrier function.

**OBJECTIVE:** To report the effect of dupilumab treatment on skin barrier function and patient-reported outcomes (PROs) in patients aged 6–11 years with moderate-to-severe AD.

**METHODS:** PELISTAD (NCT04718870) was an open-label study in which patients aged 6–11 years were treated with dupilumab for 16 weeks based on baseline weight (≥15 kg to <30 kg: 300 mg every 4 weeks; ≥30 kg to <60 kg: 200 mg every 2 weeks) and matched with healthy volunteers. Transepidermal water loss (TEWL) area under the curve (AUC) for up to 20 skin tape strippings (STS) was longitudinally assessed over time in the lesional and non-lesional skin of patients with AD and in healthy skin. Patient-Oriented Eczema Measure (POEM) and Children's Dermatology Life Quality Index (CDLQI) were assessed for 16 weeks.

**RESULTS:** 23 dupilumab-treated patients and 18 healthy volunteers were included in the study. At baseline, median (95%CI) TEWL AUC was significantly higher in AD skin, both lesional (1447.9 [1064.1–1831.8]) and non-lesional (1107.0 [787.0–1426.9]), compared with healthy skin (358.2 [178.9–537.4]) ($P$<0.0001 for lesional and non-lesional skin). Following dupilumab initiation, median (95%CI) TEWL AUC significantly decreased starting at Week (W)4 (853.2 [678.0–1028.3], $P$<0.001 vs baseline for lesional skin, and 771.6 [518.9–1024.3], $P$<0.01 vs baseline for non-lesional skin). At W16, there was no significant difference in least squares mean TEWL AUC between AD skin ($P$=0.7866 for lesional and $P$=0.9997 for non-lesional skin) and healthy skin. Mean (standard deviation [SD]) POEM decreased from 22.3±5.7 at baseline to 9.8±7.1 at W16 and mean (SD) CDLQI decreased from 18.0±7.7 at baseline to 6.8±7.1 at W16. Out of 23, 21 patients reported treatment-emergent adverse events. None were serious, severe, or led to treatment discontinuation.

**CONCLUSION:** Dupilumab treatment normalizes skin barrier function in lesional and non-lesional skin of pediatric patients with moderate-to-severe AD and improves PROs.

**ACKNOWLEDGMENTS AND FUNDING:** Data first presented at the 5th Inflammatory Skin Disease Summit (ISDS); Vienna, Austria; November 15-18, 2023. Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT04718870. Medical writing/editorial assistance was provided by Marie Vidal, PhD of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guideline.

**DISCLOSURES:** MJC has served as an investigator and/or consultant for: AbbVie, Astellas Pharma, Boots, Dermavant, Galapagos, Galderma, Hyphens Pharma, Johnson & Johnson, LEO Pharma, L'Oréal, Menlo Therapeutics, Novartis, Oxagen, Pfizer, Procter & Gamble, Reckitt Benckiser, Regeneron Pharmaceuticals Inc., and Sanofi. DYML has served as a consultant for: Boehringer Ingelheim, Evommune, Genentech, Incyte, and LEO Pharma; reports research grants from: Sanofi. PO reports research grants from: AbbVie, Incyte, Pfizer, and Regeneron Pharmaceuticals Inc. SGD has served as an investigator and/or consultant for: Almirall, Hyphens Pharma, Johnson & Johnson, LEO Pharma, L'Oréal, Perrigo, Pfizer, Rohto Pharmaceutical, and Sanofi. MR-G, SG, and PT have no conflicts of interest to disclose. JZ is an employee and shareholder for: Regeneron Pharmaceuticals Inc. GB is an employee of: Ividata Life Sciences (contracted by Sanofi). AP and AZ are employees and may hold stock and/or stock options in the company of: Sanofi.

## Abstract AD-04

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

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**BACKGROUND:** Dupilumab has previously shown overall efficacy in treating atopic hand and foot dermatitis.
**OBJECTIVE:** To report the effect of dupilumab treatment on individual signs of atopic hand and foot dermatitis.
**METHODS:** The phase 3, randomized, double-blind LIBERTY-AD-HAFT (NCT04417894) trial enrolled patients aged ≥12 years with moderate-to-severe (Investigator's Global Assessment [IGA] score of 3/4) atopic hand and foot dermatitis. Patients were randomized to dupilumab monotherapy 300 mg every 2 weeks (q2w) in adults; 200/300 mg q2w in adolescents, or placebo for 16 weeks. This analysis presents the proportion of patients reporting absent, mild, moderate, or severe erythema, scaling/flaking, lichenification, vesiculation/erosion, edema, and fissures, assessed by the modified total lesion sign score (mTLSS) in hands and feet.
**RESULTS:** At baseline, most patients had scores of moderate or severe signs on their hands. Of the 133 patients enrolled, over 65% of patients treated with dupilumab (n=67) achieved an absent or mild score by Week 16 in each of the signs/symptoms assessed. Proportion of patients with absent or mild hand scores increased from baseline to Week 16 in erythema (9% vs 71.6%), scaling/flaking (16.4% vs 74.7%), lichenification (4.5% vs 65.6%), vesiculation/erosion (43.3% vs 89.6%), edema (44.7% vs 86.6%), and fissures (23.9% vs 83.5%). Proportion of patients with absent or mild foot scores increased from baseline to Week 16 in erythema (56.7% vs 80.6%), scaling/flaking (56.7% vs 82.1%), lichenification (53.8% vs 82.1%), vesiculation/erosion (76.1% vs 86.6%), edema (76.1% vs 88.1%), and fissures (77.6% vs 86.6%). Safety was consistent with the known dupilumab safety profile in patients with atopic dermatitis.
**CONCLUSIONS:** Dupilumab treatment in patients improves signs of atopic hand and foot dermatitis, including erythema, scaling/flaking, lichenification, vesiculation/erosion, edema, and fissures.
**ACKNOWLEDGMENTS AND FUNDING:** Data first presented at the Revolutionizing Atopic Dermatitis (RAD) Virtual Conference - December 10, 2023. Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT04417894. Medical writing/editorial assistance was provided by Nigel De Melo, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guideline.
**DISCLOSURES:** ELS has served as an investigator for: AbbVie, Eli Lilly and Company, Galderma, Kyowa Hakko Kirin, LEO Pharma, Merck, Pfizer, and Regeneron Pharmaceuticals Inc.; has received consultant fees for: AbbVie, Boehringer Ingelheim, Dermavant, Eli Lilly and Company, Forté, Incyte, LEO Pharma, Menlo Therapeutics, Pfizer, Pierre Fabre Dermo-Cosmetics, Regeneron Pharmaceuticals Inc., Sanofi, and Valeant. WS has served on the advisory board for: AbbVie, Eli Lilly and Company, Genentech, Incyte, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, and UCB; has received research grants for: Allakos, ASLAN, Dermavant, Escient, Galderma, Incyte, LEO Pharma, and Pfizer; has received research grants and served as speaker for: AbbVie, Amgen, AstraZeneca, GlaxoSmithKline, Regeneron Pharmaceuticals Inc., and Sanofi. MW has served on the advisory board and/or received consulting fees for: AbbVie, Almirall, Amgen, Bayer, Boehringer Ingelheim, Eli Lilly, LEO Pharma, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi, and Viatris. AP has served as an investigator and/or advisor and/or speaker for: AbbVie, Almirall Hermal, Amgen, Biogen Idec, BioNTech, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly and Company, Galderma, GlaxoSmithKline, Hexal, Janssen, Klinge Pharma, LEO Pharma, MC2 Pharma, Medac, Merck-Serono, Merck Sharp & Dohme, Mitsubishi Tanabe Pharma, Novartis, Pascoe, Pfizer, Regeneron Pharmaceuticals Inc., Roche, Sandoz, Sanofi, Schering-Plough, Tigercat Pharma, UCB Pharma, and Zuellig Pharma. KM has served as a speaker for: Eli Lilly Japan K.K., Maruho Co., Ltd, Mitsubishi Tanabe Pharma Corporation, and Sanofi; has served as an investigator for: Eli Lilly Japan K.K. LS, AB, and AK are employees and shareholders for: Regeneron Pharmaceuticals Inc. AD-B and ABR are employees and may hold stock and/or stock options in the company of: Sanofi.

## Abstract AD-05

### Efficacy and Safety of Baricitinib Treatment in Pediatric Patients With Atopic Dermatitis Aged 2 to Less than 18 years (Up to 3.6 Years of Exposure)

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**BACKGROUND:** This study describes the efficacy (through 52 weeks) and safety (up to 3.6 years) results from the

Phase-3 study (BREEZE-AD-PEDS) evaluating Baricitinib (BARI) in pediatric patients (pts) (2- <18 years [yrs] of age) with moderate-to-severe atopic dermatitis (AD).

**METHODS:** Efficacy analyses were conducted on the intent-to-treat population using mLOCF (modified last observation carried forward) imputation or observed case. Efficacy results are presented by treatment groups (PBO, BARI low, BARI medium, BARI high dose) across the entire patient population, using vIGA-AD® (measures AD-severity). Response (vIGA-AD® of 0/1) at Week 52 was assessed for partial responders and responders (vIGA-AD® of 0/1/2) at Week 16 who remained on the same treatment, and for non-responders (vIGA-AD® of 3-4) at Week 16 who transitioned to BARI high dose at Week 16. Safety analyses were done on pts who received ≥1 BARI dose and are reported for: BARI extended (continuously treated from baseline with BARI low/medium/high dose [1 mg, 2 mg, or 4 mg exposure equivalents, respectively] and censored after dose change) and All-BARI (any BARI dose at any time). Incidence rates (IR)/100 patient-years at risk were calculated.

**RESULTS:** 467 pts received BARI for 750.7 patient-years (maximum exposure 3.6 yrs). Among Week 16 responders and partial responders (IGA 0/1/2 with no prior rescue) who remained on double-blind study drug, the proportion achieving an IGA 0/1 at Week 52 was greater for pts receiving BARI high dose versus other groups. Among Week 16 non-responders (IGA 3/4 having previous rescue) who transitioned to open-label BARI high dose at Week 16, all groups showed improvement at Week 52 in the proportion achieving an IGA 0/1. Most treatment-emergent adverse events (TEAEs) were mild-to-moderately severe and the discontinuation rate due to AEs was low (IR=1.7). 6.6% (n=31) of the All-BARI population reported ≥1 serious adverse event (IR=4.2), with worsening AD (n=3), asthma (n=2), herpes simplex (n=2), and ophthalmic herpes simplex (n=2) most frequently reported; 60.8% (n=284) of the All-BARI population reported ≥1 TEAE of infection (IR=64.4) with COVID-19, nasopharyngitis, and upper respiratory tract infection most frequently reported. One opportunistic infection (herpes zoster) was reported. No deaths, pulmonary embolisms, deep vein thromboses/arterial thrombotic events, major adverse cardiovascular events, malignancies, tuberculosis, or gastrointestinal perforations were reported.

**CONCLUSION:** AD symptoms continued to improve up to 52 weeks. The safety profile was consistent with that established for baricitinib in adults with moderate-to-severe AD. No new safety signals were identified.

**ACKNOWLEDGMENTS AND FUNDING:** Sponsored by Eli Lilly and Company. Presented at EADV, 2023.

**DISCLOSURES:** AW has served as an advisor and/or paid speaker for and/or participated in clinical trials sponsored by: AbbVie, Almirall, Amgen, Beiersdorf, Bioderma, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai Pharmaceutical, Eli Lilly and Company, Galapagos NV, Galderma, Janssen Cilag, L'Oréal, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Regeneron, and Sanofi. MI has received a scholarship donation from the Central Research Institute of Pias; has participated in clinical trials and/or has received honoraria as a speaker/consultant for: AbbVie, AstraZeneca, Eli Lilly and Company, GlaxoSmithKline, Hisamitsu, Janssen, Maruho, MedImmune, Novo Nordisk, Pfizer, and Sanofi. C-YC is an investigator, consultant, speaker, and/or advisory board member for: AbbVie, Dermira, Eli Lilly and Company, Janssen, Mylan, Novartis, Oneness Biotech, Pfizer, Regeneron, Roche, Sanofi, United BioPharma, and Viatris. LFE has been an advisory board member and/or speaker and/or consultant and/or has participated in clinical studies for: AbbVie, Almirall, Amgen, ASLAN Pharmaceuticals, Bausch Health, Castle Biosciences, Dermavant, Eli Lilly and Company, Forté, Galderma, Incyte Corporation, Janssen, LEO Pharma, Novartis, Otsuka, Pfizer, Regeneron, Sanofi Genzyme, Seanergy, and UCB Pharma. MMBS received grants from and/or was involved in clinical trials and/or served as a consultant for: AbbVie, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, and Pfizer; fees were paid directly to the institution. AP, DZ, MP and WRZ are employees and shareholders of: Eli Lilly and Company. AP is a consultant with honorarium for: Aegerion Pharma, Azitra, BioCryst, Boehringer Ingelheim, Bristol Myers Squibb, Castle Creek Biosciences, Eli Lilly and Company, Janssen, Krystal Biotech, LEO Pharma, Novartis, Regeneron, Sanofi Genzyme, Seanergy, TWI Biotechnology, and UCB Pharma; is an investigator for: AbbVie, Dermavant, Eli Lilly and Company, Incyte Corporation, Janssen, Krystal Biotech, and UCB Pharma; is on the Data Safety Monitoring Board for: AbbVie, Abeona Therapeutics, Catawba, Galderma, and InMed.

## Abstract AD-06

### Efficacy and Safety of Delgocitinib Cream in Adults With Moderate to Severe Chronic Hand Eczema: Results of the Phase 3 DELTA 1 Trial

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**BACKGROUND:** Chronic Hand Eczema (CHE) is the most frequent inflammatory disorder affecting hands. It is associated with pain, pruritus, and significant occupational, functional, social, and psychological burden. Delgocitinib is a topical pan-JAK inhibitor targeting key mediators involved in the immunopathogenesis of CHE.

**OBJECTIVES:** The objectives of this study were to: (1) study the efficacy of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle; (2) evaluate the safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle; and (3) study the effect on health-related quality of life of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle, in the treatment of adults with moderate to severe chronic hand eczema in the Phase 3 DELTA 1 trial.

**METHODS:** In the Phase 3 DELTA 1 trial (NCT04871711), adults (aged ≥18) with moderate to severe CHE were randomized 2:1 to twice-daily delgocitinib cream 20 mg/g (n=325) or cream vehicle (n=162) for 16 weeks followed by a 36-week extension trial (NCT04949841). The primary endpoint was Investigator's Global Assessment for CHE (IGA-CHE) treatment success at Week 16 (IGA-CHE TS), defined as IGA-CHE score of 0/1 (clear/almost clear) with ≥2-step improvement. Key secondary endpoints included ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) and ≥4-point improvement in the Dermatology Life Quality Index (DLQI).

**RESULTS:** At Week 16, a significantly greater proportion of delgocitinib-treated patients, compared to cream vehicle, achieved IGA-CHE TS (19.7% vs. 9.9%; $p$=0.006), HECSI-75 (49.2% vs. 23.5%; $p$<0.001), HECSI-90 (29.5% vs. 12.3%; $p$<0.001), and ≥4-point improvement in DLQI (74.4% vs. 50.0%; $p$<0.001). There was no difference between delgocitinib and cream vehicle in proportion of patients who presented adverse events (AEs; 45.2% vs. 50.6%) and serious AEs (1.8% vs. 1.9%). Rates of AEs related to IMP or leading to discontinuation of IMP were numerically higher with cream vehicle compared to delgocitinib (delgocitinib 3.7% vs. vehicle 8.0% and 0.6% vs. 3.7%, respectively).

**CONCLUSIONS:** Overall, delgocitinib cream provided greater improvements in both patient- and clinician-reported efficacy outcomes versus cream vehicle and was well-tolerated over 16 weeks.

**ACKNOWLEDGEMENTS AND FUNDING:** The DELTA 1 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark. Medical writing and editorial support from Alphabet Health by Matthew Hartmann, PhD, was funded by LEO Pharma A/S, Ballerup, Denmark. RBW is supported by the Manchester NIHR Biomedical Research Centre. This work was previously presented at EADV 2023.

**DISCLOSURES:** RB is an advisory board member, consultant, speaker and/or investigator for and receives honoraria and/or grant from: AbbVie, Arcutis, Arena Pharma, Asana BioSciences, Bellus Health, Boehringer Ingelheim, CARA, Dermavant, Eli Lilly and Company, EMD Serono, Galderma, Incyte, Kiniksa, Kyowa Kirin, LEO Pharma, Novan, Pfizer, Ralexar, RAPT, Regeneron, Sanofi Genzyme, and Sienna; and is an employee and shareholder of: Innovaderm Research. RBW has received research grants or consulting fees from: AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DiCE, Eli Lilly and Company, GlaxoSmithKline, Janssen, LEO Pharma, Medac, Novartis, Pfizer, Sanofi, Sun Pharma, UCB, and UNION. LS has been principal investigator in clinical trials sponsored by and/or has received personal fees for participation in advisory board from: AbbVie, LEO Pharma, Novartis, and Sanofi, outside the submitted work. KB, MK, and UP are employees of: LEO Pharma A/S. KM is an employee of: LEO Pharma Inc. M-NC has received research grants or consulting fees from: AbbVie, Eli Lilly and Company, LEO Pharma, Novartis, Pfizer, and Sanofi.

## Abstract AD-07

### Efficacy and Safety of Delgocitinib Cream in Adults With Moderate to Severe Chronic Hand Eczema: Results of the Phase 3 DELTA 2 Trial

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**BACKGROUND:** Chronic Hand Eczema (CHE) is an inflammatory, pruritic, often painful disorder of the hands and wrists that strongly impacts quality of life and occupational capabilities of patients. Delgocitinib is a topical pan-Janus kinase (JAK) inhibitor that was well tolerated and demonstrated significant improvement in primary and all key secondary efficacy endpoints in the DELTA 1 (NCT04871711) pivotal phase 3 trial.

**OBJECTIVE:** The aim of this study was to confirm the efficacy, safety, and effect on health-related quality of life of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle in the treatment of adults with moderate to severe CHE in the Phase 3 DELTA 2 trial (NCT04872101).

**METHODS:** DELTA 2 was a randomized, double-blind, vehicle-controlled trial. Adults (aged ≥18 years) with moderate to severe CHE were randomized 2:1 to twice-daily delgocitinib cream 20 mg/g (n=314) or cream vehicle (n=159) for 16 weeks followed by 2-week safety follow up or transfer to a 36-week open-label extension trial (NCT04949841). The primary endpoint was Investigator's Global Assessment for CHE (IGA-CHE) treatment success at Week 16 (IGA-CHE TS), defined as IGA-CHE score of 0/1 (clear/almost clear, defined as only barely perceptible erythema) with ≥2-step improvement. Key secondary endpoints included ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) and ≥4-point improvement in the Dermatology Life Quality Index (DLQI) from baseline at Week 16.

**RESULTS:** At Week 16, a significantly greater proportion of delgocitinib-treated patients, compared to cream vehicle, achieved IGA-CHE TS (29.1% vs. 6.9%; $p$<0.001), HECSI-75 (49.5% vs. 18.2%; $p$<0.001), HECSI-90 (31.0% vs. 8.8%; $p$<0.001), and ≥4-point improvement in DLQI (72.2% vs. 45.8%; $p$<0.001). There was no difference between delgocitinib and cream vehicle in proportion of patients who reported adverse events (AEs; 45.7% vs. 44.7%) and serious AEs (1.6% vs. 1.9%). Rates of AEs assessed as probably or possibly related to study drug were consistent between delgocitinib (31.29 per 100-patient years of observation [PYO])

and cream vehicle (30.87 per 100 PYO). Rates of AEs leading to discontinuation of study drug were numerically higher with cream vehicle (11.02 per 100 PYO) compared to delgocitinib (1.04 per 100 PYO).

**CONCLUSION:** Overall, delgocitinib cream demonstrated greater improvements in both patient- and clinician-reported efficacy outcomes versus cream vehicle and was well-tolerated over 16 weeks. These results were consistent with those previously reported from the identically designed DELTA 1 study.

**ACKNOWLEDGEMENTS AND FUNDING:** The DELTA 2 trial was sponsored by LEO Pharma A/S, Ballerup, Denmark. Medical writing and editorial support from Alphabet Health by Clair Geary PhD, was funded by LEO Pharma A/S, Ballerup, Denmark. This work was previously presented at EADV 2023.

**DISCLOSURES:** SS reports consulting fees (personal) and payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from: AbbVie, Celegene, LEO Pharma, Lilly Pharma, Novartis Pharma, and Sanofi-Aventis; participation on a Data Safety Monitoring Board or Advisory Board for: LEO Pharma, Lilly Pharma, Novartis Pharma, and Sanofi-Aventis; leadership or fiduciary role in other board, society, committee or advocacy group, paid (board member in the Arbeitsgemeinschaft für Berufs- und Umweltdermatologie) and unpaid (co-author of existing and planned update of German Guideline Berufliche Hautmittel); other financial or nonfinancial interests: conduct of nonpharmaceutical and nonprofit IIT studies on irritant contact dermatitis, development of efficacy models and in vivo efficacy test studies for occupational skin protection products (cosmetics) in terms of financial support paid to institution by the employer's liability insurance coverage 'Berufsgenossenschaft für Nahrungsmittel und Gastgewerbe Erfurt', others without payment. AP has served as an investigator and/or speaker and/or advisor for: AbbVie, Almirall-Hermal, Amgen, Biogen Idec, Biontec, Boehringer Ingelheim, Celgene, Celltrion, GlaxoSmithKline, Eli Lilly and Company, Galderma, Hexal, Janssen, LEO Pharma, MC2, Medac, Merck Serono, Merck Sharp & Dohme, Mitsubishi, Novartis, Pascoe, Pfizer, Tigercat Pharma, Regeneron, Roche, Sandoz Biopharmaceuticals, Sanofi-Genzyme, Schering-Plough, und UCB Pharma. MLAS has been a consultant, advisory board member, investigator, and/or speaker for: AbbVie, Amgen, Eli Lilly and Company, Galderma, LEO Pharma, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., and Sanofi Genzyme. ES-B has served as an investigator and/or speaker and/or advisor for: AbbVie, Almirall-Hermal, Galderma, LEO-Pharma, Lilly, Novartis, Pfizer, and Sanofi. KB and UP are employees of: LEO Pharma A/S. SK was formerly an employee of: LEO Pharma A/S. KM is an employee of: LEO Pharma Inc. MG has been an investigator, speaker and/or advisor for: AbbVie, Amgen, Akros, AnaptysBio, Apogee, Arcutis, Aristea, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly and Comapny, Galderma, GlaxoSmithKline, Incyte, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, Moonlake, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Tarsus, Takeda, UCB, Union, and Ventyx.

## Abstract AD-08

### Investigator- and Patient-Rated Local Tolerability in Phase 3 Trials of Topical Roflumilast in Patients With Psoriasis, Seborrheic Dermatitis, and Atopic Dermatitis

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**BACKGROUND:** Formulating a topical medication that does not irritate the skin is an important factor contributing to patient treatment adherence and satisfaction. Many topical prescription products use penetration enhancers (including propylene glycol, polyethylene glycol, and ethanol) to overcome barrier properties of the skin. However, these excipients may irritate the skin causing tolerability reactions such as burning and stinging, which can reduce patient treatment adherence. Topical roflumilast is a highly potent (Kd~0.7 nM) phosphodiesterase 4 inhibitor formulated as a water-based cream or foam that does not contain penetration enhancers or fragrances.

**OBJECTIVE:** We present prospectively assessed investigator- and patient-rated local tolerability from Phase 3 trials of topical roflumilast for patients with psoriasis (DERMIS-1, DERMIS-2, ARRECTOR), seborrheic dermatitis (SD; STRATUM), and atopic dermatitis (AD; INTEGUMENT-1, INTEGUMENT-2).

**METHODS:** Patients were randomized to apply topical roflumilast (DERMIS: 0.3% cream; ARRECTOR and STRATUM: 0.3% foam; INTEGUMENT: 0.15% cream) or vehicle once daily for 8 weeks (DERMIS, ARRECTOR, and STRATUM) or 4 weeks (INTEGUMENT). Investigators assessed local tolerability on an 8-point scale (0 [no evidence of irritation] to 7 [strong reaction spreading beyond application site]) in the clinic before investigational product (IP) application. Patients reported local tolerability on a 4-point scale

(0 [none: no sensation] to 3 [severe: hot, tingling/stinging sensation that has caused definite discomfort]) in the clinic 10-15 minutes after IP application. Tolerability was also assessed by reviewing documented adverse events.

**RESULTS:** As assessed by investigators, ≥96.5% of patients in the roflumilast-treated groups had no evidence of irritation at the application site across all trials at all timepoints. Patient-rated local tolerability was favorable and improved with treatment: across all trials, 1% of roflumilast-treated patients reported a score of 3 (severe; defined as a "hot tingling/stinging sensation that has caused definite discomfort") after the first application (day 1) and <1% at each subsequent assessment. Rates of adverse events, including those at the application site, were low for all trials.

**CONCLUSIONS:** Roflumilast cream and foam formulations demonstrated favorable local tolerability based on investigator- and patient-rated assessments in patients with psoriasis, SD, and AD, including application to sensitive areas such as the face and intertriginous areas.

**FUNDING:** Sponsored by Arcutis Biotherapeutics, Inc.

**DISCLOSURES:** CGB, NB, JDR, ZDD, LFE, LHK, MGL, MG, LJG, AAH, RBV, MZ, ELS, and LSG are investigators and/or consultants for and received grants/research funding and/or honoraria from: Arcutis Biotherapeutics, Inc. MS, SS, DWO, PB, RCH, DHC, and DRB are employees of: Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

## Abstract AD-09

### Laboratory Safety of Long-Term Dupilumab Treatment in a 5-Year Open-Label Extension Study of Adults With Moderate-to-Severe Atopic Dermatitis

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**BACKGROUND:** Long-term systemic treatments for atopic dermatitis (AD) typically require laboratory monitoring for patient safety.

**OBJECTIVE:** To present laboratory safety findings in adults with moderate-to-severe AD treated with dupilumab for up to 5 years.

**METHODS:** The LIBERTY AD open-label extension (OLE; NCT01949311) enrolled adults with moderate-to-severe AD who had participated in any dupilumab parent study; 2,207/557/334 patients completed treatment up to Weeks 52/148/260. During the OLE, patients received 300 mg dupilumab weekly; 226 patients transitioned to 300 mg every 2 weeks to align with approved dosage. Concomitant topical treatments were permitted. Laboratory safety assessments are shown for the overall study population (n=2,677) at OLE baseline (BL; n=2,660), Week 148 (Wk148; n=336), and end of study (EOS, 12 weeks after the last dose of dupilumab; n=55). Per study protocol amendment 6, hematology and chemistry analyses at EOS were no longer mandatory. The primary reason (26.4%) for study withdrawal was dupilumab approval/commercialization.

**RESULTS:** Mean (SD) eosinophil levels were slightly lower than OLE BL ($0.43x10^9$/L [0.43]) at Wk148 ($0.27x10^9$/L [0.32]) and EOS ($0.23x10^9$/L [0.20]). Neutrophil levels (mean [SD]) remained consistent at OLE BL ($4.19x10^9$/L [1.53]), Wk148 ($4.12x10^9$/L [1.72]), and EOS ($4.12x10^9$/L [1.22]). Platelet levels (mean [SD]) were slightly lower than OLE BL ($270.8x10^9$/L [67.72]) at Wk148 ($266.1x10^9$/L [63.17]) and EOS ($258.8x10^9$/L [47.44]). Mean levels in serum chemistry analyses including aspartate aminotransferase, alanine aminotransferase, cholesterol, and triglycerides remained stable from OLE BL through EOS. Lactate dehydrogenase levels (mean [SD]) were lower than OLE BL (205.3 IU/L [62.04]) at Wk148 (174.2 IU/L [69.57]) and EOS (169.1 IU/L [33.90]). Most (n=82/89) patients with high baseline lactate dehydrogenase shifted to normal by Wk148 (n=299 patients' data available).

**CONCLUSIONS:** No clinically meaningful adverse changes were observed in mean values of laboratory safety parameters with dupilumab treatment for up to 5 years in adults with moderate-to-severe AD.

**ACKNOWLEDGMENTS AND FUNDING:** Data first presented at the 5th Inflammatory Skin Disease Summit (ISDS); Vienna, Austria; November 15-18, 2023. Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT01949311. Medical writing/editorial assistance was provided by Jamie Church, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guideline.

**DISCLOSURES:** LAB has served as a consultant for: Allakos, Arena Pharmaceuticals, DermTech, Evelo Biosciences, Galderma, Incyte, Janssen, LEO Pharma, Merck, Nektar Therapeutics, Numab Therapeutics, Pfizer, RAPT Therapeutics, Regeneron Pharmaceuticals Inc., Ribon Therapeutics, Sanofi, Stealth BioTherapeutics, Trevi Therapeutics, Union Therapeutics, and Xencor; has served as an investigator for: AbbVie, AstraZeneca, DermTech, Kiniksa Pharmaceuticals, Pfizer, Regeneron Pharmaceuticals Inc., Ribon Therapeutics, and Sanofi. RB has served as a consultant and/or received grants/research support for: AbbVie, Aquinox Pharmaceuticals, Arcutis Biotherapeutics, Asana BioSciences, Astellas Pharma, Boehringer Ingelheim, Brickell Biotech, Dermavant, Dermira, Dignity Sciences, Eli Lilly and Company, Galderma, Glenmark, Hoffman-La Roche, Incyte, Kiniksa Pharmaceuticals, LEO Pharma, NeoKera, Pfizer, Ralexar Therapeutics, Regeneron Pharmaceuticals Inc., Sanofi, Stiefel, and Vitae Pharmaceuticals; is a shareholder of: Innovaderm Research. MD has received research support/consulting/advisory board agreements and/or honoraria for lectures for: AbbVie, Almirall, Eli Lilly and Company, Incyte, Kymab, La Roche-Posay, LEO Pharma, Pfizer, Pierre Fabre, Regeneron Pharmaceuticals Inc., and Sanofi. TN has received laboratory funds from: Maruho;

has received speaker fees from: Maruho and Sanofi. RG has served as an investigator and/or consultant for: Amgen, Boehringer Ingelheim, Chugai, Dermira, Evelo Biosciences, Galderma, Glenmark, Incyte, Janssen, Kymab, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi, and UCB. FAK, AC, ZC, EA, and AS are employees and shareholders of: Regeneron Pharmaceuticals Inc. GG and AD-B are employees and may hold stock and/or stock options in the company of: Sanofi.

## Abstract AD-10

### Lebrikizumab Delivers Clinically Meaningful and Continuous Improvement in Itch-Free Days in Atopic Dermatitis Through One Year

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**BACKGROUND:** Itch is the most burdensome symptom for patients with atopic dermatitis (AD). Lebrikizumab has shown efficacy in 2 phase 3 monotherapy studies (ADvocate1 and ADvocate2) of moderate-to-severe AD, including itch reduction, with higher proportions of patients achieving ≥4-point improvement in Pruritus Numeric Rating Scale (NRS) versus placebo.

**OBJECTIVE:** Here we evaluated itch-free or virtually itch-free days per month (and week) during the double-blind induction and maintenance periods of these studies.

**METHODS:** ADvocate1 and ADvocate2 were phase 3 monotherapy studies with 16-week induction and 36-week maintenance periods conducted in adults and adolescents. Itch-free days were calculated as area under the curve based on response rates of patients achieving a Pruritus NRS score of 0 or 1 (range, 010; collected over time by daily diary) and then expressed as days/month (days/week). Analyses were performed on the pooled ADvocate1/2 populations. Missing data due to lack of efficacy or data after rescue medication use were imputed with non-responder imputation. Other missing data were imputed with multiple imputation. The induction period was analyzed for the modified intent-to-treat population. Data through Week 52 were analyzed for the modified maintenance primary population, defined as lebrikizumab responders at Week 16 (Investigator's Global Assessment score of 0 or 1 with a ≥2-point improvement or ≥75% improvement in the Eczema Area and Severity Index without rescue medication). Patients were randomized 2:1 to receive lebrikizumab 250 mg or placebo every 2 weeks (Q2W) in the induction period and responders were rerandomized 2:2:1 to receive lebrikizumab 250 mg Q2W, lebrikizumab 250 mg every 4 weeks (Q4W), or placebo Q2W (lebrikizumab withdrawal) in the maintenance period.

**RESULTS:** At Week 16 during the induction period, the number of itch-free days/month (days/week) for the overall population was 5.5 (1.4) for lebrikizumab Q2W (N=564) and 1.3 (0.3) for placebo (N=287). Among Week 16 lebrikizumab Q2W responders (N=291), itch-free days/month (days/week) at Week 16 were 7.7 (1.9). At the end of the maintenance period at Week 52 (among rerandomized Week 16 lebrikizumab Q2W responders), itch-free days/month (days/week) were 10.9 (2.7) for lebrikizumab Q2W, 11.9 (3.0) for lebrikizumab Q4W, and 8.0 (2.0) for the lebrikizumab withdrawal arm.

**CONCLUSIONS:** In the ADvocate1 and ADvocate2 monotherapy trials, lebrikizumab treatment provided up to 3 itch-free days per week (12 days/month) in patients with AD who responded to lebrikizumab.

**ACKNOWLEDGMENTS AND FUNDING:** These studies were funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications including atopic dermatitis in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe. Abstract previously presented at Fall Clinical Dermatology Conference, Oct 19-22, 2023, Las Vegas, NV.

**DISCLOSURES:** GY has conducted clinical trials for or received research funds and/or honoraria for serving on the scientific advisory boards of: AbbVie, Arcutis, Eli Lilly and Company, Escient Pharmaceuticals, Galderma, Kiniksa Pharmaceuticals, LEO Pharma, Novartis, Pfizer, Regeneron, and Sanofi. CZ has conducted clinical trials for or received research funds and/or honoraria for lectures and/or authorships of: AbbVie, Almirall, Beiersdorf, Boehringer Ingelheim, DERMASENCE, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, UCB Pharma, and Unna Academy. CJA has received institutional funding from: the Dr Wolff Group and Bionorica; and consultancy fees from: the Dr Wolff Group, LEO Pharma, RHEACELL, and Sanofi. VL is a consultant with honorarium for: Cara Therapeutics, Eli Lilly and Company, and Galderma; and is an investigator for: AbbVie, Amgen, AnaptysBio, Arcutis, argenx, ASLAN Pharmaceuticals, Biofrontera, Bristol Myers Squibb, Castle Biosciences, Dermavant, Eli Lilly and Company, Galderma, Incyte Corporation, Janssen, Kiniksa Pharmaceuticals, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, RAPT Therapeutics, Sun Pharma, and UCB Pharma. BSK is founder of: Klirna Biotech; has served as a consultant for: 23andMe, AbbVie, ABRAX Japan, Almirall, Amagma Therapeutics, Amgen, Arcutis, Arena Pharmaceuticals, argenx, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Clexio Biosciences, Eli Lilly and Company, Escient Pharmaceuticals, Evommune, Galderma, Genentech, GlaxoSmithKline, Granular Therapeutics, Incyte Corporation, Innovaderm Research, Janssen, Kiniksa Pharmaceuticals, LEO Pharma, Maruho, Novartis, Pfizer, Recens Medical, Regeneron Pharmaceuticals, Sanofi, Septerna, Vial, and WebMD; has stock

in: ABRAX Japan, KliRNA Biotech, Locus Biosciences, and Recens Medical; holds a patent for the use of JAK1 inhibitors for chronic pruritus; has a patent pending for the use of JAK inhibitors for interstitial cystitis; has research grants from: AbbVie, Cara Therapeutics, LEO Pharma, and Veradermics. MC, EP and BRM are employees and shareholders of: Eli Lilly and Company. SC and MQ are employees of: Tigermed. HA is an employee of: Almirall. JDR has served as a research investigator, consultant, and/or speaker for: AbbVie, Allergan, Almirall, Amgen, Arcutis, Bayer Pharmaceuticals, Bausch Health (Ortho Dermatologics), Beiersdorf, Biofrontera, Biorasi, Bristol Myers Squibb, Cara Therapeutics, Cassiopea Pharmaceuticals, Cutera, Dermavant, Dr. Reddy, Eli Lilly and Company, EPI Health, Evommune, Ferndale Laboratories, Galderma, Incyte Corporation, JEM Health, Journey Medical Corporation, Johnson & Johnson, LaRoche Posay, LEO Pharma, L'Oreal, Mayne Pharma, MC2 Therapeutics, Novan (EPI Health), Pfizer, Regeneron, Sanofi, Sebacia, Sol-Gel, Sun Pharma, UCB Pharma, and Vyne Therapeutics (Foamix).

## Abstract AD-11

### Lebrikizumab Demonstrates Consistent Efficacy at 16 Weeks in Patients With Moderate to Severe Atopic Dermatitis Regardless of Baseline Disease Severity

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**BACKGROUND:** Lebrikizumab demonstrated robust efficacy in moderate-to-severe atopic dermatitis (AD) in the ADvocate1 and ADvocate2 trials.

**OBJECTIVE:** Here we assessed efficacy within subgroups of patients with moderate versus severe AD at baseline.

**METHODS:** At baseline, patients had at least moderate AD. During the 16-week induction period, patients received lebrikizumab 250 mg or placebo (randomized 2:1) subcutaneously every 2 weeks. Treatment difference was assessed for lebrikizumab versus placebo on pooled ADvocate 1 and 2 data comparing patients with baseline IGA=3 (moderate AD) versus IGA=4 (severe AD). Outcomes measures were analyzed at Week 16 and included an Investigator's Global Assessment of 0 or 1 (IGA 0/1), ≥75% improvement in the Eczema Area and Severity Index (EASI75), EASI 90, and a ≥4-point improvement in the Pruritus Numeric Rating Scale (NRS). CochranMantelHaenszel tests adjusted by study were applied to test the treatment group difference within each subgroup. Logistic regression analysis examined the interaction effects of treatment by disease severity subgroup. Data collected after rescue medication use or after discontinuation due to lack of efficacy were imputed as non-responders. Multiple imputation was used for other missing data.

**RESULTS:** At baseline, 61.2% (n=345/564) and 62.0% (178/287) of lebrikizumab and placebo treated patients, respectively, had IGA=3, while 38.8% (219/564) and 38.0% (109/287), respectively, had IGA=4. Baseline age and body mass index were comparable between the IGA=3 and IGA=4 subgroups. In the IGA=4 subgroup (vs IGA=3), prior systemic therapy was more common (lebrikizumab, 63.5% vs 46.7%; placebo, 70.6% vs 50.0%), and patients had a higher mean body surface area (lebrikizumab, 55.7% vs 39.3%; placebo, 60.1% vs 38.8%). Across outcome measures, no significant treatment differences were seen between the baseline IGA=3 and IGA=4 subgroups. Mean treatment differences (95% confidence interval) between lebrikizumab versus placebo for the baseline IGA=3 and IGA=4 subgroups, respectively, were 28.7 (21.036.4) and 22.7 (14.930.6) for IGA 0/1; 37.5 (29.245.7) and 39.5 (30.448.7) for EASI 75; 23.6 (16.430.9) and 27.9 (20.435.4) for EASI 90; and 28.2 (20.436.0) and 34.2 (25.343.1) for Pruritus NRS.

**CONCLUSIONS:** Regardless of baseline disease severity, lebrikizumab 250 mg every 2 weeks demonstrated consistent and robust efficacy for skin clearance and relief of itch at Week 16 in patients with moderate to severe AD.

**ACKNOWLEDGMENTS AND FUNDING:** These studies were funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications including atopic dermatitis in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe. Abstract previously presented at Fall Clinical Dermatology Conference, Oct 19-22, 2023, Las Vegas, NV.

**DISCLOSURES:** LSG is an investigator and/or consultant and/or speaker for: AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Galderma, Incyte Corporation, Janssen, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, and UCB Pharma. KE has received speaker's fees from and/or has been a member of advisory boards for: AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Hexal, Janssen, LEO Pharma, Novartis, Sanofi, and UCB Pharma. HS is a consultant for: Amgen, Celgene, Eli Lilly and Company, Janssen, Novartis, and Pfizer. LK has served as an investigator, consultant, and/or speaker, and/or has served on an advisory board for: AbbVie, Acambis, Amgen, Anacor Pharmaceuticals, AnaptysBio, Arcutis, Arena Pharmaceuticals, Assos Pharmaceuticals, Astellas, Asubio Pharma, Dermavant, Dermira, Dow Pharmaceutical Sciences, Eli Lilly and Company, Ferndale Pharma Group, Galderma, Genentech, HealthPoint, Incyte Corporation, INNOCUTIS, INNOVAIL, Kyowa Kirin, LEO Pharma, L'Oréal, Nano Bio, Novartis, NUCRYST Pharmaceuticals, Onset, Ortho Dermatologics, Ortho Neutrogena, Pediapharm, Pfizer, Pharmaderm, Promius Pharma, PuraCap Pharmaceuticals, Quinnova Pharmaceuticals, Regeneron, Sanofi, SkinMedica, Stiefel, Sun Pharma, Taro Pharmaceutical Industries, Triax Technologies,

and Valeant Pharmaceuticals. TB has received honoraria and/or consulting fees from: AbbVie, Almirall, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Sanofi, and UCB Pharma. PH is/has been an investigator, lecturer, and/or consultant for: AbbVie, Almirall, Eli Lilly and Company, Galderma, Kymab, LEO Pharma, Novartis, Pfizer, Sanofi/Regeneron, and UCB Pharma. EW, GG, YD, FEY and BRM are employees and shareholders of: Eli Lilly and Company. IP-Ch is an employee of: Almirall. MG has been an investigator, speaker, and/or advisor for: AbbVie, Akros Pharma, Amgen, Arcutis, Aristea Therapeutics, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte Corporation, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Merck, MoonLake Immunotherapeutics, Nimbus Therapeutics, Novartis, Pfizer, Regeneron, Reistone Biopharma, Roche, Sanofi Genzyme, Sun Pharma, and UCB Pharma.

## Abstract AD-12

### Lebrikizumab Treatment Results in Rapid Improvement of Atopic Dermatitis Disease Cytokines and Pathways

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**BACKGROUND:** Lebrikizumab is a monoclonal antibody specifically targeting interleukin (IL)-13. It demonstrated statistical superiority vs. placebo in patients with moderate-to-severe atopic dermatitis (AD) across all primary and key secondary endpoints at week 4 and week 16 of ADvocate1 (NCT04146363) and ADvocate2 (NCT04178967).

**OBJECTIVE:** The objective of this analysis is to determine the biological pathways by which lebrikizumab treatment positively impacts clinical severity measures in patients with AD by investigating changes in serum proteins using the Olink® Explore 3072 biomarker panel.

**METHODS:** Protein biomarkers were determined in available serum samples from a subset of ADvocate1 and ADvocate2 patients who consented to biomarker sampling. Patients were dosed with lebrikizumab 250 mg every 2 weeks (n=72) or placebo (n=36) and were compared to age-, sex-, race-, and ethnically matched healthy controls (HC, n=29). The analysis included biomarkers that were detected in at least 25% of patients. A linear model R package (limma) compared biomarker changes in patients treated with lebrikizumab vs. placebo from baseline to weeks 4 and 16. Gene set enrichment analysis was performed using a curated pathway and protein signature database for AD.

**RESULTS:** The Olink biomarker data revealed that, following lebrikizumab treatment, CCL26 (eotaxin-3) was significantly reduced from baseline as early as week 4 and progressively to week 16. Several AD-related pathways were significantly changed during lebrikizumab treatment. Additionally, the level of biomarkers in lebrikizumab-treated AD patients approached HC levels as early as week 4 and continuously to week 16. This trend was not seen with placebo-treated patients.

**CONCLUSION:** In patients with AD, selective targeting of IL-13 with lebrikizumab treatment rapidly interrupts and normalizes several biomarker pathways toward healthy control levels. Data analysis across the curated pathways demonstrated changes in both serum immune response related protein signatures as well as skin cell specific signatures from keratinocytes and fibroblasts suggesting lebrikizumab treatment improved multiple facets of disease activity.

**ACKNOWLEDGMENTS AND FUNDING:** These studies were funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications including atopic dermatitis in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe. Abstract previously presented at 5th Inflammatory Skin Disease Summit, November 15-18, Vienna, Austria.

**DISCLOSURES:** EG-Y is an employee of: Mount Sinai; and has received research funds (grants paid to institution) from and/or been a consultant for: AbbVie, Almirall, Amgen, AnaptysBio, Asana BioSciences, ASLAN Pharmaceuticals, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Connect Biopharma, Eli Lilly and Company, EMD Serono, Evidera, Galderma, Incyte Corporation, Innovaderm Research, Janssen, Kiniksa, Kyowa Kirin, LEO Pharma, Novartis, Pfizer, RAPT Therapeutics, Regeneron, Sanofi, Sato Pharmaceutical, TARGET PharmaSolutions, UCB Pharma, and Ventyx Biosciences. AO, ZS, CP, CRN, GG, EW, RJB and BRM are employees and/or shareholders of: Eli Lilly and Company. BJN is retired from and a current stockholder of: Eli Lilly and Company; is a part-time independent contractor (Net2Source Inc.) working with: Lilly. KE reports consulting fees/honoraria from: AbbVie, Almirall, Bristol Myers Squibb, Janssen, LEO Pharma, Lilly, Sanofi, Boehringer Ingelheim, Galderma, Pfizer, UCB, and Novartis; contract services from: AbbVie, Janssen, UCB, and LEO Pharma. MA was an employee of: Almirall S.A (at the time this work was performed); and is now an employee of: AstraZeneca Early Clinical Development Immunology.

## Abstract AD-13

### Multidisciplinary Atopic Dermatitis Program: A Novel Approach to Managing Difficult-to-Control Atopic Dermatitis Patients

**Lauren Loop, BS[1]; Christine Anterasian, MD[2]; Caitlyn Kellogg, MD[3]; Nicole Navasero, BS[1]; Kathryn Smiley, PA-C[3]; Alyssa Wu, PharmD[3]; Bob Geng, MD[1]; Lawrence Eichenfield, MD[4]**

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**BACKGROUND:** A significant challenge in caring for patients with atopic dermatitis (AD) is lack of collaboration between healthcare providers, leading to disjointed care, inconsistent treatment plans, and conflicting dialogue with patients.[1]

**OBJECTIVE:** Here we describe our model of a multidisciplinary clinic with dermatology and allergy and immunology, and its success in improving the management of disease and patient satisfaction.

**METHODS:** The Multidisciplinary Atopic Dermatitis Program (MADP) was developed through collaborations with the Rady Children's Hospital and UC San Diego Health Divisions of Dermatology, Allergy & Immunology and Clinical Pharmacy, to create team-based evaluation and management of children and adolescents with AD. During each visit, the patient/family met with a clinical pharmacist, a dermatology team, an allergy team, and a patient educator. The program includes extensive patient education to support shared decision-making. Objective severity measures and patient reported outcome data were collected, along with assessment of patient and family satisfaction with the MADP.

**RESULTS:** Out of 70 patients, we evaluated 44 patients with a history of moderate-to-severe, persistent AD who had between one to three follow-up visits. Data showed significant improvement in AD severity by the first follow-up visit. BSA mean percentage decreased by up to 56% by the 7th visit, and pruritus (NRS), CLDQI and POEM mean scores decreased by more than 4 points, 12 points, and over 11 points, respectively. After management was initiated in the MADP, 72.73% of patients achieved an EASI 50 and 47.73% achieved an EASI 75 from a baseline mean of 21.7 (Figure 1; Table 1). Patients who continued in clinic beyond the second visit showed further clinically significant decreases in disease measures. Qualitatively, patient/family satisfaction with the MADP was high.

**CONCLUSIONS:** The multidisciplinary approach shows success in the treatment of moderate-to-severe AD patients, with improvements in clinician and patient reported outcome measures. These results demonstrate that these patients can truly benefit from a multidisciplinary approach. Limitations include that no control group with single-specialty visits was included in the data analysis.

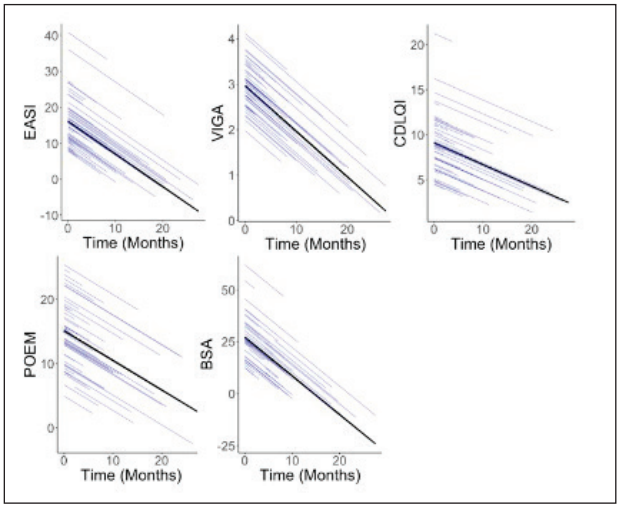


**FIGURE 1.** A linear mixed effects model blocked by patient was fit for each outcome variable. Blue = predicted effect for each patient, Black = model trend line

**REFERENCES:**

1. Eichenfield LF, et al. Systemic therapy of atopic dermatitis: welcome to the revolution. *Sem Cutan Med Surg.* 2017;36(4S):S103-S105.

**TABLE 1.** Statistical Data for Each Outcome Variable.

| Outcome | n | Estimate | Std. Error | Marginal R2 | Conditional R2 | *P* Value |
|---|---|---|---|---|---|---|
| EASI | 221 | -0.91 | 0.11 | 0.18 | 0.59 | <0.001 |
| VIGA | 221 | -0.10 | 0.01 | 0.25 | 0.50 | <0.001 |
| CLDQI | 221 | -0.24 | 0.08 | 0.04 | 0.35 | 0.003 |
| POEM | 221 | -0.46 | 0.07 | 0.12 | 0.62 | <0.001 |
| BSA | 221 | -1.86 | 0.25 | 0.22 | 0.58 | <0.001 |

*Marginal R2 reflects the amount of variance explained by the fixed effect (ie time)
*Conditional R2 reflects the amount of variance explained by the entire model

**DISCLOSURES:** BG has served as a speaker and/or adviser for: AbbVie, Pfizer, Regeneron, and Sanofi; adviser for Eli Lilly and Company, Incyte–Galderma, and LEO Pharma. LE has served as a scientific advisor, consultant, and/or clinical trial investigator for: AbbVie, Amgen, ASLAN, Castle Biosciences, Dermavant, Eli Lilly and Company, Forté, Galderma, Incyte, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Regeneron Pharmaceuticals, Sanofi-Genzyme, Trialspark, and UCB.

## Abstract AD-14

### Once-Daily Roflumilast Cream 0.15% for Atopic Dermatitis: Pooled Results From INTEGUMENT-1/2 Phase 3 Trials

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**BACKGROUND:** Roflumilast cream 0.15% is a selective, highly potent phosphodiesterase 4 inhibitor under investigation as a non-steroidal, once-daily treatment for atopic dermatitis (AD).
**OBJECTIVE:** Here, pooled results from two identical Phase 3 randomized controlled trials (INTEGUMENT-1: NCT04773587 and INTEGUMENT-2: NCT04773600) are presented.
**METHODS:** Patients with AD aged ≥6 years with baseline Eczema Area and Severity Index (EASI) score ≥5 and Validated Investigator Global Assessment-AD (vIGA-AD) score of Mild or Moderate were randomized 2:1 to apply roflumilast (n=884) or vehicle (n=453) once daily for 4 weeks.
**RESULTS:** A significantly greater percentage of roflumilast- versus vehicle-treated patients achieved the primary endpoint, vIGA-AD Success (Clear or Almost Clear vIGA-AD plus ≥2-grade improvement from baseline) at Week 4 (31.3% vs. 14.1%; *P*<0.0001). Significant differences favoring roflumilast were observed for multiple secondary endpoints at Week 4: percentage of patients achieving vIGA-AD of Clear or Almost Clear (41.1% vs. 21.4%; *P*<0.0001), percentage achieving 75% reduction in EASI (42.7% vs. 20.6%; P<0.0001), and percentage with baseline Worst Itch-Numeric Rating Scale ≥4 achieving a 4-point reduction (31.9% vs. 16.6%; *P*<0.0001). Improvement in itch was reported as early as 24 hours. Both groups had low incidences of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation. Local tolerability was favorable, with >90% of patients reporting no or mild sensation across both treatment groups at all timepoints.
**CONCLUSIONS:** Once-daily roflumilast cream 0.15% provided improvement across multiple efficacy endpoints by Week 4 with favorable safety and tolerability in patients aged ≥6 years with AD in two Phase 3 trials.
**FUNDING:** Sponsored by Arcutis Biotherapeutics, Inc.
**DISCLOSURES:** LFE, ELS, AB, MG, and EL are investigators and/or consultants for and received grants/research funding and/or honoraria from: Arcutis Biotherapeutics, Inc. MB is a consultant for: Arcutis Biotherapeutics, Inc. DHC and RCH are employees of: Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

## Abstract AD-15

### Rapid and Early Onset of Itch Relief With Tapinarof Cream 1% Once Daily in Two Pivotal Phase 3 Trials in Adults and Children Down to Two Years of Age With Atopic Dermatitis

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**BACKGROUND:** Itch is the most bothersome symptom for patients with atopic dermatitis (AD), with a significant negative impact on health-related quality of life. Rapid onset of pruritus relief with sustained efficacy is a key outcome for AD therapies. In a phase 2 trial in adults and adolescents with AD, tapinarof cream 1% once daily (QD) demonstrated efficacy versus vehicle and was well tolerated.
**OBJECTIVE:** Here, we evaluate time to onset of itch relief in the pivotal phase 3 trials with tapinarof cream 1% QD in the treatment of adults and children down to 2 years of age with AD.
**METHODS:** In ADORING 1 and 2, two identical, double-blind, vehicle-controlled trials, patients were randomized 2:1 to tapinarof cream 1% or vehicle cream QD for 8 weeks. Patients with a Validated Investigator Global Assessment for Atopic Dermatitis™ score of ≥3, an Eczema Area and Severity Index score of ≥6, and body surface area involvement of 5–35% were included. Efficacy endpoints that evaluated itch relief were mean changes in Peak Pruritus Numerical Rating Scale (PP-NRS) score (daily and by visit [Weeks 1, 2, 4, and 8]) from baseline through Week 8. The PP-NRS considers a person's worst itch over the past

24 hours, assessed on an 11-point scale (0 indicates "no itch" and 10 is "worst imaginable itch"). Daily PP-NRS scores were recorded in diaries. Patients aged ≥12 years self-completed the PP-NRS, while caregivers completed it for children aged <12 years.

**RESULTS:** 407 and 406 patients were randomized in ADORING 1 and 2. At baseline, mean (standard deviation [SD]) PP-NRS scores were 6.7 (2.4) and 6.8 (2.3) in both trials, respectively. For daily evaluations of itch from baseline, greater reductions in PP-NRS scores (mean [SD]) for tapinarof versus vehicle were observed as early as Day 1, 24 hours after initial application, in ADORING 1 (–1.2 [2.2] vs –0.9 [2.0]) and Day 2 in ADORING 2 (–1.6 [2.4] vs –1.4 [2.1]). Improvements in daily PP-NRS scores (mean [SD]) with tapinarof versus vehicle continued through the first 2 weeks (Day 14; –3.0 [2.8] vs –2.0 [2.4] and –2.9 [2.7] vs –1.8 [2.6]), and through Week 8 of both trials. There were statistically significant and clinically meaningful reductions in mean weekly PP-NRS scores as early as Week 1, the first assessment, for patients treated with tapinarof compared with vehicle (–2.0 vs –1.2 [$P$<0.0001]) and (–2.0 vs –1.3 [$P$=0.0010]), in ADORING 1 and 2, respectively. Significantly greater reductions in mean PP-NRS scores with tapinarof versus vehicle were seen for all visits through Week 8 (–4.1 vs –2.6 and –4.1 vs –2.4 [both $P$<0.0001]), for both trials.

**CONCLUSIONS:** Tapinarof cream 1% QD demonstrated rapid, clinically meaningful, and significant onset of pruritus relief as early as 24 hours after initial application compared with vehicle. Improvements in itch with tapinarof cream increased through Week 8 in both trials in adults and children down to 2 years of age with AD.

**FUNDING:** Dermavant Sciences, Inc.

**DISCLOSURES:** ES reports grants and fees for participation as a consultant and principal investigator from: Eli Lilly and Company, LEO Pharma, Pfizer, and Regeneron; grants for participation as a principal investigator from: Galderma and Merck & Co.; and fees for consultant services from: AbbVie, Boehringer Ingelheim, Dermavant Sciences, Inc., Forte Bio, Incyte, Pierre Fabre Dermo, and Sanofi-Genzyme. JIS has received honoraria as a consultant and/or advisory board member for: AbbVie, Alamar, Aldena, Amgen, AObiome, Arcutis, Arena, Asana, ASLAN, BioMX, Biosion, Bodewell, Boehringer Ingelheim, Bristol Myers Squibb, Cara, Castle Biosciences, Celgene, Connect Biopharma, Corevitas, Dermavant Sciences, Inc., Dermira, Dermtech, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte, Kiniksa, LEO Pharma, Menlo, Novartis, Optum, Pfizer, RAPT, Recludix, Regeneron, Sanofi-Genzyme, Shaperon, TARGET-RWE, Union, and UpToDate; is a speaker for: AbbVie, Eli Lilly and Company, LEO Pharma, Pfizer, Regeneron, and Sanofi-Genzyme; and received institution grants from: Galderma, Incyte, and Pfizer. RB has served as a consultant/investigator/advisory board member for: AbbVie, Almirall, Alumis, Amgen, AnaptysBio, Arcutis, Aristea, Bausch Health, Boehringer Ingelheim, Boston Pharmaceuticals, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, Escalier, Janssen, Kyowa Kirin, LEO Pharma, Nimbus, Novartis, Pfizer, Regeneron, Sienna, and UCB Biopharma; and is an employee and shareholder of: Innovaderm Research. LSG has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from: Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB Biopharma. AA has served as a research investigator and/or scientific advisor for: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Dermira, Eli Lilly and Company, EPI, Incyte, Janssen, LEO Pharma, Modmed, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Biopharma. AAH has received research support paid to the medical school from: AbbVie, Arcutis, Dermavant Sciences Inc., and Pfizer; and honoraria received from: Arcutis, Dermavant Sciences, Inc., Galderma, GlaxoSmithKline, Incyte, LEO Pharma, Novan, Ortho Dermatologics (as part of a data safety monitoring board), Pfizer, Sanofi Regeneron, Sun Pharma, and Verrica. RTS has served as a consultant and/or has received payment for the development of educational presentations, and/or has received grants from: Abbott, AbbVie, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, Incyte, Janssen, Pfizer, Regeneron, and Sanofi-Genzyme. JRJ is a clinical investigator for: the ADORING trials; an employee of SUNY Downstate Health Sciences University, which received compensation from Dermavant Sciences, Inc. for trial participation; and an investigator, advisor, and/or consultant for: Amgen, Arcutis, Galderma, Incyte, Pfizer, Regeneron, and Verrica. PMB, DSR, SCP, and AMT are employees of: Dermavant Sciences, Inc., with stock options. LFE has served as a consultant, advisor, or investigator for: AbbVie, Almirall, Amgen, Arcutis, Arena, ASLAN, Dermavant Sciences, Inc., Eli Lilly and Company, Forté, Galderma, Incyte, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi-Genzyme, and UCB Pharma.

## Abstract AD-16

### Recapture of Response With Lebrikizumab: An Evaluation of Patients From ADvocate1 and ADvocate2

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**BACKGROUND:** In ADvocate1 and ADvocate2, most patients treated with lebrikizumab (LEB) monotherapy every 2 weeks (Q2W) achieved statistically and clinically meaningful improvements in the signs and symptoms of atopic dermatitis (AD) during the first 16 weeks of treatment. At 52 weeks of treatment, LEB showed durability of response in the signs and symptoms of AD.

**OBJECTIVE:** To report the efficacy data of patients from ADvocate1 and ADvocate2 who met LEB response criteria at Week 16, were re-randomized to the placebo withdrawal arm during the maintenance period, lost response, and were then readministered their original dose of LEB Q2W.

**METHODS:** Patients who met response criteria to LEB monotherapy at the end of the 16-week induction period were re-randomized 2:2:1 to receive LEB Q2W, LEB every 4 weeks (Q4W), or placebo (LEB withdrawal) for an additional 36 weeks (Figure). Response at Week 16 was defined as achieving a 75% reduction in EASI from baseline (EASI 75) or an Investigator's Global Assessment (IGA) of 0 or 1 with a ≥2-point improvement, and without rescue medication use. During the maintenance period, re-randomized patients who did not maintain at least a 50% reduction in the Eczema Area and Severity Index from baseline (EASI 50) at weeks 24, 32, 40, or 48 were assigned to an Escape Arm to be readministered LEB Q2W as open-label treatment. Intermittent use of topical rescue medications for AD was permitted during the maintenance period. All data reported are as observed.

**RESULTS:** In ADvocate1 and ADvocate2, 291 patients met the criteria for response at Week 16 and were re-randomized to LEB Q2W (n=113), LEB Q4W (n=118), or placebo (LEB withdrawal; n=60). From the LEB withdrawal arm, 10 patients were moved to the Escape Arm and readministered their original dose after falling below EASI 50 (ADvocate1: 7 patients; ADvocate2: 3 patients). The baseline (Week 0) EASI mean score for these 10 patients was 26.65 and IGA severity was distributed evenly between IGA 3 (n=5) and IGA 4 (n=5) (Table). At the time of readministration of LEB, the mean EASI % change from baseline (CFB) was -24.2 (n=10). After 4 and 8 weeks in the Escape Arm, the mean EASI % CFB was -70.9 (n=10) and -89.1% (n=8), respectively. Topical rescue medication was started by 3 of 10 patients during the maintenance blinded period and before entering the Escape Arm. Approximately two weeks after moving to the Escape Arm, one patient used systemic rescue medication (oral prednisolone).

**CONCLUSION:** EASI improvements were seen in patients who were withdrawn from lebrikizumab after meeting response criteria at week 16 and then readministered lebrikizumab as open-label treatment. Most of these patients recaptured EASI 75 upon readministration of lebrikizumab. Additional data are needed to confirm this finding due to the limitations of this analysis including a low number of patients, as observed results, differing times of assignment to the escape arm, and an unblinded readministration period.

**ACKNOWLEDGMENTS AND FUNDING:** These studies were funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications including atopic dermatitis in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe. Abstract previously presented at European Academy of Dermatology and Venereology (EADV), October 11-14, 2023, Berlin, Germany.

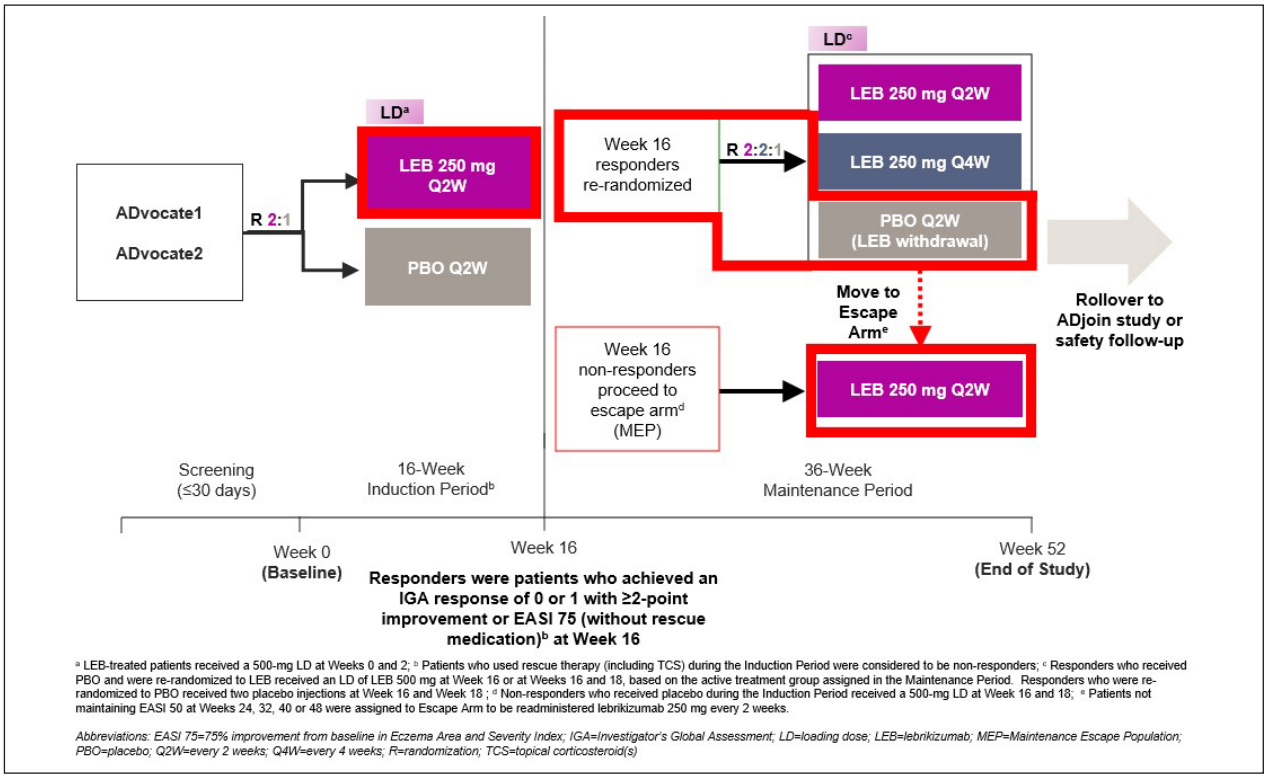


**FIGURE 1.** Advocate1 and Advocate2 study design

**TABLE.** Mean EASI Scores in Lebrikizumab Withdrawal Patients Who Were Readministered Lebrikizumab During the Maintenance Period.

| | At Time of LEB Q2W Readministration[a] | 4 Weeks After LEB Q2W Readministration | 8 Weeks After LEB Q2W Readministration |
|---|---|---|---|
| Number of patients | 10 | 10 | 8 |
| EASI total score (mean) | 20.63 | 7.49 | 2.52 |
| EASI % CFB (mean) | -24.21 | -70.94 | -89.09 |

[a]Patients not maintaining EASI 50 at Weeks 24, 32, 40, or 48 were assigned to Escape Arm to be readministered lebrikizumab 250 mg every 2 weeks.

Abbreviations: CFB=Change from Baseline; EASI=Eczema Area and Severity Index; LEB=lebrikizumab; Q2W=every 2 weeks

**DISCLOSURES:** MG has been an investigator, speaker and/or advisor for: AbbVie, Amgen, Akros, AnaptysBio, Apogee, Arcutis, Aristea, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, Moonlake, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Takeda, Tarsus, UCB, Union, and Ventyx. MdB-W has been a consultant, advisory board member, and/or speaker for: AbbVie, Almirall, Arena, ASLAN, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Pfizer, Regeneron, and Sanofi-Genzyme. AA has received grants (funds to institution) from: AbbVie, Almirall, Amgen, Arcutis, Bristol Myers Squibb, Cara, Castle, Dermavant, Galderma, LEO Pharma, Novartis, Valeant (Bausch Health), and Vyne; has served on the advisory board or as a consultant for: AbbVie, Allergan, Almirall, Amgen, Apogee, Arcutis, Bausch health, Beiersdorf, Bristol Myers Squibb, Canfield, Cara, Castle, Cutera, Dermavant, Eli Lilly and Company, EPI, Galderma, Incyte, Janssen, L'Oreal, LEO Pharma, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, Swiss American, UCB, VisualDx, and Vyne; and has received royalties from: Springer, Wiley-Blackwell, and Wolters Kluwer Health. LK has received grants and/or honoraria from: AbbVie, Acambis, Amgen Inc., Anacor Pharmaceuticals, Anaptys, Arcutis, Arena, Assos Pharma, Astella Pharma US Inc., Asubio, Dermavant, Dermira, Dow Pharmaceutical Sciences Inc., Eli Lilly and Company, Ferndale Laboratories Inc., Galderma, Genentech Inc., GlaxoSmithKline PLC, Glenmark, Health Point LTD, Incyte, Innocutis, Innovail, Kyowakirin, LEO Pharma, L'Oreal, Nano Bio, Novartis AG, Nucryst Pharmaceuticals Corp, Onset, Ortho Dermatologics, Ortho Neutrogena, PediaPharma, PharmaDerm, Pfizer, Promius, PuraCap, Quinnova, Regeneron, Sanofi, SkinMedica Inc., Steifel Laboratories Inc., Sun Pharma, Taro, Triax, and Valean Pharmaceuticals Intl. TT declares the following conflicts of interest: AbbVie, Almirall, Amgen, Arena Pharmaceuticals, Biocad, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Fresenius Kabi, Janssen, LEO Pharma, Merck Sharp & Dohme, Mylan, Novartis, Pfizer, Samsung-Bioepis, Sandoz, Sanofi-Genzyme, UCB, and Viatris. HE, ARA, EP, YD, ZL and BRM are employees and stockholders of: Eli Lilly and Company. HA is an employee of: Almirall S.A. DT has acted as a consultant, investigator, speaker, and participant in scientific advisory boards for: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Galapagos, Janssen-Cilag, LEO Pharma, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, La Roche-Posay, Samsung, Sanofi, Sun Pharma, and UCB.

## Abstract AD-17

### Safety of Baricitinib Across Dermatology Indications: Atopic Dermatitis and Alopecia Areata

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**BACKGROUND:** Baricitinib, a selective Janus kinase (JAK)1/JAK2 inhibitor, is approved for treatment of moderate-to-severe atopic dermatitis (AD) in adults who are candidates for systemic therapy and adults with severe alopecia areata (AA).

**OBJECTIVE:** To inform clinicians on the safety profile of baricitinib in patients with AD or AA.

**METHODS:** Data are reported from the All-bari AD dataset derived from 8 clinical trials and the All-bari AA dataset integrated from 2 clinical trials. All-bari refers to patients receiving any dose of baricitinib at any time during the studies. Incidence rates/100 patient years (PY) at risk were calculated. Results are descriptive only.

**RESULTS:** Datasets included adult patients with AD (N=2636; 4628 PY) or with AA (N=1303; 1868 PY). For both AD and AA, treatment-emergent adverse events (TEAEs) occurred in approximately 75% of patients and were usually mild or moderate in severity. Common TEAEs in AD and AA largely overlapped with the five most common events in All-bari AD being nasopharyngitis, headache, upper respiratory tract infection, oral herpes, and influenza and in All-bari AA being upper respiratory tract infection, headache, nasopharyngitis, acne, and urinary tract infection. Incidence rates for serious adverse events and adverse events leading to discontinuation were low and comparable in both datasets. Incidence rates for adverse events of special interest were: major adverse cardiovascular events (AD, 0.15; AA, 0.05), serious infections (AD, 1.8; AA, 0.8), pulmonary embolism (AD, 0.06; AA, 0.05), and malignancy excluding nonmelanoma skin cancer (NMSC) (AD, 0.3; AA, 0.2), NMSC (AD, 0.2; AA, 0.1).

**CONCLUSIONS:** Overall, the types of adverse events in AD and AA largely overlap with a few differences. The incidence rates of adverse events of special interest, including serious infections, MACE, DVT/PE and malignancies are low and within the background rates for the disease population.

**ACKNOWLEDGMENTS AND FUNDING:** Study was sponsored by Eli Lilly and Company, under license from Incyte Corporation. Abstract previously presented at 25th World Congress of Dermatology, July 3-8, 2023, Singapore.

**DISCLOSURES:** TB is a speaker, consultant, and/or investigator for: AbbVie, Affibody, Almirall, AnaptysBio, Arena Pharmaceuticals, Asana BioSciences, ASLAN Pharmaceuticals, Bayer Pharmaceuticals, BioVersys, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Domain Therapeutics, Eli Lilly and Company, EQRx, Galderma, GlaxoSmithKline, Glenmark Pharmaceuticals, Incyte Corporation, Innovaderm Research, IQVIA, Janssen, Kymab, Kyowa Kirin, L'Oréal, LEO Pharma, LG Chem, Merck Sharp & Dohme, Novartis, Numab, OM Pharma, Pfizer, Pierre Fabre, Q32 Bio, RAPT Therapeutics, Sanofi Regeneron, and UCB Pharma; and is Founder and Chairman of the Board of the non-profit biotech: DavosBiosciences. BK has served on advisory boards and/or is a consultant and/or clinical trial investigator for: AbbVie, Almirall, AltruBio, AnaptysBio, Arena Pharmaceuticals, Bioniz Therapeutics, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, Horizon Therapeutics, Incyte Corporation, LEO Pharma, Otsuka/Visterra, Pfizer, Regeneron, Sanofi Genzyme, TWi Biotechnology, and Viela Bio; and is on speaker's bureaus for: AbbVie, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, and Sanofi Genzyme. NK has served as an advisor and/or paid speaker for and/or participated in clinical trials sponsored by: AbbVie, Boehringer Ingelheim, Eli Lilly Japan, and LEO Pharma. JPT is an advisor/speaker for and/or has received research grants from: AbbVie, Almirall, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Coloplast, Eli Lilly and Company, LEO Pharma, OM Pharma, Pfizer, Regeneron, Sanofi Genzyme, and UNION Therapeutics. AS, FEY, FD, KH, NS, SB and WRZ are employees and shareholders of: Eli Lilly and Company. JIS has received grants and/or personal fees from: AbbVie, AFYX Therapeutics, Arena Pharmaceuticals, Asana BioSciences, Bluefin Biomedicine, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte Corporation, Kiniksa Pharmaceuticals, LEO Pharma, Luna Pharma, Menlo Therapeutics, Novartis, Pfizer, RAPT Therapeutics, Regeneron, and Sanofi.

## Abstract AD-18

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

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**BACKGROUND:** Delgocitinib is a topical pan-Janus kinase (JAK) inhibitor that was well tolerated and demonstrated significant improvement in primary and all secondary efficacy endpoints in the DELTA 1 (NCT04871711) pivotal phase 3 trial for treatment of chronic hand eczema (CHE). The identical DELTA 2 pivotal phase 3 trial (NCT04872101) was designed to confirm the efficacy, safety, and effect on health-related quality of life of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle in adults with moderate to severe CHE.

**OBJECTIVE:** Here we present additional DELTA 2 analyses examining systemic exposure parameters of delgocitinib cream, which allow comparisons with systemic exposure data of oral delgocitinib from a phase 1 trial (NCT05050279).

**METHODS:** DELTA 2 was a randomized, double-blind, vehicle-controlled trial. Adults (aged ≥18 years) with moderate to severe CHE were randomized 2:1 to twice-daily delgocitinib cream 20 mg/g (n=314) or cream vehicle (n=159) for 16 weeks followed by a 2-week safety follow-up or were transferred to a 36-week extension trial (NCT04949841). Blood samples collected 2–6 hours after application of the investigational medicinal product at Weeks 1, 4, and 16 were used to analyse plasma concentrations of delgocitinib using a liquid chromatography/mass spectrometry-based method with a lower limit of quantitation of 5 pg/ml. The inhibitory concentration of 50% (IC50) of delgocitinib was assessed using an in vitro IL-4 release assay in whole-blood of healthy volunteers (n=4). In the phase 1 trial, single oral doses of delgocitinib (1.5, 3, 6, and 12 mg) were tested in healthy volunteers (n=40). Data are reported as geometric means.

**RESULTS:** The DELTA 2 analysis included samples from 313 subjects on active treatment. The plasma concentration of delgocitinib was 0.21, 0.20, and 0.12 ng/ml at Weeks 1, 4, and 16, respectively (Figure 1). IC50 of delgocitinib was 17.2 ng/ml. In the phase 1 study, the lowest tested oral dose of delgocitinib (1.5 mg) was perceived as a sub-therapeutic dose. Peak systemic exposure ($C^{max}$) of the 1.5 mg orally dosed delgocitinib was 7.2 ng/ml, meaning that systemic

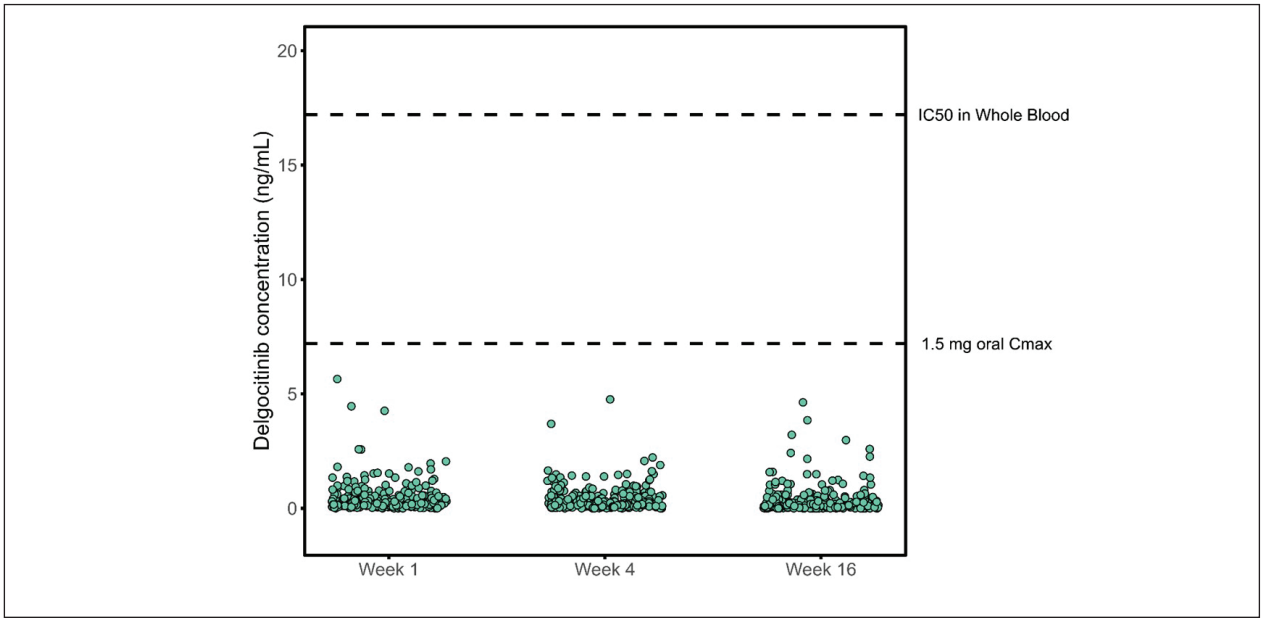


**FIGURE 1.** Scatter plot[a] of delgocitinib concentration by visit at Week 1 (n=286), Week 4 (n=275), and Week 16 (n=261)
[a]One subject was excluded from this analysis due to an outlier value at Week 4.

exposure after topical application in DELTA 2 was ≥30-fold lower (7.2 ng/ml divided by 0.21 ng/ml).

**CONCLUSION:** Twice daily application of delgocitinib cream resulted in minimal systemic exposure, at least 80-fold below the whole-blood IC50 over 16 weeks (17.2 ng/ml divided by 0.21 ng/ml), and at least 30-fold below oral 1.5 mg delgocitinib dose with no overlap in plasma exposure between oral and topical administration. These data further support the favourable safety profile of topical delgocitinib cream and suggest that no systemic pharmacological effect is expected with 20 mg/g dosing in patients with moderate to severe CHE.

**ACKNOWLEDGEMENTS AND FUNDING:** DELTA 2 was sponsored by LEO Pharma A/S, Ballerup, Denmark. Medical writing and editorial support from Alphabet Health by Sue Ulm PhD, was funded by LEO Pharma A/S, Ballerup, Denmark. This work was previously presented at EADV 2023.

**DISCLOSURES:** DT has served as an investigator and/or consultant/adviser for: AbbVie, Almirall, Amgen, Asana Biosciences, Biogen Idec, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Galapagos, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi, Target-Solution, and UCB; and has received grants from: AbbVie, LEO Pharma, and Novartis. DM and KS are employees of: LEO Pharma A/S. KM is an employee of: LEO Pharma Inc. MG has been an investigator, speaker, and/or advisor for: AbbVie, Akros, Amgen, AnaptysBio, Apogee, Arcutis, Aristea, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb Company, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, Moonlake, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Takeda, Tarsus, UCB, Union, and Ventyx.

## Abstract AD-19

### Tapinarof Cream 1% Once Daily: Significant Efficacy in Atopic Dermatitis in Two Phase 3 Trials in Adults and Children Down to 2 Years of Age

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**BACKGROUND:** Tapinarof cream 1% once daily (QD) demonstrated efficacy versus vehicle and was well tolerated in adults and adolescents with atopic dermatitis (AD) in a previously reported phase 2 trial.

**OBJECTIVE:** Here, we report pivotal phase 3 efficacy and safety results for tapinarof cream 1% QD in the treatment of adults and children down to 2 years of age with AD.

**METHODS:** ADORING 1 and 2 were two identical phase 3, randomized, double-blind, vehicle-controlled trials. Eligibility criteria included a Validated Investigator Global Assessment for Atopic Dermatitis™ (vIGA-AD™) score of ≥3, Eczema Area and Severity Index (EASI) score of ≥6, and body surface area (BSA) involvement of 5–35%. Patients were randomized 2:1 to receive tapinarof cream 1% or vehicle cream QD for 8 weeks. The primary efficacy endpoint was vIGA-AD™ response, defined as a score of clear (0) or almost clear (1) and ≥2-grade improvement from baseline at Week 8. Secondary efficacy endpoints included ≥75% improvement in EASI score (EASI75) and proportion of patients (aged ≥12 years) with a baseline Peak Pruritus Numerical Rating Scale (PP-NRS) score of ≥4 who achieved a ≥4-point reduction at Week 8. Adverse events (AEs) included rates of AEs of special interest (AESIs): contact dermatitis, follicular event, and headache.

**RESULTS:** 407 and 406 patients aged 2–81 years were randomized in ADORING 1 and 2, respectively. At baseline, 84.0–89.9% of patients had a vIGA-AD™ score of 3 (moderate), mean EASI score of 12.5–13.3, and mean BSA affected of 16.7–16.9% across trials. At Week 8, both the primary and all secondary efficacy endpoints were met with statistical significance in the tapinarof groups versus vehicle: vIGA-AD™ response rates were 45.4% vs 13.9% and 46.4% vs 18.0% (both $P<0.0001$); EASI75 response rates were 55.8% vs 22.9% and 59.1% vs 21.2% (both $P<0.0001$); and a ≥4-point reduction in PP-NRS was achieved by 55.8% vs 34.2% ($P=0.0366$) and 52.8% vs 24.1% ($P=0.0015$), in ADORING 1 and 2, respectively. AEs were mostly mild or moderate; the most frequent (≥5% in any group) were folliculitis, headache, and nasopharyngitis. Trial discontinuation rates due to AEs were lower with tapinarof versus vehicle (ADORING 1: 1.9% vs 3.6%; ADORING 2: 1.5% vs 3.0%, respectively). Rates of AESIs with tapinarof versus vehicle were: contact dermatitis 1.5% vs 2.2% and 1.1% vs 1.5%; follicular events 10.0% vs 0.7% and 8.9% vs 1.5%; and headache 7.0% vs 2.2% and 1.5% vs 0%, in each trial, respectively.

**CONCLUSIONS:** Tapinarof cream 1% QD demonstrated statistically significant efficacy compared with vehicle for primary and secondary efficacy endpoints in adults and children down to 2 years of age with AD. Tapinarof was well tolerated, with no new safety or tolerability signals. AEs were mostly mild or moderate and led to low rates of trial discontinuation, demonstrating the predictable safety profile of tapinarof cream 1% QD.

**FUNDING SUPPORT:** Dermavant Sciences, Inc.

**DISCLOSURES:** JIS has received honoraria as a consultant and/or advisory board member for: AbbVie, Alamar, Aldena, Amgen, AObiome, Arcutis, Arena, Asana, ASLAN, BioMX, Biosion, Bodewell, Boehringer Ingelheim, Bristol Myers Squibb, Cara, Castle Biosciences, Celgene, Connect Biopharma, Corevitas, Dermavant Sciences, Inc., Dermira, Dermtech, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte, Kiniksa, LEO Pharma, Menlo, Novartis, Optum, Pfizer, RAPT, Recludix, Regeneron, Sanofi-Genzyme, Shaperon, TARGET-RWE, Union, and UpToDate; speaker for: AbbVie, Eli Lilly and Company, LEO Pharma, Pfizer, Regeneron, and Sanofi-Genzyme; and institution received grants from: Galderma, Incyte, and Pfizer. LFE has served as a consultant, advisor, or investigator for: AbbVie, Almirall, Amgen, Arcutis, Arena, ASLAN, Dermavant Sciences, Inc., Eli Lilly and Company, Forté, Galderma, Incyte, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi-Genzyme, and UCB Pharma. AAH has received research support paid to the medical school from: AbbVie, Arcutis, Dermavant Sciences Inc., and Pfizer; and honoraria received from: Arcutis, Dermavant Sciences, Inc., Galderma, GlaxoSmithKline, Incyte, LEO Pharma, Novan, Ortho Dermatologics (as part of a Data Safety Monitoring Board), Pfizer, Sanofi Regeneron, Sun Pharma, and Verrica. ELS reports grants and fees for participation as a consultant and principal investigator from: Eli Lilly and Company, LEO Pharma, Pfizer, and Regeneron; grants for participation as a principal investigator from: Galderma and Merck & Co.; and fees for consultant services from: AbbVie, Boehringer Ingelheim, Dermavant Sciences, Inc., Incyte, Forte Bio, Pierre Fabre Dermo, and Sanofi-Genzyme. LSG has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from: Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB Biopharma. RB has served as a consultant/investigator/advisory board member for: AbbVie, Alumis, Almirall, Amgen, AnaptysBio, Arcutis, Aristea, Bausch Health, Boehringer Ingelheim, Boston Pharmaceuticals, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, Escalier, Janssen, Kyowa Kirin, LEO Pharma, Nimbus, Novartis, Pfizer, Regeneron, Sienna, and UCB Biopharma; and is an employee and shareholder of: Innovaderm Research. KAP has served as a consultant/speaker/scientific officer/has attended advisory boards for, or received grants or honoraria from: AbbVie, Akros, Amgen, Anacor, Arcutis, Astellas, Bausch Health/Valeant, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly and Company, Evelo, Galapagos, Galderma, Genentech, Gilead, GlaxoSmithKline, Janssen, Kyowa Kirin, LEO Pharma, Medimmune, Meiji Seika Pharma, Merck (Merck Sharp & Dohme), Merck-Serono, Mitsubishi Pharma, Moberg Pharma, Novartis, Pfizer, PRCL Research, Regeneron, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda, and UCB Biopharma. JB has served as an investigator for: AbbVie, Acelyrin, Amgen, Arcutis, Dermavant, Inc., Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, UCB Pharma, and Vyne; and as a speaker for: Krystal, Pfizer, and Regeneron. PK is a consultant, speaker, or principal investigator for: AbbVie, Almirall, Amgen, Arcutis, Dermavant Sciences, Inc., Eli Lilly and Company, Galderma, Incyte, L'Oréal, Novartis, Novum, Ortho Dermatologics, Pfizer, Regeneron/Sanofi, Sun Pharma, UCB Pharma, and Verrica. NJK has served as an investigator and speaker for and received grants and honoraria from: Abbott Labs, Astellas, and Genentech; served on the advisory board and was an investigator for and received grants and residency/fellowship program funding from: Centocor; and was investigator and speaker for and received grants and honoraria from: Amgen. PMB, DSR, SCP, MCS, and AMT are employees of: Dermavant Sciences, Inc. with stock options. LK has served as a consultant, speaker, investigator, or advisory board member for: 3M, Anacor Pharmaceuticals, AnaptysBio, Abbott Laboratories, AbbVie, Ablynx, Acambis, Aclaris, Allergan, Inc., Almirall, Amgen, Inc., Arcutis Biotherapeutics, Arena Pharmaceuticals, Assos Pharmaceuticals, Astellas Pharma US, Inc., Asubio Pharmaceuticals, Bausch Health, Berlex Laboratories

(Bayer HealthCare Pharmaceuticals), Biogen Idec, BioLife, Biopelle, Boehringer Ingelheim, Breckenridge Pharma, Bristol Myers Squibb, Cassiopea SpA, Cellceutix, Centocor, Inc., Cipher Pharmaceuticals, Coherus BioSciences, Colbar LifeScience, Combinatrix, Connetics Corporation, Coria Laboratories, Dermavant Sciences, Inc., Dermik Laboratories, Dermira, Dow Pharmaceutical Sciences, Inc., Dr. Reddy's Laboratories, DUSA Pharmaceuticals, Eli Lilly and Company, Embil Pharmaceutical Co. Ltd., EOS, Exeltis, Ferndale Laboratories, Inc., Ferrer, Foamix Pharmaceuticals, Galderma, Genentech, Inc., GlaxoSmithKline, Glenmark Pharmaceuticals, Healthpoint, Ltd, Idera Pharmaceuticals, Incyte, Innocutis, Innovail, Intendis, ISDIN, Johnson & Johnson, Kyowa Kirin, Laboratory Skin Care Inc., LEO Pharma, L'Oréal, Maruho Co., Ltd., Medical International Technologies, Medicis Pharmaceutical Corp., Merck, Merz Pharma, NanoBio, Novartis AG, Noven Pharmaceuticals, Nucryst Pharmaceuticals Corp., Obagi, Onset Dermatologics, Ortho Neutrogena, Pediapharma, Pfizer, Pharmaderm, Promius Pharma, PuraCap, QLT, Inc., Quatrix, Quinnova Pharmaceuticals, Regeneron, Sanofi, Serono (Merck Serono International SA), SkinMedica, Inc., Stiefel Laboratories, Inc., Sun Pharma, Taro Pharmaceutical Industries, Toler Rx, Triax Pharmaceuticals, UCB Pharma, Valeant Pharmaceuticals Intl., Warner Chilcott, XenoPort, and ZAGE.

## Cutaneous Malignancies

### Abstract CM-01

### Seasonal Variation Among United States Population in Cutaneous Malignant Melanoma Incidence Rates and Prevalence of Metastatic Disease at Diagnosis

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**BACKGROUND:** European epidemiologic studies have demonstrated seasonal variations in cutaneous malignant melanoma (CMM) diagnosis, most recently among populations in Eastern England and Scotland,[1] Italy,[2] and the Netherlands.[3] We aimed to perform the first large population-based study evaluating whether seasonal variations exist in CMM diagnosis among the modern U.S. population.

**METHODS:** We conducted a retrospective database study utilizing the Surveillance, Epidemiology, and End Results (SEER) database of the National Cancer Institute. The study population included CMM cases featuring patient age 20 or older, diagnosis 2010 through 2019, histologic confirmation of diagnosis, and known month of diagnosis. Our study population featured a total of 213,570 cases. Using the SEER*Stat software, the crude incidence rates for CMM cases based on month of diagnosis were calculated, along with corresponding rate ratios relative to March. Frequency data was also extracted and evaluated with Chi-square analysis and simple linear regression models using SPSS statistical software.

**RESULTS:** Seasonal variation is apparent among the crude incidence rates for CMM cases based on calculated rate ratios (Table 1). Relative to March, there are significantly increased CMM crude incidence rates observed in May ($p < 0.001$), June ($p < 0.001$), July ($p < 0.001$), August ($p < 0.001$), September ($p = 0.017$), and October ($p < 0.001$). Additionally, relative to March, there are significantly decreased CMM crude incidence rates observed in November ($p < 0.001$), December ($p < 0.001$), January ($p < 0.001$), and February ($p < 0.001$). There was no significant difference in the CMM crude incidence rate between March and April ($p = 0.467$).

The proportion of CMM cases with metastatic disease at diagnosis varied significantly based on the month of diagnosis ($p < 0.001$). The months of May through October featured CMM cases with proportions of metastatic disease lower than the monthly average, whereas the months of November through April featured cases with proportions higher than the monthly average (Figure 1).

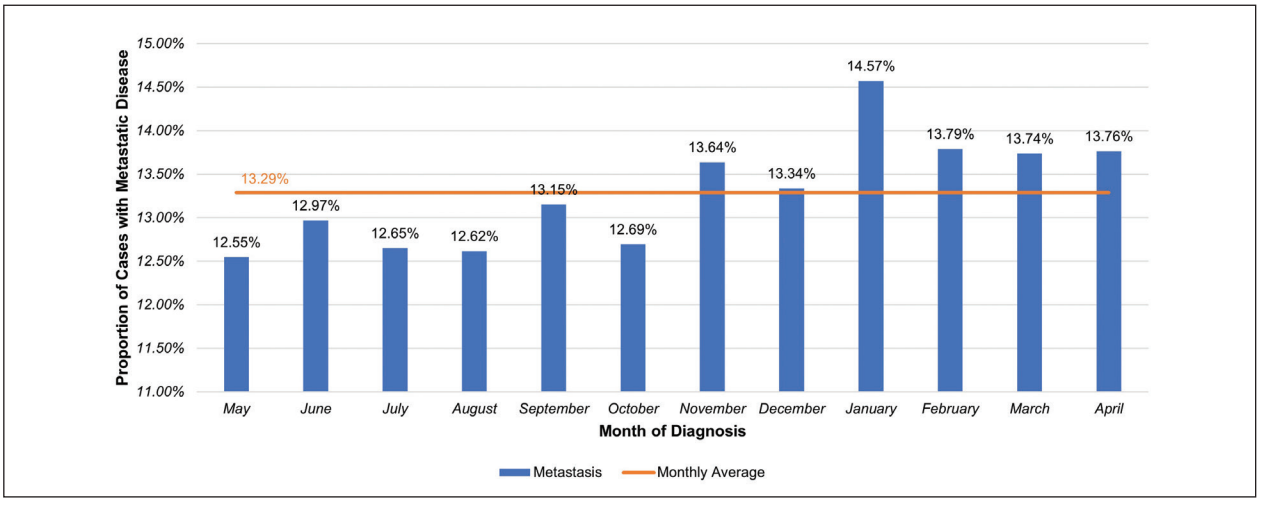


**FIGURE 1.** Proportion of Cutaneous Malignant Melanoma Cases with Metastatic Disease at Diagnosis Based on Month of Diagnosis

**TABLE 1.** Crude Incidence Rates and Corresponding Rate Ratios Based on Month of Diagnosis for Cutaneous Malignant Melanoma Cases Diagnosed in the United States 2010-2019.

| Month | Crude Incidence Rate | Rate Ratio | Confidence Interval | Ratio *P* Value |
|---|---|---|---|---|
| March | 2.824 | [Reference] | -- | |
| April | 2.846 | 1.008 | [0.987-1.029] | .467 |
| May | 3.068 | 1.086* | [1.064-1.109] | <.001 |
| June | 3.131 | 1.109* | [1.086-1.131] | <.001 |
| July | 3.040 | 1.076* | [1.055-1.099] | <.001 |
| August | 3.142 | 1.113* | [1.090-1.135] | <.001 |
| September | 2.897 | 1.026* | [1.005-1.047] | .017 |
| October | 2.989 | 1.058* | [1.037-1.081] | <.001 |
| November | 2.601 | 0.921* | [0.902-0.941] | <.001 |
| December | 2.411 | 0.854* | [0.835-0.872] | <.001 |
| January | 2.704 | 0.958* | [0.938-0.978] | <.001 |
| February | 2.503 | 0.886* | [0.867-0.906] | <.001 |

*Indicates a rate ratio corresponding to a crude incidence rate for a month that is significantly different than the crude incidence rate for March ($P$ <0.05).

January represented the peak month for the highest proportion of CMM cases with metastatic disease (14.57%) (Figure 1). Simple linear regression models demonstrated a significant and positive trend in the proportion of metastatic disease from May through April (slope 0.14%, R 0.795, p = 0.002).

**CONCLUSION:** The U.S. population features seasonal variation in CMM diagnosis, with November representing an annual inflection point with decreased crude incidence rates subsequently through February and increased proportion of metastatic disease subsequently through April. Explanations may include targeted melanoma awareness campaigns during summer, decreased clothing during summer, reduced access to care during holiday months, and the effect of UV on progression to advanced tumor.


REFERENCES:

1. Walter FM, et al. Seasonal variation in diagnosis of invasive cutaneous melanoma in Eastern England and Scotland. *Cancer Epidemiol.* 2015;39(4):554-61.
2. Bianconi F, et al. Seasonal variation in skin cancer diagnosis. *Frontiers of Public Health.* 2016;4:2296-2565.
3. Singh K, et al. Seasonal variation in diagnosis of cutaneous invasive melanoma and cutaneous squamous cell carcinoma: a nationwide study in the Netherlands. *Cancer Epidemiol.* 2022;81:102289.


**DISCLOSURES:** The authors have no disclosures to report.

## Other Medical Dermatology Topics

### Abstract OM-01

### Assessment of Physical Tinted Sunscreen Blendability on Multiple Fitzpatrick Skin Types


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**BACKGROUND:** Physical tinted sunscreen is becoming an increasingly popular option among consumers. However, it is important for consumers to pick a product that matches their individual skin tone and undertone. Although many available tinted sunscreens are marketed as being suitable for all skin tones, to our knowledge, an assessment of the universal nature of these tinted sunscreens on multiple Fitzpatrick skin types has not been previously performed.

**OBJECTIVE:** Our study sought to examine the blendability of various widely available physical tinted sunscreens on individuals of varying Fitzpatrick skin types.

**METHODS:** Three healthy volunteers (one of Fitzpatrick skin type I/II, III/IV, and V/VI respectively) applied 9

different commercially available physical tinted sunscreens (Tizo Primer/Sunscreen Tinted, La Roche-Posay Tinted Mineral, Alastin Hydratint Pro Mineral, SkinCeuticals Physical Fusion Universal Tint, EltaMD Tinted Physical Sunscreen, Eucerin Sensitive Mineral Tinted, Color Science Face Shield for Fair Skin Tones, Color Science Face Shield for Deep Skin Tones, and Color Science Face Shield for Medium Skin Tones) and one non-tinted physical sunscreen (Eucerin Sensitive Mineral) to the dorsal, sun-exposed forearm (Table 1). All sunscreens contained zinc oxide and/or titanium dioxide as well as iron oxides. Participants were blinded to the product applied. A small amount of product was applied to the tip of a cotton applicator and swiped on the dorsal forearm. The participant was instructed to rub in the product for 15 seconds. The participants wiped their hands in between application of sunscreens to prevent cross-contamination. Afterwards, participants rated how well the sunscreen blended with their skin tone on a scale of 1-5, with the following scale: 1- did not blend, 2- blends poorly, 3- blends somewhat, 4- blends fairly well, and 5- fully blends. Additional optional comments regarding each product were also collected.

**RESULTS:** There was a wide range of blendability among the skin types, with no product uniformly achieving full blendability (a rating of 5) on all skin types. Four products achieved an average rating of 4 (blends fairly well) between the three participants (Tizo, SkinCeuticals, Elta MD, and Eucerin). Color Science Medium and Dark were the lowest rated, with an average score of 1.6 and 1 respectively (did not blend). Only one product was rated a 5 by Fitzpatrick I/II subject (SkinCeuticals). Two products were rated a 5 by Fitzpatrick III/IV subject (Elta MD and Eucerin). No products were rated a 5 by Fitzpatrick V/VI subject (Figure 1).

**CONCLUSIONS:** It is difficult to achieve a universal tinted sunscreen that works on all Fitzpatrick skin types; however, Tizo, SkinCeuticals, Elta MD, and Eucerin all blended fairly well on a wide range of skin tones. Fitzpatrick I/II and Fitzpatrick V/II skin tones may be more difficult to match than medium skin tones.

**DISCLOSURES:** The authors have no disclosures to report.

**TABLE 1. Product Name, Ingredients, Size, and Price for All Tested Sunscreens.**

| Sunscreen Name | Active Ingredient | Iron Oxide | Approximate Price (US dollars) | Size (oz) | Price (US dollars) per oz |
|---|---|---|---|---|---|
| Eucerin Sensitive Mineral Non-Tinted | Zinc oxide 24% | No | 13.99 | 4.0 | 3.5 |
| Tizo Primer/Sunscreen Tinted | Zinc Oxide 3.8%/ Titanium Dioxide 8% | Yes | 45.00 | 1.75 | 25.7 |
| La Roche-Posay Tinted Mineral | Titanium dioxide 11% | Yes | 37.99 | 1.7 | 22.3 |
| Alastin Hydratint Pro Mineral | Titanium dioxide 8.9%/ Zinc oxide 3.4% | Yes | 64.00 | 3.2 | 20.0 |
| SkinCeuticals Physical Fusion Universal Tint | Titanium dioxide 6%/ Zinc oxide 5% | Yes | 42.00 | 1.7 | 24.7 |
| EltaMD Tinted Physical Sunscreen | Zinc oxide10.0%/ Titanium dioxide 5.7% | Yes | 40.00 | 2.0 | 20.0 |
| Eucerin Sensitive Mineral Tinted | 24% Zinc oxide | Yes | 15.99 | 1.7 | 9.40 |
| Color Science Face Shield for Fair Skin Tones | Zinc oxide 12% | Yes | 49.00 | 1.8 | 27.20 |
| Color Science Face Shield for Deep Skin Tones | Zinc oxide 12% | Yes | 49.00 | 1.8 | 27.20 |
| Color Science Face Shield for Medium Skin Tones | Zinc oxide 12% | Yes | 49.00 | 1.8 | 27.20 |

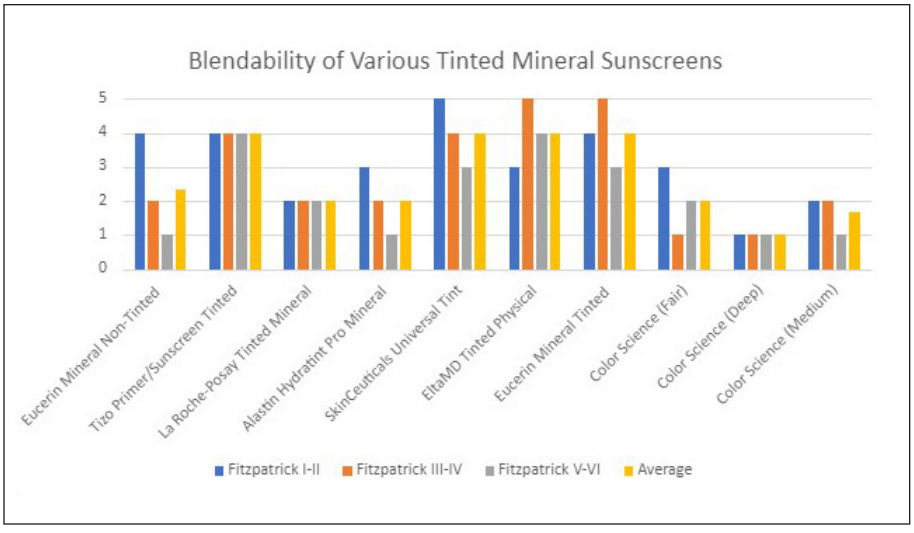


**FIGURE 1.** Blendability rating by Fitzpatrick skin type and average rating across skin types for various physical tinted sunscreens and one non-tinted physical sunscreen.

## Abstract OM-02

### Clinical Efficacy and Patient-Reported Impacts of Roflumilast Foam 0.3% in Seborrheic Dermatitis: An Analysis of STRATUM Data in Patients Unresponsive or Intolerant to Topical Corticosteroids

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**BACKGROUND:** Roflumilast foam 0.3% has demonstrated efficacy and tolerability in a Phase 3 clinical trial of moderate-to-severe seborrheic dermatitis (SD) patients (STRATUM).
**OBJECTIVE:** The aim of this subgroup analysis is to assess the efficacy and patient-reported quality of life (QOL) effects of roflumilast vs vehicle in patients with an inadequate response, intolerance, or contraindication to topical corticosteroids (TCS).
**METHODS:** Patients 9 years or older with at least moderate seborrheic dermatitis (Investigator Global Assessment [IGA] ≥3) were randomized 2:1 to roflumilast or vehicle for 8 weeks. Patients reporting a history of inadequate response, intolerance, or contraindication to topical corticosteroids (TCS) were included in this subgroup analysis. The primary efficacy endpoint was IGA success (Clear or Almost Clear with at least a 2-grade improvement) at Week 8. QOL was assessed using the Dermatology Life Quality Index (DLQI) for patients aged ≥17 years. QOL endpoints included percentage change from baseline in DLQI score, achievement of a minimal important difference (MID; defined as at least a 4-point reduction in DLQI score), and patients achieving a DLQI score of 0 or 1 by treatment group at weeks 2, 4, and 8. Differences in change from baseline DLQI scores were assessed using the Kruskal-Wallis rank sum test. The Cochran–Mantel–Haenzel test was used to assess differences in the proportion of patients achieving binary endpoints between treatments.
**RESULTS:** 189 patients (129 roflumilast, 60 vehicle) were included in the subgroup analysis. At Week 8, 78.8% of roflumilast patients achieved IGA success vs. 48.3% of vehicle patients (odds ratio [OR] 3.45; 95% confidence interval [CI]: 1.62, 7.36; $p<0.001$). At each time point, percentage change from baseline in DLQI score was significantly larger for roflumilast-treated patients relative to vehicle ($p\leq0.0001$ at each time point). Treatment with roflumilast significantly increased the odds of achieving an MID in DLQI across all time points (OR: 6.97; 95% confidence interval [CI]: 3.97, 12.24; $p<0.001$) and achieving a DLQI score of 0 or 1 (OR: 2.46; 95% CI: 1.58, 3.81; $p<0.001$).
**CONCLUSIONS:** Roflumilast foam 0.3% provided significant and meaningful efficacy with improved QOL in patients with moderate-to-severe SD who had a prior history of an inadequate response, intolerance, or contraindication to TCS. Clinical improvement aligned with patient-reported outcomes at all key assessment periods.
**FUNDING:** Sponsored by Arcutis Biotherapeutics, Inc.
**DISCLOSURES:** DHC and BS are employees of: Arcutis Biotherapeutics, Inc. JL, BB, CH, and TW are employees of: Lumanity Inc., a consulting company that provides paid consulting services to Arcutis Biotherapeutics, Inc. MZ is an investigator and consultant for and received grants/research funding and/or honoraria from: Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

## Abstract OM-03

### Concurrent Improvement in Scalp Hair and Eyebrow or Eyelash Regrowth in Patients With Severe Alopecia Areata Treated With Baricitinib

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**BACKGROUND:** Baricitinib demonstrated efficacy in clinical trials versus placebo in scalp-hair, eyebrow (EB), and eyelash (EL) regrowth in patients with severe alopecia areata (AA). Holistic regrowth is an important treatment objective.
**OBJECTIVE:** To evaluate concurrent clinically meaningful scalp-hair, and EB or EL responses among baricitinib-treated patients with severe AA.
**METHODS:** Patients received once-daily oral baricitinib (2 mg or 4 mg) for 52 weeks in two phase 3 clinical trials (BRAVE-AA1/2). Integrated data from patients with coincident baseline Severity of Alopecia Tool score ≥50 (SALT≥50), and a Clinician-Reported Outcome Measure for both EB and EL Hair Loss (ClinRO EB and ClinRO EL) ≥2, were selected. Endpoints were meaningful scalp-hair (SALT≤20), and either EB or EL (ClinRO EB or ClinRO EL 0/1 with ≥2-point improvement) responses at Weeks 36 and 52.
**RESULTS:** Among 2 mg (n=195) and 4 mg (n=286) patients, respectively, the proportions with baseline ClinRO EB (2,3) were: 2mg:(23%,77%); 4mg:(26%,74%). Those with ClinRO EL (2,3) were 2mg:(29%,71%); 4mg:(34%,66%). Patients with SALT≥95 were 2mg:76%; 4mg:72%. Patients with a ≥4-year current episode duration were 2mg:35%; 4mg:39%. Among 2mg-treated patients, at Weeks 36/52 respectively, there were 15%/20% EB-responders, and 12%/25% EL-responders. Among EB responders, there were 43%/46% SALT≤20 co-responders. Among EL responders, 33%/35% SALT≤20 co-responders. Among 4mg-treated patients, at Weeks 36/52 respectively, there were 29%/42% EB-responders, and 34%/45% EL-responders. Among EB responders, there were 54%/50% SALT≤20 co-responders. Among EL responders, 50%/51% SALT≤20 co-responders.
**CONCLUSION:** These analyses highlight the holistic efficacy of baricitinib treatment in concurrent scalp-hair, and EB or EL responses in patients with severe AA.
**ACKNOWLEDGMENTS AND FUNDING:** Study was sponsored by Eli Lilly and Company, under license from Incyte Corporation. Abstract previously presented at American Academy of Dermatology – 81st Annual Meeting, Mar 17 - 21, 2023 in New Orleans, Louisiana, USA.
**DISCLOSURES:** BK has served on advisory boards and/or is a consultant and/or clinical trial investigator for: AbbVie, Almirall, AltruBio, AnaptysBio, Arena Pharmaceuticals, Bioniz Therapeutics, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, Horizon Therapeutics, Incyte Corporation, LEO Pharma, Otsuka/Visterra, Pfizer, Regeneron, Sanofi Genzyme, TWi Biotechnology, and Viela Bio; and is on speaker's bureaus for: AbbVie, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, and Sanofi Genzyme. JK has served on advisory boards and/or is a consultant and/or clinical investigator for and/or has received consulting fees from: AbbVie, Dermira, Eli Lilly and Company, Pfizer, Regeneron, and Sanofi. MS has served on advisory boards and/or has been a consultant for: Arena Pharmaceuticals, Concert Pharmaceuticals, Eli Lilly and Company, and Pfizer; and is a clinical trial investigator for: Concert Pharmaceuticals, and Eli Lilly and Company. AT is a compensated consultant and/or advisory board member for: Eli Lilly and Company; and is a consultant for: Almirall, Bristol Myers Squibb, DS Laboratories, MONAT Global, Myovant Thirty Madison, Pfizer, and Procter and Gamble. MO has received advisory fees from: Eli Lilly Japan K.K., Janssen, Pfizer Japan, Rohto Pharmaceutical, and Taisho Pharmaceutical; and has received research grants from: Maruho, Shiseido, and Sun Pharma Japan. YD, Y-FC, GY, W-SW and WRZ are employees and shareholders of: Eli Lilly and Company. SGS is a consultant for: Concert Pharmaceuticals; and is a former employee and shareholder of: Eli Lilly and Company.

## Abstract OM-04

### Contact Leukoderma Following Patch Testing to Acrylates

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A 73-year-old woman with no prior history of vitiligo presented with enlarging depigmented patches on her back in a distribution consistent with positive reactions during previous patch testing. She was initially seen by the dermatology department in 2009 for a one-year history of dermatitis of the head and neck and subsequently underwent patch testing in 2010 with positive reactions to fragrance mix (2+), cobalt chloride (2+), ethyl acrylate (1+), methyl methacrylate (3+), triethanolamine (2+), benzalkonium chloride (2+), and gold sodium thiosulfate (2+). The reactive areas of skin healed without long term sequelae, and the dermatitis resolved with allergen avoidance. She later developed a flare of dermatitis in 2022, which persisted despite topical corticosteroids and allergen avoidance. Due to concern for possible new contact allergen, repeat patch testing was performed. Positive reactions to ethyl acrylate (2+), methyl methacrylate (2+), ethyl cyanoacrylate (2+), 2-hydroxyethyl methacrylate (2+), gold sodium thiosulfate (2+), thimerosal (2+), and hydroquinone (2+) were noted (Figure 1). Her positive patch test reaction sites initially resolved as expected, and her dermatitis resolved with topical tacrolimus 0.1% ointment and allergen avoidance. However, she presented one year later with three, discrete, depigmented patches of

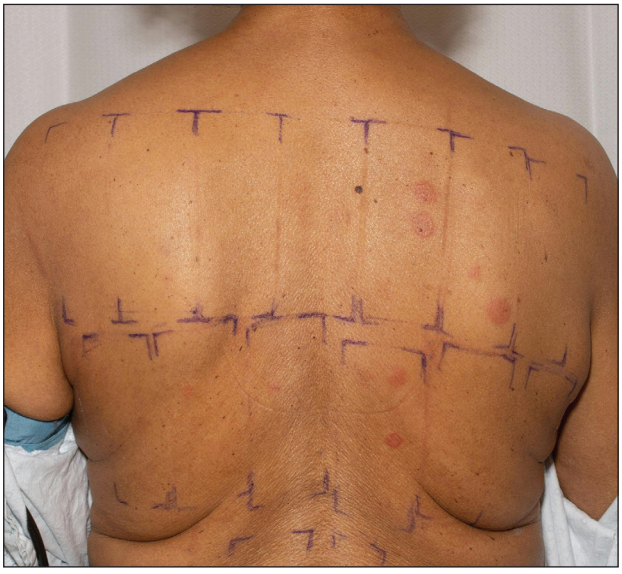

**FIGURE 1.** Cutaneous reactions to contact allergens noted during September 2022 patch testing

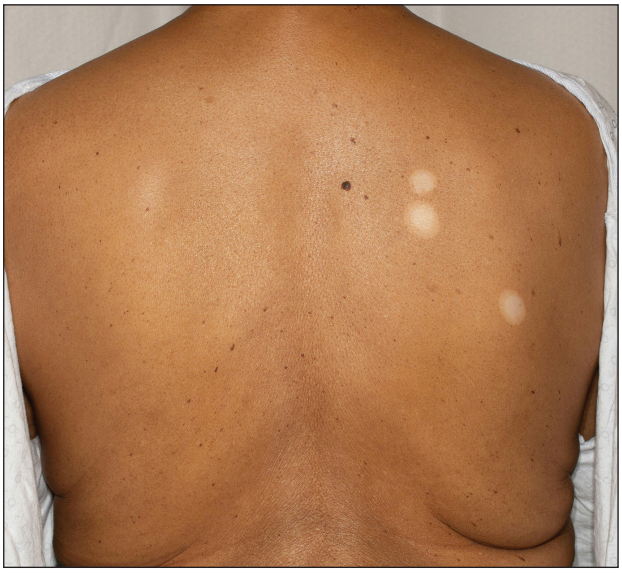

**FIGURE 2.** Depigmentation noted on exam in September 2023 to contact allergens ethyl acrylate, methyl methacrylate, and 2-hydroxyethyl methacrylate

skin with surrounding rings of hypopigmentation at the sites of prior positive patch test reactions to ethyl acrylate, methyl methacrylate, and 2-hydroxyethyl methacrylate (Figures 1, 2), which had developed slowly within the preceding six months. She was diagnosed with contact leukoderma associated with cutaneous acrylate exposure. Upon follow up after 2 months of daily application of clobetasol 0.05% cream, no changes were noted.

Contact leukoderma is a form of acquired depigmentation that mimics idiopathic vitiligo in a small number of people that develop contact or occupational vitiligo following exposure to chemicals.[1,2] It is thought to be due to accelerating stress pathways in healthy melanocytes and lowering the threshold of tolerability of the immune system.[3] Contact leukoderma following patch testing is rare, with a few reported cases associated with acrylate exposure.[4,5,6] This case is unique in that contact leukoderma developed only after a second patch test exposure to acrylates, over a decade after initial exposure, implicating contact sensitization as an inducing factor. This case highlights an infrequent, but serious, risk of patch testing and the importance of considering removal of previously identified allergens in the setting of subsequent patch testing.

### REFERENCES


1. Boissy RE, et al. On the etiology of contact/occupational vitiligo. *Pigment Cell Res*. 2004;17(3):208-214.
2. Bonamonte D, et al. Chemical leukoderma. *Dermatitis*. 2016;27(3): 90-99.
3. Doolan BJ, et al. Systematic review of occupational chemical leukoderma. *Int J Dermatol.* 2020;59(3):e50-e52.
4. Kanerva L, et al. Contact leukoderma caused by patch testing with dental acrylics. *Am J Contact Dermat.* 1998;9(3):196-198.
5. Kwok C, et al. A rare case of acquired leukoderma following patch testing with an acrylate series. *Contact Dermatitis.* 2011;64(5):292-294.
6. Panasoff J. Leukoderma as a side-effect of patch testing with acrylates: a case report. *Contact Dermatitis*. 2020;82(6):403-404.


**DISCLOSURES**: The authors have no disclosures to report.

## Abstract OM-05

### Distribution of SALT Scores by Therapeutic Response in Patients With Severe Alopecia After 52 Weeks of Baricitinib Therapy


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**BACKGROUND:** In pivotal BRAVE-AA1 and AA2 phase 3 clinical trials, the Janus kinase (JAK)1/JAK2 inhibitor baricitinib has demonstrated efficacy in achieving clinically meaningful regrowth of hair in patients with severe alopecia areata. While a significant proportion of patients achieve regrowth by weeks 36 and 52 on baricitinib versus placebo. Other patients, particularly those with longer episode duration or with higher disease severity, require more time on therapy to see full treatment benefit. The treatment

benefit and distribution of SALT scores at Week 52 across the spectrum of responders is reported here.

**METHODS:** Adults with Severity of Alopecia Tool (SALT) score ≥50 (≥50% scalp hair loss) were enrolled into BRAVE-AA1 and BRAVE-AA2. Patients were randomized 2:2:3 to receive once-daily placebo (N=345), baricitinib 2 mg (BARI-2MG) (N=340), or baricitinib 4 mg (BARI-4MG) (N=515). Patients randomized to baricitinib retained their treatment allocation through Week 52. Pooled outcomes were assessed by baricitinib group and in patients with SALT score ≤20 versus SALT score >20 at Week 52. Median and interquartile range (IQR) of SALT scores was assessed with last observation carried forward.

**RESULTS:** At baseline, the median SALT score across 1200 randomized patients was 96 (near-total hair loss), with 638 (53.2%) having SALT score 95-100. At Week 52, 24.1% of patients who received BARI-2MG and 41.6% of patients who received BARI-4MG had SALT score ≤20; median (IQR) absolute SALT scores in this group were 7 (1-12) with BARI-2MG treatment and 3 (0-11) with BARI-4MG treatment. 17.9% of patients who received BARI-2MG and 18.8% of patients who received BARI-4MG patients achieved SALT scores of 21-49 at Week 52; median (IQR) scores were 34 (27-41) following BARI-2MG treatment and 31 (26-42) following BARI-4MG treatment.

**CONCLUSIONS:** While a significant proportion of patients achieved SALT ≤20, the findings of this analysis indicate that partial benefit across scalp hair regrowth is achieved even if patients do not meet clinical response criteria of SALT ≤20. There is a substantial proportion of patients who demonstrate movement towards improvement across the SALT score spectrum. In these patients, a longer treatment course may be necessary to achieve optimal treatment outcomes.

**ACKNOWLEDGMENTS AND FUNDING:** Study was sponsored by Eli Lilly and Company, under license from Incyte Corporation. Previously presented at Fall Clinical Dermatology Conference, Oct 19-22, 2023, Las Vegas, NV, USA.

**DISCLOSURES:** NM has provided professional services for: AbbVie, Arena Pharmaceuticals, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, La Roche-Posay, and Pfizer. MS has served on advisory boards and/or has been a consultant for: Arena Pharmaceuticals, Concert Pharmaceuticals, Eli Lilly and Company, and Pfizer; and is a clinical trial investigator for: Concert Pharmaceuticals, and Eli Lilly and Company. AM has been a consultant for: AbbVie, ASLAN Pharmaceuticals, Concert Pharmaceuticals, Digital Diagnostics, Eli Lilly and Company, Equillium, Hims & Hers Health, and Pfizer. JS has received consulting fees from: AbbVie, Eli Lilly and Company, LEO Pharma, Novartis, Pierre Fabre, Pfizer, and Sanofi-Genzyme. AM has received grants/research support from and/or has been a consultant for: Allergan, Almirall, Cassiopea Pharmaceuticals, Concert Pharmaceuticals, Eli Lilly and Company, Galderma, Incyte Corporation, Pfizer, Proctor & Gamble, and Revian. NS, JJ, HT-I and WRZ are employees and shareholders of: Eli Lilly and Company. NL is an employee of: Precision Statistics Consulting. JZ is an employee of: TechData Services. JS is a consultant or clinical trial investigator for: Pfizer; and is a consultant for: Eli Lilly and Company.

## Abstract OM-06

### Dupilumab Is Efficacious in Patients With Prurigo Nodularis Regardless of History of Atopic Comorbidities: Pooled Results From Two Phase 3 Trials (LIBERTY-PN PRIME and PRIME2)

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**BACKGROUND:** Prurigo nodularis (PN) is a chronic inflammatory skin condition characterized by severely itchy skin nodules. Nearly half of affected adult patients have a history of atopic comorbidity, such as atopic dermatitis (AD).

**OBJECTIVE:** To report the efficacy of dupilumab in patients with PN with or without a history of atopic comorbidities, in a pre-specified analysis of pooled data from two phase 3 trials.

**METHODS:** In the randomized, double-blind, placebo-controlled, 24-week studies, LIBERTY-PN PRIME (NCT04183335) and PRIME2 (NCT04202679), adults with PN inadequately controlled by topical prescription therapies were randomized 1:1 to dupilumab 300 mg every 2 weeks or matched placebo. Atopic patients were defined as patients with a physiciandocumented history, or current diagnosis, of at least one of the following atopic comorbidities: AD, allergic rhinitis/rhinoconjunctivitis, asthma, or food allergy. Efficacy was assessed from baseline to Week 24 using the Worst Itch Numerical Rating Scale (WI-NRS; 0–10) and the Investigator's Global Assessment for PN-Stage score (IGA PN-S; 0–4).

**RESULTS:** A total of 311 patients were randomized (dupilumab n=153, atopic/non-atopic N=67/86; placebo n=158, atopic/non-atopic N=68/90). At Week 24, significantly more atopic and nonatopic dupilumabtreated patients achieved a ≥4-point improvement in WI-NRS (58.2%/59.3%), and an IGA PN-S score of 0 or 1 (52.2%/41.9%) vs placebo (20.6%/17.8% [nominal $P<0.0001$/$P<0.0001$] and 16.2%/17.8% [nominal $P<0.0001$/$P=0.0005$], respectively). The proportion of patients achieving concomitant ≥4-point improvement in WINRS and IGA PN-S score of 0 or 1 was higher for both dupilumabtreated atopic and nonatopic patients (37.3%/33.7%) vs placebo (7.4%/10.0% [nominal $P=0.0057$/$P<0.007$]). Overall safety was consistent with the known dupilumab safety profile, with no remarkable differences between atopic and non-atopic patients.

**CONCLUSION:** Dupilumab treatment improves itch and skin lesions in patients with both atopic and non-atopic PN, indicating that underlying type 2 inflammation is present in patients with PN regardless of their history of atopic comorbidities.

**ACKNOWLEDGMENTS AND FUNDING:** Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifiers: NCT04183335 and NCT04202679. Data included in this abstract were originally presented at the 25th World Congress of Dermatology, July 3–8, 2023, Suntec City, Singapore. Medical writing support for the original abstract was provided by Benjamin Danet, PhD, and Maria Coimbra-Dores, PhD, of Excerpta Medica and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guideline. Editorial assistance for this abstract was provided by Tanya Kapur, MSc, of Sanofi.

**DISCLOSURES:** BSK has served as a consultant for: AbbVie, Almirall, Amagma, Argenx, AstraZeneca, Bellus Health, Blueprint Medicines, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Daewoong Pharmaceutical, Eli Lilly and Company, Genzyme, GlaxoSmithKline, Guidepoint Global, Incyte, Janssen, LectureLinx, LEO Pharma, OM Pharma, Pfizer, RecensMedical, Regeneron Pharmaceuticals Inc., Shaperon, Trevi Therapeutics, and WebMD; may hold stock and/or stock options in the company of: Locus Biosciences. MG has served as an advisory board member and/or speaker for: AbbVie, LEO Pharma, Lilly, Novartis, Pfizer, Sanofi, and Takeda. TU has received honoraria for lectures from: AbbVie, Kyorin, Mitsubishi Tanabe, and Takeda. KN, AP, MM, and SW are employees and may hold stock and/or stock options in the company for: Sanofi. JZ and AB are employees and shareholders of: Regeneron Pharmaceuticals Inc.

## Abstract OM-07

### Duration of Current Episode of Alopecia Areata (AA) Influences Prognosis During Treatment With Baricitinib in Patients With Severe AA

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**BACKGROUND:** Baricitinib demonstrated efficacy in scalp-hair regrowth in two phase 3 trials of severe alopecia areata (AA). Previous literature suggests that, among patients with severe AA, longer current episode duration is associated with decreased treatment response.

**OBJECTIVE:** To evaluate the association between duration of current hair-loss episode and clinically-meaningful hair regrowth in baricitinib-treated patients with severe AA.

**METHODS:** Patients with severe AA (Severity of Alopecia Tool (SALT) score of ≥50, or ≥50% scalp hair loss) received oral baricitinib, 2 mg or 4 mg once-daily, for 52 weeks in two phase 3 trials (BRAVE-AA1/2). The proportion of patients with a SALT score ≤20 at Week 36 was numerically higher for 4 mg vs 2 mg-treatment. Post-hoc analyses of integrated data were conducted to demonstrate SALT score ≤20 responses in 4 mg-treated patients at Weeks 36 and 52 by baseline current episode duration, based on <1, 1-2, 2-3, 3-4, and >4-year cut-offs.

**RESULTS:** Of the 515 included patients, 60% were female, the mean (SD) age was 37 (13), and the mean (SD) SALT score was 85 (18). Based on cut-offs of <1/1-2/2-3/3-4/>4 years duration of current episode, the proportions of patients achieving SALT score ≤20 at Week 36 was 44%/40%/40%/24%/25%. At Week 52, these values were 49%/48%/48%/30%/27%. These trends persisted regardless of baseline AA severity. Among patients with SALT score ≥95 (n=267), the proportions achieving SALT score ≤20 were 25%/33%/28%/15%/12% and 35%/39%/37%/23%/15% at Weeks 36 and 52, respectively. Among patients with SALT score 50-94 (n=248), the proportions achieving SALT score ≤20 were 59%/47%/54%/32%/42% and 59%/58%/59%/36%/43% at Weeks 36 and 52, respectively.

**CONCLUSION:** These analyses reveal a trend toward better treatment response in patients with shorter duration of current episode, regardless of baseline disease severity, and that early intervention may confer greater treatment efficacy among baricitinib-treated patients with severe AA.

**ACKNOWLEDGMENTS AND FUNDING:** Study was sponsored by Eli Lilly and Company, under license from Incyte Corporation. Abstract previously presented at 25th World Congress of Dermatology, July 3-8, 2023, Singapore.

**DISCLOSURES:** BK has served on advisory boards and/or is a consultant and/or a clinical trial investigator for: AbbVie, Almirall, AltruBio, AnaptysBio, Arena Pharmaceuticals, Bioniz Therapeutics, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, Horizon Therapeutics, Incyte Corporation, LEO Pharma, Otsuka/Visterra, Pfizer, Regeneron, Sanofi Genzyme, TWi Biotechnology, and Viela Bio; and is on speaker's bureaus for: AbbVie, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, and Sanofi Genzyme. JS is a consultant or clinical trial investigator for: Pfizer; and is a consultant for: Eli Lilly and Company. MO has received lecture and advisory fees from: AbbVie, Bristol Myers Squibb K.K., Eli Lilly Japan K.K., Maruho, Pfizer Japan, Rohto Pharmaceutical, and Taisho Pharmaceutical; and has received research grants from: Advantest, Maruho, Shiseido, and Sun Pharma Japan. AE has received research funding from: AbbVie, Boehringer Ingelheim, Danish National Psoriasis Foundation, Eli Lilly and Company, Janssen, Kgl. Hofbundtmager Aage Bang Foundation, Novartis, and Pfizer; and has received honoraria as a consultant and/or speaker from: AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Galapagos NV, Galderma, Horizon Therapeutics, Janssen, LEO Pharma, Mylan, Novartis, Pfizer, Samsung Bioepis, Sun Pharma, UCB Pharma, and UNION Therapeutics. RS has been an investigator for and/or provided professional services to: AbbVie, Aerotek Scientific, Akeso Biopharma, Amgen, Arcutis, Arena Pharmaceuticals, Ascend Laboratories, AstraZeneca, Bayer Pharmaceuticals, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Coherus BioSciences, Connect Biopharma, Cutanea, Dermira, Eli Lilly and Company,

Galderma, GlaxoSmithKline, Janssen, LEO Pharma, MedImmune/AstraZeneca, Merck Sharp & Dohme, Novartis, Oncobiologics, Pfizer, Regeneron, Reistone Biopharma, Roche, Samson Medical Technologies, Sanofi, Sun Pharma, and UCB Pharma. W-SW, YD, Y-FC, YD, NS and WRZ are employees and stockholders of: Eli Lilly and Company.

## Abstract OM-08

### Examining Social Media's Influence on Patients' Understanding of Dermatologic Information

**Kylee Wang[1]; Ethan Yu[2]; Jennifer Soung, MD[3]**

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**BACKGROUND:** Social media has become a major source of medical information for patients. With this comes the critical issue of an abundance of misinformation circulating across all platforms. Often, a large portion of the content currently available on medical topics is not created by healthcare professionals.
**OBJECTIVE:** The purpose of the study is to examine which social media platforms are most commonly used to obtain dermatologic information and how they influence behaviors. The current understanding is that people use social media as their primary source of information when curious or concerned about a dermatologic condition.
**METHODS:** Using an online survey platform (SurveyMonkey), we distributed an online survey with 79 questions to US citizens who are SurveyMonkey users. Participants qualified if they had seen a dermatologist in the last six months and used social media for their dermatologic condition. 223 responses were recorded within 2 days on 09/12/2023 and the data was compiled by SurveyMonkey.
**RESULTS:** Of 386 people who attempted the survey, 58% qualified and completed the survey. Most respondents were between 43-58 years old (47.17%); 52% were male, 48% were female, and 41.41% had an advanced degree. 73.57% of respondents were White/Caucasian and 59% had an annual household income between $52,200 and $156,600. The top reasons for social media use were: finding educational information (73%), getting medical advice from a doctor (65%), finding a doctor (45%), and peer/emotional support from other patients (41%). The most preferred social media platform was YouTube (26%), followed by Instagram, Facebook, TikTok, and Twitter. All social media platforms prompted users to make a decision about healthcare: On average, 91% of respondents would try a new product, 87% would seek consultation with a doctor, and 89% would ask their doctor a question. 43% of respondents perceived social media information to be extremely trustworthy. 47% of respondents perceived social media information to be extremely helpful. Information was trusted if it was from a certified doctor (64%) or another patient (50%). Acne (55%) and atopic dermatitis (47%) were the most searched skin conditions on social media. YouTube was the most used (81%) and preferred platform (26%), and was also used by at least 70% of each age group. TikTok had the least percentage of users (62%), but respondents recorded the highest percentages for: trying a new product (95%), consulting with a doctor (95%), asking their doctor a question (89%), and questioning a doctor's advice (87%).
**CONCLUSIONS:** Since social media users trust the content they come across and make healthcare decisions based on this information, healthcare professionals have a critical role in embracing social media's influence to counter misinformation.
**DISCLOSURES:** The authors have no disclosures to report.

## Abstract OM-09

### Improvements in Health-Related Quality of Life and Psychological Symptoms in Patients With Severe Alopecia Areata Achieving Scalp Hair Regrowth: Results From Two Randomized Controlled Trials

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**BACKGROUND:** Baricitinib has demonstrated efficacy on hair regrowth in patients with severe alopecia areata (AA) in two phase 3 trials (BRAVE-AA1/2). Improving health-related quality of life (HRQoL) and psychological symptoms are important treatment objectives in this population.
**OBJECTIVE:** To report the evolution of HRQoL and psychological symptoms in patients who achieved and maintained meaningful scalp hair regrowth (SALT≤20).
**METHODS:** Patients randomized to baricitinib 4 mg, or 2 mg at baseline in BRAVE-AA1/2 who achieved SALT≤20 by Week 36 and maintained SALT≤20 through Week 76 on the same dose were included in this analysis of integrated data. Improvements in HRQoL and psychological burden were measured using Skindex-16 AA domains (Symptoms/Emotions/Functioning) and Hospital Anxiety and Depression Scales (HADS). Changes from baseline were summarized using descriptive statistics. Missing data were imputed by the last observation carried forward method.
**RESULTS:** Patients on 4 mg (n=90), had baseline mean SALT score of 77, Skindex-16 Symptoms/Emotions/Functioning values of 19.5/71.7/60.5, and HADS Anxiety/Depression values of 7.01/4.16. Mean changes from baseline at Weeks 36/76 were: Symptoms (-7.46/-9.27), Emotions (-38.56/-44.21), Functioning (-30.5/-38.96), HADS Anxiety (-1.72/-1.90), HADS Depression (-0.81/-1.05). Patients on 2 mg (n=45), had baseline mean SALT score of 74, Skindex-16 Symptoms/

Emotions/Functioning values of 22.1/74.3/49.1, and HADS Anxiety/Depression values of 5.8/3.4. Mean changes from baseline at Weeks 36/76 were: Symptoms (-5.81/-5.98), Emotions (-46.68/-53.6), Functioning (-26.67/-34.96), HADS Anxiety (-1.49/-1.56), HADS Depression (-0.73/-1.41).

**CONCLUSIONS:** This analysis reveals improvements in HRQoL and psychological symptoms in baricitinib-treated patients with severe AA who achieved meaningful scalp hair regrowth by Week 36 which were maintained up to Week 76.

**ACKNOWLEDGEMENTS AND FUNDING:** Study was sponsored by Eli Lilly and Company, under license from Incyte Corporation. Abstract previously presented at American Academy of Dermatology – 81st Annual Meeting, Mar 17 - 21, 2023 in New Orleans, Louisiana, USA.

**DISCLOSURES:** BC has received fees and/or honoraria from: Concert Pharmaceuticals, Eli Lilly and Company, Incyte Corporation, Pfizer, Regeneron, and Sanofi Genzyme. YWL has received research funding from: Eli Lilly and Company. SV-G has been an advisor for: Eli Lilly and Company, and Pfizer. AE has received research funding from: AbbVie, Boehringer Ingelheim, Danish National Psoriasis Foundation, Eli Lilly and Company, Janssen, Kgl. Hofbundtmager Aage Bang Foundation, Novartis, and Pfizer; and has received honoraria as a consultant and/or speaker from: AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Galapagos NV, Galderma, Horizon Therapeutics, Janssen, LEO Pharma, Mylan, Novartis, Pfizer, Samsung Bioepis, Sun Pharma, UCB Pharma, and UNION Therapeutics. YD, FD, EP, YD, Y-FC and WRZ are employees and stockholders of: Eli Lilly and Company. AM has been a consultant for: AbbVie, Concert Pharmaceuticals, Digital Diagnostics, Eli Lilly and Company, and Pfizer.

## Abstract OM-10

### Metals Patch Testing in Patients With Orthopedic Implants: A 13 Year Retrospective Review

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**BACKGROUND:** Orthopedic implants into major joints (shoulders, hips, knees) are becoming increasingly common. A small proportion of patients may develop a contact allergy to a metal present in the implant.[1] The most common metals used in orthopedic joint implants include titanium, stainless steel (typically an alloy containing mostly iron with chromium, nickel, and molybendum with or without manganese), cobalt and tantalum.[2,3] Previous studies have suggested that common allergens in orthopedic implants include nickel, cobalt, and chromium.[4]

**OBJECTIVES:** This study sought to identify the most commonly identified metal allergens in patients who underwent joint replacement of a major joint (shoulder, hip, or knee) over the past 13 years.

**METHODS:** An IRB-exempt retrospective review identified patients who had a shoulder, hip, or knee replacement and subsequently underwent patch testing to a series of 46 unique metal compounds from 2009 – 2022 at a large academic institution. The most frequently positive allergens were identified.

**RESULTS:** 17 patients were identified who underwent joint replacement and subsequent metals patch testing. The most commonly identified metal allergens were manganese chloride 2% (positive in 46.7% of cases), potassium dichromate 0.5% (22.2%), potassium dicyanoaurate 0.1% (20%), rhodium (III) chloride hydrate 2.0% (20%), silver nitrate 1% Aq (20%), cobalt (II) chloride hexahydrate 1% (18.8%), cobalt (II) sulfate 2.5% (18.8%), nickel (II) sulfate hexahydrate 2.5% (18.8%), zirconium chloride 1% (16.7%), amalgam 5% (15.4%), and ferric chloride 2% (14.3%) (Table 1, Figure 1). There were no positive reactions to titanium (including titanium IV oxide 0.1%, titanium 10%, and titanium alloy disc), other forms of chromium (including chromium (III) chloride 1% and cobalt chromium disc), or molybendum 5% in our cohort (Figure 1).

**CONCLUSIONS:** Overall, patch testing to metals in patients who have undergone joint replacement is rare, with a 13-year study only identifying 17 cases. When positive patch testing results are identified in such cases, they are not always to metals present in the implants. Of metals commonly present in implants, manganese was the most commonly identified allergen (positive in almost half of cases), followed by potassium dichromate, cobalt, nickel, and ferric chloride, though these were only positive in less than a quarter of cases.

**TABLE 1. Most Common Metal Allergens Identified in Patients with Orthopedic Implants.**

| Allergen | Negative | Positive | Percent Positive |
|---|---|---|---|
| Manganese chloride 2% | 8 | 7 | 46.7% |
| Potassium dichromate 0.5% | 7 | 2 | 22.2% |
| Potassium dicyanoaurate 0.1% Aq | 12 | 3 | 20.0% |
| Rhodium (III) chloride hydrate 2.0% | 4 | 1 | 20.0% |
| Silver nitrate 1% Aq | 12 | 3 | 20.0% |
| Cobalt (II) Chloride Hexahydrate 1% | 13 | 3 | 18.8% |
| Colbalt (II) sulfate 2.5% | 13 | 3 | 18.8% |
| Nickel (II) sulfate hexahydrate 2.5% | 13 | 3 | 18.8% |
| Zirconium chloride 1% | 5 | 1 | 16.7% |
| Amalgam 5% | 11 | 2 | 15.4% |

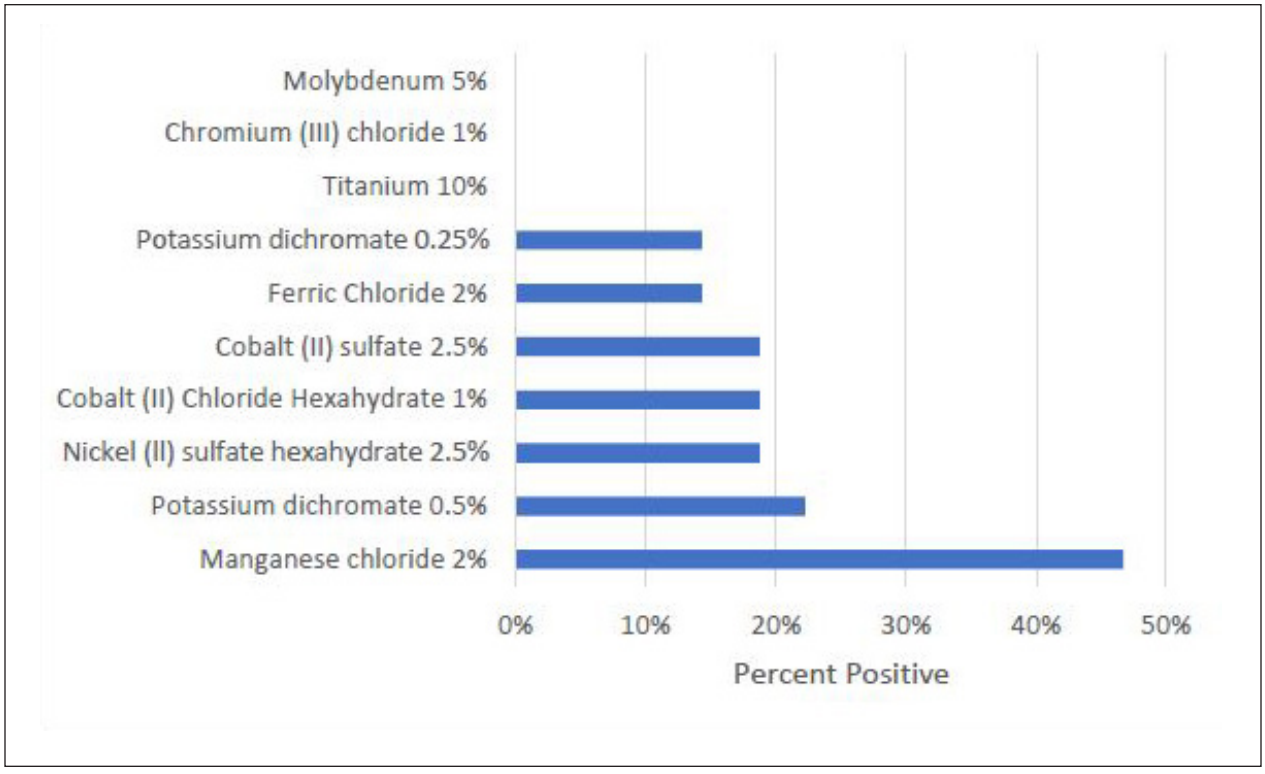


**FIGURE 2.** Most common allergens identified on patch testing which are also frequently found in orthopedic implants.

Titanium, though commonly used in joint implants, does not appear to be a common allergen.


REFERENCES

1. Haddad SF, et al. Exploring the incidence, implications, and relevance of metal allergy to orthopaedic surgeons. *J Am Acad Orthop Surg Glob Res Rev.* 2019;3(4):e023.
2. Tapscott DC, et al. Orthopedic Implant Materials. [Updated 2023 Jul 25]. In: StatPearls [Internet]. Treasure Island (FL): *StatPearls Publishing;* 2023 Jan.
3. Zeng Y, et al. Metal allergy in patients with total hip replacement: a review. *J Int Med Res.* 2013;41(2):247-252.
4. Pacheco KA. Allergy to surgical implants. *Clin Rev Allergy Immunol.* 2019;56(1):72-85.


**DISCLOSURES:** The authors have no disclosures to report.

## Abstract OM-11

### Pemphigus Is Associated With Behçet's Disease and Psoriasis: A Korean Population-Based Study


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**BACKGROUND:** Pemphigus is a chronic autoimmune blistering disease affecting the skin and mucous membranes. Several reports have suggested the association between pemphigus and autoimmune diseases such as psoriasis. In addition, a few case reports documented the coexistence of pemphigus and Behcet's disease (BD). Until now, there has been no large-scale epidemiologic study demonstrating a causal relationship between the occurrence of pemphigus and these two autoimmune conditions.

**OBJECTIVE:** This study aimed to investigate the association between pemphigus and BD, as well as psoriasis.

**METHODS:** Patients newly diagnosed with pemphigus (n=815) from 2012 to 2017 were analyzed using a large, nationwide data from the Korean National Health Insurance database from 2007 to 2017. An age-, sex-, and index year-matched control population of individuals without pemphigus was sampled at a ratio of controls to pemphigus cases of 5:1 (n=4,075). Both cohorts were analyzed for the presence of Behçet's disease and psoriasis within a minimum of 5 years prior to their pemphigus diagnosis.

**RESULTS:** Patients with pemphigus had higher odds of ratios for Behçet's disease (10.35 [95% CI, 3.91–27.41]) and psoriasis (9.15 [95% CI, 7.29– 11.49]) compared to the control group after adjustment for diabetes mellitus, hypertension, and dyslipidemia.

**CONCLUSION:** Our results suggest that pemphigus is associated with BD, as well as psoriasis. Physicians who care for patients with pemphigus should be aware of the association.


**DISCLOSURES:** The authors have no disclosures to report.

## Abstract OM-12

### Reduction in Pruritus Across Indications in Phase 3 Trials of Topical Roflumilast

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**BACKGROUND:** Pruritus is a burdensome symptom in patients with seborrheic dermatitis (SD), psoriasis, and atopic dermatitis (AD), affecting sleep and quality of life (QOL). Phosphodiesterase-4 (PDE4) inhibitors may reduce pruritus by reducing generation of inflammatory itch mediators. Roflumilast is a selective, highly potent PDE4 inhibitor. Topical roflumilast, formulated as a water-based foam or cream without penetration enhancers or irritating fragrances, is being investigated to treat SD, psoriasis, and AD. The US Food and Drug Administration approved roflumilast cream 0.3% to treat plaque psoriasis, including intertriginous areas, in patients aged ≥12 years, on July 29, 2022.

**OBJECTIVE:** To evaluate itch response in phase 3 clinical trials of topical roflumilast.

**METHODS:** We evaluated itch response in patients aged ≥9 years with SD (STRATUM [NCT04973228]) or ≥12 years with psoriasis (DERMIS-1 [NCT04211363], DERMIS-2 [NCT04211389], ARRECTOR [NCT05028582]) and AD (INTEGUMENT-1 [NCT04773587], INTEGUMENT-2 [NCT04773600]) using the Worst Itch-Numeric Rating Scale (WI-NRS).

**RESULTS:** Efficacy, safety, and tolerability were previously reported. More roflumilast- than vehicle-treated patients achieved WI-NRS Success (≥4-point improvement in patients with baseline score ≥4) at the final assessment (Week 4 for INTEGUMENT, Week 8 for the other trials): STRATUM (SD): 62.8% vs. 40.6%; DERMIS (psoriasis): 68.5% vs. 31.3%; ARRECTOR (psoriasis): 63.1% vs. 30.1%; INTEGUMENT (AD): 31.9% vs. 16.6%, respectively (all $P<0.0001$). Differences favoring roflumilast were also observed for achievement of WI-NRS 0/1 (in patients with baseline score ≥2) after the first or second application (STRATUM, ARRECTOR, INTEGUMENT; all nominal $P<0.05$) and at final assessment: STRATUM: 70.7% vs. 52.9%; DERMIS: 55.4% vs 19.4%; ARRECTOR: 55.4% vs. 19.8%; INTEGUMENT: 28.8% vs. 18.5%, respectively (all nominal $P<0.01$).

**CONCLUSIONS:** Once-daily topical roflumilast provided consistent and rapid improvements in itch across SD, psoriasis, and AD, highlighting roflumilast's potential to reduce this burdensome symptom and improve QOL across indications.

**DISCLOSURES:** GY, SGK, JDR, LKF, MG, AAH, EL, ML, VHP, TS, and JS are investigators and/or consultants for and received grants/research funding and/or honoraria from: Arcutis Biotherapeutics, Inc. MS, DK, PB, RCH, DHC, and DRB are employees of: Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

## Abstract OM-13

### Results From Two Phase 3 Studies of Dupilumab in CSU

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**BACKGROUND:** Many patients with chronic spontaneous urticaria (CSU) remain symptomatic despite H1-antihistamine (H1-AH) and/or anti-IgE (omalizumab) treatment.

**OBJECTIVE:** To examine the safety and efficacy of dupilumab in patients who remained symptomatic despite (H1-AH) and were omalizumab-naïve or omalizumab-intolerant/incomplete responders.

**METHODS:** LIBERTY-CSU CUPID (NCT04180488) was a randomized, placebo-controlled, 24-week phase 3 trial of dupilumab in patients with CSU who were symptomatic despite (H1-AH) (up to 4-fold approved dose) and omalizumab-naive (Study A; aged ≥6 years) or omalizumab-intolerant/incomplete responders (Study B; aged ≥12 years). Patients received dupilumab (300 mg) subcutaneously every 2 weeks (Study A/Study B: n=70/n=54) or matched placebo (Study A/Study B: n=68/n=54). Planned interim analysis for Study B met prespecified futility criteria. Early termination letters were issued to investigators, although the majority of patients completed Week 24 of the study. The fully blinded dataset (N=108) was available to test against the

remaining alpha (0.043) for statistical significance. Efficacy endpoints included Urticaria Activity Score over 7 days (UAS7; range 0–42; EU primary/US key secondary) and Itch Severity Score over 7 days (ISS7; range 0–21; US primary/EU key secondary).

**RESULTS:** In Study A, Week 24 least squares (LS) mean change from baseline (dupilumab/placebo) in UAS7 was –20.5/–12.0 ($P$=0.0003); ISS7, –10.2/–6.0 ($P$=0.0005). In Study B, Week 24 LS mean change from baseline in UAS7 (dupilumab/placebo) was –14.4/–8.5 ($P$=0.0390; statistically significant as EU primary endpoint; nominally significant as US key secondary endpoint). Numerical improvement in ISS7 at Week 24 (dupilumab/placebo: –7.7/–4.8) was not statistically significant ($P$=0.0449; significance at $P$<0.043). Incidence of treatment-emergent adverse events for dupilumab/placebo was 38 (54.3%)/40 (58.8%) in Study A and 33 (61.1%)/29 (53.7%) in Study B.

**CONCLUSIONS:** Study A met EU/US primary endpoints (UAS7/ISS7). Study B met EU primary endpoint (UAS7) but not US primary endpoint (ISS7; $P$=0.0449; prespecified threshold $P$<0.043 postinterim analysis). Overall tolerability was consistent with the known dupilumab profile.

**ACKNOWLEDGMENTS AND FUNDING:** Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT04180488. The data were originally presented at Global Allergy and Asthma European Network - 4th Urticaria Centers of Reference and Excellence (UCARE 2023), December 7-9, Sao Paulo, Brazil. Medical writing support for the original abstract was provided by Jessica F. Olive, PhD, of Excerpta Medica and was funded by Sanofi and Regeneron Pharmaceuticals Inc. according to the Good Publication Practice guideline. Editorial assistance for this abstract was provided by Tanya Kapur, MSc, of Sanofi.

**DISCLOSURES:** MM has served as a speaker and/or consultant and/or received institutional research support for: Allakos, Almirall, Amgen, AstraZeneca, Blueprint Medicines, Celldex Therapeutics, Faes Farma, Genentech, GI Innovation, Kyowa Kirin, LEO Pharma, Lilly, Merck Sharp & Dohme, Merckle Recordati, Moxie Pharmaceutical, Novartis, Riemser, Sanofi-Aventis, Third Harmonic, Tribute Pharmaceuticals, UCB, and Uriach. TBC has received research support from: American Lung Association, Genentech, National Institutes of Health, Novartis, PCORI, and Sanofi; has served as a consultant for: AstraZeneca, Boehringer Ingelheim, Genentech, Novartis, and Regeneron Pharmaceuticals Inc.; has served on the speakers bureau for: Genentech. SSS has received research grants from: National Institutes of Health, Novartis, and Regeneron Pharmaceuticals Inc.; has served as consultant for: Allakos, Aquestive, Celltrion, Escient Pharmaceuticals, Genentech, Generation Bio, GI Innovation, Granular Therapeutics, Innate Therapies, MedImmune, Novartis, Ono Pharmaceutical, Regeneron Pharmaceuticals Inc., and Sanofi. MB-S has served as a consultant for: Novartis, and Sanofi. AMG-A has served as a medical advisor for: Almirall, Amgen, Celldex, Escient, Faes Farma, Genentech, GlaxoSmithKline, LEO Pharma, Novartis, Regeneron Pharmaceuticals Inc., Sanofi, Thermo Fisher Scientific, and Uriach Pharma/Neucor; has received research support from: Novartis and Uriach Pharma; has received grants from: Instituto Carlos III-FEDER; has served on educational activities for: Almirall, Avene, Genentech, GlaxoSmithKline, LEO Pharma, Menarini, Merck Sharp & Dohme, Novartis, Sanofi, and Uriach Pharma. JAB has served as a principal investigator and consultant and speaker for: AstraZeneca, Genentech, Novartis, Regeneron Pharmaceuticals, Inc., and Sanofi; has served as a principal investigator and consultant for: Allakos, Amgen, Blueprint Medicines, and Celldex; has served as a consultant for: Escient Pharmaceuticals and Ono Pharmaceutical. AY has received lecture fees from: Lilly, Novartis, Sanofi, and Taiho Pharma; has received consigned/joint research expenses from: Maruho. AR, EM, and SLC are employees and shareholders of: Regeneron Pharmaceuticals Inc. NK, DB, TG, PS, and EL are employees and may hold stock and/or stock options in the company of: Sanofi.

## Psoriasis

### Abstract PS-01

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

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**BACKGROUND:** Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials in moderate to severe plaque psoriasis. Upon completing the parent trials, patients could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial.

Deucravacitinib-treated patients maintained long-term efficacy through 2 years with no new safety signals vs Year 1.

**OBJECTIVE:** Report deucravacitinib efficacy and safety through 3 years (Week 148; cutoff date 6/15/2022).

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

**RESULTS:** 1519 patients received ≥1 deucravacitinib dose; 513 patients received continuous deucravacitinib from Day 1 in PSO-1/PSO-2 and were enrolled/treated in the LTE. Cumulative exposure from parent trial randomization was 3294.3 PY for this analysis. EAIRs/100 PY were similar, or decreased, from the 2- to 3-year cumulative period, respectively, for AEs (154.4, 144.8), serious AEs (SAEs; 6.1, 5.5), discontinuation due to AEs (2.8, 2.4), herpes zoster (0.7, 0.6), malignancies (0.9, 0.9), major adverse cardiovascular events (0.4, 0.3), venous thromboembolism (0.1, 0.1), and deaths (0.4, 0.3). Clinical response rates were maintained at Week 148 by mNRI (PASI 75, 73.2% [95% CI, 68.7%, 77.8%]; PASI 90, 48.1% [95% CI, 43.2%, 53.1%]; sPGA 0/1, 54.1% [95% CI, 49.1%, 59.1%]), with similar results regardless of data imputation method.

**CONCLUSION:** Deucravacitinib demonstrated a consistent safety profile through 3 years with no increases in AE or SAE rates over time and no emergence of new or long-term safety signals. Efficacy was sustained through 3 years in patients treated continuously with deucravacitinib. Since it is important to provide long-term safety for this new class of drugs, these findings provide additional support for deucravacitinib having a consistent safety profile and durable efficacy through 3 years of use.

**ACKNOWLEDGMENTS AND FUNDING:** This study was sponsored by Bristol Myers Squibb. Writing and editorial assistance was provided by Julianne Hatfield, PhD, of Peloton Advantage, LLC, an OPEN Health company, funded by Bristol Myers Squibb.

**DISCLOSURES:** AWA has served as a research investigator, scientific advisor, and/or speaker: AbbVie, Almirall, Arcutis, ASLAN, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, EPI Health, Incyte, Janssen, LEO Pharma, Lilly, Mindera Health, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. ML has received research funds on behalf of Mount Sinai: AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly and Company, Incyte, Janssen, Ortho Dermatologics, Regeneron, and UCB; has served as a consultant for: Almirall, AltruBio, AnaptysBio, Arcutis, Avotres, Boehringer Ingelheim, Brickell Biotech, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas Psoriasis Registry, Dermavant, EPI Health, Evommune, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera Health, Pfizer, Seanergy, Strata, Trevi, and Verrica. RBW has received research grants from: AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; has received consulting fees from: AbbVie, Almirall, Amgen, Astellas, Boehringer Ingelheim, Celgene, DICE Therapeutics, Eli Lilly and Company, GlaxoSmithKline, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, UCB, and UNION Therapeutics. HS has served as a clinical investigator for: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, and Sun Pharma. SI has received grants and personal fees from: AbbVie, Eisai, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Sun Pharma, Taiho Yakuhin, Tanabe Mitsubishi, and Torii Yakuhin; has received personal fees from: Amgen (Celgene), Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly and Company, GlaxoSmithKline, Novartis, and UCB. MO has received honoraria and/or research grants from: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sanofi, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, and UCB. LS has served as a consultant, paid investigator, and/or speaker for: AbbVie, Amgen, Anacor, Ascend, Astellas, AstraZeneca, Blaze Bioscience, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Galderma, Genentech, GlaxoSmithKline, Hexima, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Merck, MerckSerono, Novartis, Otsuka, Pfizer, Phosphagenics, Photon MD, Regeneron, Roche, Samumed, Sanofi Genzyme, SHR Pharmacy, Sun Pharma ANZ, Trius, UCB, and Zai Lab. TP has served on the advisory board and received consulting fees from: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi Genzyme, Sun Pharma, and UCB. KAP has served as a consultant for: AbbVie, Acelyrin, Akros, Amgen, Aralez, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celgene, Celltrion, Coherus, Dermavant, Dermira, DICE Therapeutics, Dow Pharma, Eli Lilly and Company, Evelo Biosciences, Forbion, Galderma, Incyte, Janssen, Kyowa Kirin, LEO Pharma, Meiji Seika Pharma, Merck, Mitsubishi Pharma, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, UCB, vTv Therapeutics, and Xencor; has served on the speakers bureau for: AbbVie, Amgen, Bausch Health/Valeant, Celgene, Eli Lilly and Company, Galderma, Incyte, Janssen, Kyowa Kirin, LEO Pharma, Merck, Novartis, Pfizer, and Sanofi Genzyme; has received clinical research grants from: AbbVie, Akros, Amgen, Anacor, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celgene, Coherus BioSciences, Dermavant, Dermira, DICE Therapeutics, Dow Pharma, Eli Lilly and Company, Evelo Biosciences, Galderma, Gilead, GlaxoSmithKline, Incyte, Janssen, Kyowa Kirin, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Takeda, and UCB; has received

honoraria from: AbbVie, Acelyrin, Akros, Amgen, Aralez, Bausch Health/Valeant, Boehringer Ingelheim, Celgene, Celltrion, Coherus BioSciences, Dermavant, DICE Therapeutics, Eli Lilly and Company, Forbion, Galderma, Janssen, Kyowa Kirin, LEO Pharma, Meiji Seika Pharma, Merck, Mitsubishi Pharma, Novartis, Pfizer, Reistone, Sanofi Genzyme, Sandoz, Sun Pharma, Takeda, UCB, vTv Therapeutics, and Xencor; has served as a scientific officer for: Akros, Anacor, Arcutis, DICE Therapeutics, and Kyowa Kirin; steering committees: AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Janssen, Kyowa Kirin, Merck, Novartis, Pfizer, Regeneron, Reistone, and Sanofi Genzyme; has served on the advisory boards for: AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Dow Pharma, Eli Lilly and Company, Galderma, Janssen, Merck, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. RMK, VB, EV, MJC, and SB are employees and shareholders for: Bristol Myers Squibb. KH has served as a consultant for: Bristol Myers Squibb. BS has served as a consultant (honoraria) for: AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly and Company, Equillium, GlaxoSmithKline, Immunic Therapeutics, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, Ventyx Biosciences, and vTv Therapeutics; has served as a speaker for: AbbVie, Eli Lilly and Company, Janssen, and Sanofi Genzyme; has served as a co-scientific director (consulting fee) for: CorEvitas' (Corrona) Psoriasis Registry; has served as an investigator for: AbbVie, Cara Therapeutics, CorEvitas' (Corrona) Psoriasis Registry, Dermavant, Dermira, and Novartis. DT has received research support and served as a principal investigator (clinical trials funds to institution) for: AbbVie, Almirall, Amgen, Biogen Idec, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Galderma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sandoz-Hexal, Sanofi, and UCB; has served as a consultant for: AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Galapagos, LEO Pharma, Novartis, Pfizer, and UCB; has served as a lecturer for: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, Merck Sharp & Dohme, Novartis, Pfizer, Roche-Posay, Sandoz-Hexal, Sanofi, Target RWE, and UCB; has served on the scientific advisory board for: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen-Cilag, LEO Pharma, Merck Sharp & Dohme, Morphosis, Novartis, Pfizer, Sanofi, and UCB. AB has served as a speaker (with honoraria) for: AbbVie, Bristol Myers Squibb, Eli Lilly and Company, Pfizer, Regeneron, and Sanofi; has served as a scientific adviser (with honoraria) for: AbbVie, Abcentra, Aclaris, Affibody, Aligos, Almirall, Alumis, Amgen, AnaptysBio, Apogee, Arcutis, Arena, ASLAN, Athenex, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, CTI BioPharma, Dermavant, EcoR1, Eli Lilly and Company, Escient, Evelo Biosciences, Evommune, Forte Biosciences, Galderma, HighlightII Pharma, Incyte, InnoventBio, Janssen, Landos, LEO Pharma, Lipidio, Merck, Nektar, Novartis, Pfizer, Rani, Rapt, Regeneron, Sanofi Genzyme, Spherix Global Insights, Sun Pharma, Takeda, TLL Pharmaceutical, TrialSpark, UCB, UNION Therapeutics, Ventyx Biosciences, Vibliome, and Xencor; has served as a clinical study investigator (clinical study funds received by institution) for: AbbVie, Acelyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, Eli Lilly and Company, Evelo Biosciences, Evommune, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB, and Ventyx Biosciences.

## Abstract PS-02

### Efficacy of Tapinarof Cream 1% Once Daily for the Treatment of Mild to Severe Intertriginous Plaque Psoriasis

**Howard Sofen, MD[1]; Stephen Tyring, MD, PhD, MBA[2]; Sandra Marchese Johnson, MD, FAAD[3]; Scott Guenthner, MD[4]; Patrick Shannon, MD[5]; Philip M. Brown, MD, JD[6]; Katherine Tillman, BS[6]; Nancy Fitzgerald, MS, MBA[6]; Brandon Kirsch, MD[6]; Anna M. Tallman, PharmD[6]**

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**BACKGROUND:** Tapinarof cream 1% is a non-steroidal, topical aryl hydrocarbon receptor agonist approved for the treatment of plaque psoriasis in adults with no restrictions on location, extent, or duration of use. Psoriasis affecting intertriginous skin is difficult to treat; topical corticosteroids have restrictions on strength and duration on use, with the risk of potentially irreversible side effects (e.g. striae). In the phase 3 PSOARING trial program, tapinarof cream 1% once daily (QD) was efficacious and well tolerated for the treatment of psoriasis, including in intertriginous areas.

**OBJECTIVE:** Here, we assess efficacy and safety of tapinarof cream 1% QD to treat adults with mild to severe intertriginous plaque psoriasis.

**METHODS:** In this phase 4, real-world, open-label trial, adults received tapinarof cream for 12 weeks. Patients had plaque psoriasis with lesions affecting intertriginous areas that were stable for ≥3 months before trial entry, and an intertriginous Physician Global Assessment (iPGA) score of 2 (mild), 3 (moderate), or 4 (severe). The primary endpoint was the proportion of patients who achieved an iPGA response, defined as an iPGA score of clear (0) or almost clear (1) and ≥2-grade improvement from baseline at Week 12. Additional endpoints included time to achieve an iPGA response, and achievement of complete clearance (iPGA score=0) by visit. Safety and tolerability evaluations included treatment-emergent adverse events (TEAEs), and investigator-assessed Local Tolerability Scale (LTS) and LTS-external genitalia scores.

**RESULTS:** 34 patients with mild to severe psoriasis in intertriginous areas received tapinarof cream. At baseline, 29.4%, 64.7%, and 5.9% had an iPGA score of 2 (mild), 3 (moderate), and 4 (severe), respectively; 11.8% had plaque psoriasis affecting genitalia. At Week 12, 82.8% (24/29) achieved an iPGA response and 65.5% (19/29) achieved

complete clearance (iPGA score=0). There was rapid onset of efficacy with tapinarof treatment, with both iPGA response and complete clearance achieved as early as Week 2. Median time to iPGA response was approximately 6 weeks. Most TEAEs were mild or moderate, consistent with previous trials; only one patient discontinued due to a TEAE (contact dermatitis). Tapinarof was well tolerated; most patients had no irritation (LTS score=0) at all visits for intertriginous areas or genitalia specifically.

**CONCLUSIONS:** Tapinarof cream 1% QD demonstrated rapid onset of clinically meaningful efficacy in patients with intertriginous psoriasis, as early as Week 2, with 82.8% achieving the iPGA primary end point. Completely clear intertriginous skin was achieved by 65.5%. Tapinarof cream is a well-tolerated, non-steroidal treatment option in adults with mild to severe plaque psoriasis in intertriginous areas.

**FUNDING:** Dermavant Sciences, Inc.

**DISCLOSURES:** HS has served as scientific adviser and/or clinical study investigator for: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi-Genzyme, Sun Pharma, and UCB Biopharma. ST is an investigator for: Dermavant Sciences, Inc. SMJ is an advisor and/or speaker and/or editor and/or involved in clinical trials for: AbbVie, Aclaris, AFMC, Allergan, Amgen, Candela Syneron, Cassiopea, Celgene, Chemocentryx, Dermavant Sciences, Inc., Dermira, Eli Lilly and Company, Foamix, Gage, Galderma, GlaxoSmithKline, Journal of Arkansas Medical Society, LEO Pharma, National Psoriasis Foundation, Nielsen, Novartis, Practical Dermatology, Regeneron, Sanofi Genzyme, Skin Medical, TARGET Therapeutics, and the University of Pennsylvania. SG is a speaker for: AbbVie, Aclaris, Janssen, Pfizer, and Sun Pharma. PS has no conflicts to declare. PMB, KT, NF, BK, and AMT are employees of: Dermavant Sciences, Inc., with stock options.

## Abstract PS-03

### Increased Risk for Wet Age-Related Macular Degeneration in Diabetic Patients With Psoriasis: A Nationwide Population-Based Study

**Young Bok Lee, MD, PhD[1]; Ha Yeh Rin Koo, MD[1]; Mee Yon Lee, MD, PhD[2]; Min Kyung Hyun, PhD[1]; So Yeon Yun, MD[1]; Jin Young Choi, MD[1]; Dong Soo Yu, MD[1]**

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**BACKGROUND:** Psoriasis and Age-related Macular Degeneration (AMD) are known to be associated with diabetes mellitus (DM). However, the relationship between psoriasis and subsequent development of AMD in a diabetic population has not been explored.

**OBJECTIVES:** This study aimed to evaluate the relationship between psoriasis and wet AMD in DM population.

**METHODS:** This was a retrospective, nationwide, population-based cohort study using the Korean National Health Insurance Service claims database. Records from 2009 to 2012 were analyzed for patients over 20 years of age diagnosed with type 2 DM. The incidence of wet AMD was observed from the index year to 2018 in all subjects. We compared the incidence rate of wet AMD between the psoriasis group and the control group.

**RESULTS:** Out of 2,745,689 type 2 DM patients, 23,725 patients were classified in the psoriasis group, and the remaining 2,547,121 individuals were in the control group. A total of 105 wet AMD cases occurred in DM patients with psoriasis, and 7,459 cases occurred in those without psoriasis. According to multivariable Cox proportional hazard models, individuals with psoriasis had a significantly higher risk of wet AMD compared to controls (HR=1.329, 95% confidence interval: 1.096-1.612) after adjusting for covariates.

**CONCLUSION:** This study demonstrated that psoriasis was an independent risk factor for developing wet AMD in DM patients. Therefore, physicians should be alert to the development of wet AMD in DM patients with psoriasis.

**DISCLOSURES:** The authors have no disclosures to report.

## Abstract PS-04

### Tapinarof Cream 1% Once Daily Improves Patient-Reported Outcomes in the Treatment of Mild to Severe Intertriginous Plaque Psoriasis

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**BACKGROUND:** Tapinarof cream 1% once daily (QD) is a first-in-class, non-steroidal, topical aryl hydrocarbon receptor agonist approved for the treatment of plaque psoriasis in adults with no restrictions on location, extent, or duration of use. In the previously reported phase 3 PSOARING trials, tapinarof was efficacious and well tolerated in the treatment of plaque psoriasis, including when used in intertriginous and sensitive skin areas. Intertriginous or inverse psoriasis, especially in sensitive areas, has a high impact on patients' health-related quality of life (HRQoL), through pruritus, pain, and psychological distress.

**OBJECTIVE:** This open-label, phase 4 trial assessed patient-reported outcomes (PROs) in adults with mild to severe plaque psoriasis in intertriginous areas treated with tapinarof cream 1% QD.

**METHODS:** Adults with plaque psoriasis affecting intertriginous areas, and an intertriginous Physician Global

Assessment (iPGA) score of 2 (mild), 3 (moderate), or 4 (severe) were treated with tapinarof cream 1% QD for 12 weeks. PROs included Peak Pruritus Numerical Rating Scale (PP-NRS) score for intertriginous areas; achievement of a ≥4-point reduction in PP-NRS score; Dermatology Life Quality Index (DLQI) score by visit; and responses to a Patient Satisfaction Questionnaire© (PSQ) at Week 12.

**RESULTS:** In total, 34 patients received tapinarof cream 1% QD. Baseline mean intertriginous PP-NRS and total DLQI scores were 5.9 and 9.0, respectively, demonstrating significant itch and burden on HRQoL. Improvement in mean PP-NRS score was demonstrated at Week 1 (–1.1), the earliest assessment, and continued through Week 12 (–3.8). At Week 12, 75% (15/20) achieved a ≥4-point reduction in PP-NRS score. Improvement in mean DLQI score from baseline was observed as early as Week 1 (–2.4). By Week 2, the mean DLQI minimal clinically important difference of –4.0 was exceeded (–4.1), improving to mean difference of –6.3 at Week 12. Most patients strongly agreed or agreed with PSQ questions assessing satisfaction with application ease (100%), cosmetic elegance (90.3%), efficacy (80.6%), confidence in tapinarof (80.6%), and application time not impacting everyday life (90.3%). Compared with other topical drugs previously used to treat plaque psoriasis, the majority strongly agreed or agreed that tapinarof was more effective (85.7%) and was preferred (85.7%).

**CONCLUSIONS:** In patients with intertriginous plaque psoriasis, tapinarof cream 1% QD demonstrated rapid and clinically meaningful improvements in patient-reported pruritus and HRQoL, as early as Week 1, with continued improvement through Week 12. Patients also reported high rates of satisfaction and positive perceptions of tapinarof cream, which were consistent with previously reported phase 3 trials.

**FUNDING:** Dermavant Sciences, Inc.

**DISCLOSURES:** HS has served as scientific adviser and/or clinical study investigator for: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi-Genzyme, Sun Pharma, and UCB Biopharma. ST is an investigator for: Dermavant Sciences, Inc. SMJ is an advisor and/or speaker and/or editor and/or involved in clinical trials for: AbbVie, Aclaris, AFMC, Allergan, Amgen, Candela Syneron, Cassiopea, Celgene, Chemocentryx, Dermavant Sciences, Inc., Dermira, Eli Lilly and Company, Foamix, Gage, Galderma, GlaxoSmithKline, Journal of Arkansas Medical Society, LEO Pharma, National Psoriasis Foundation, Nielsen, Novartis, Practical Dermatology, Regeneron, Sanofi Genzyme, Skin Medical, TARGET Therapeutics, and the University of Pennsylvania. SG is a speaker for: AbbVie, Aclaris, Janssen, Pfizer, and Sun Pharma. PS has no conflicts to declare. PMB, KT, NF, BK, and AMT are employees of: Dermavant Sciences, Inc. with stock options.

## Abstract PS-05

### Tapinarof Cream 1% Once Daily Improves Patient-Reported Outcomes in the Treatment of Mild to Severe Plaque Psoriasis in the Head and Neck Region

**George Michael Lewitt, MD[1]; Linda Stein Gold, MD[2]; Benjamin Lockshin, MD[3]; Philip M. Brown, MD, JD[4]; Katherine Tillman, BS[4]; Nancy Fitzgerald, MS, MBA[4]; Brandon Kirsch, MD[4]; Anna M. Tallman, PharmD[4]; Abel D. Jarell, MD[5]**

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**BACKGROUND:** Tapinarof cream 1% is a non-steroidal, topical aryl hydrocarbon receptor agonist approved for the treatment of plaque psoriasis in adults with no restrictions on location, extent, or duration of use. In the phase 3 PSOARING trial program, tapinarof cream 1% once daily (QD) for the treatment of plaque psoriasis was efficacious and well tolerated. Plaque psoriasis affecting the head and neck region occurs commonly, with a high impact on patients' health-related quality of life, through pruritus and psychological distress. Patients may consider topicals unacceptable for scalp/facial use due to poor cosmetic properties (e.g., greasiness), leading to low medication adherence. There is a need for efficacious, cosmetically elegant, non-steroidal topicals that can be used without restrictions.

**OBJECTIVE:** To assess patient-reported outcomes (PROs) with tapinarof cream for adults with mild to severe plaque psoriasis in the head and neck region, including the scalp, in a phase 4, open-label trial.

**METHODS:** Adults with head and neck region target lesion Physician Global Assessment (tPGA) score of 2 (mild), 3 (moderate), or 4 (severe) received tapinarof for 12 weeks. PROs included Peak Pruritus Numerical Rating Scale (PP-NRS) score for the head and neck region; achievement of ≥4-point reduction in PP-NRS score; Dermatology Life Quality Index (DLQI) score by visit; and responses to a Patient Satisfaction Questionnaire© (PSQ) at Week 12.

**RESULTS:** 31 patients received tapinarof; 58.1% (18/31) had the target lesion on the scalp. Baseline mean PP-NRS (head and neck region) and total DLQI scores were 5.8 and 9.7, respectively, demonstrating significant pruritus and disease impact. Improvement in mean PP-NRS score was demonstrated at Week 1 (–1.6), the earliest assessment, surpassing the minimal clinically important ≥4-point improvement by Week 12 (–4.2). At Week 12, 70.0% (n=14/20) achieved ≥4-point reduction in PP-NRS score. Mean DLQI minimal clinically important difference of –4.0 was demonstrated as early as Week 1 (–4.0), improving to –7.2 at Week 12. Most patients strongly agreed or agreed with PSQ questions assessing satisfaction with cosmetic elegance (93.3%), quick absorption (96.7%), application ease (86.7%), efficacy (83.3%), and confidence in tapinarof (83.3%). Compared with topicals used previously for

plaque psoriasis, most strongly agreed or agreed that tapinarof was more effective (76.9%) and easier to use (76.9%).
**CONCLUSION:** In patients with plaque psoriasis affecting the head and neck region, tapinarof cream 1% QD demonstrated rapid and clinically meaningful improvements in patient-reported pruritus and disease impact as early as Week 1, the first assessment, with continued improvement through Week 12. Patients reported high rates of satisfaction and positive perceptions of tapinarof.
**FUNDING:** Dermavant Sciences, Inc.
**DISCLOSURES:** GML has served as a consultant, speaker, investigator, or advisory board member for and/or has received grants from: AbbVie, Amgen, Inc., Bristol Myers Squibb, Dermavant Sciences, Inc., DermTech, Eli Lilly and Company, Galderma, LEO Pharma, Janssen, Novan, Inc., Pfizer, Orthodermatologics, and UCB Pharma. LSG has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from: Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB Pharma. BL has served as a consultant, speaker, or investigator for: AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Castle, Celgene, CorronaRegistry, Dermavant Sciences, Inc., Dermira, DermTech, Eli Lilly and Company, Franklin Bioscience, Galderma, Incyte, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, Strata Skin Sciences, Trevi Therapeutics, Inc., UCB Pharma, and Vanda. PMB, KT, NF, BK, and AMT are employees of: Dermavant Sciences, Inc., with stock options. ADJ has received research funding from: Dermavant Sciences Inc. as an investigator on this trial.

## Abstract PS-06

### Tapinarof Cream 1% Once Daily is Efficacious in the Treatment of Mild to Severe Plaque Psoriasis in the Head and Neck Region

**Linda Stein Gold, MD[1]; George Michael Lewitt, MD[2]; Benjamin Lockshin, MD[3]; Philip M. Brown, MD, JD[4]; Katherine Tillman, BS[4]; Nancy Fitzgerald, MS, MBA[4]; Brandon Kirsch, MD[4]; Anna M. Tallman, PharmD[4]; Abel D. Jarell, MD[5]**

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**BACKGROUND:** Tapinarof cream 1% is a non-steroidal, topical aryl hydrocarbon receptor agonist approved for the treatment of plaque psoriasis in adults, with no restrictions on location, extent, or duration of use. In the phase 3 PSOARING trial program, tapinarof cream 1% once daily (QD) was efficacious and well tolerated for treating psoriasis, including the head and neck region. However, efficacy data specific to scalp treatment were not captured.
**OBJECTIVE:** To assess efficacy, safety, and tolerability of tapinarof cream for the treatment of adults with plaque psoriasis affecting the head and neck region, including the scalp.
**METHODS:** In this phase 4, open-label trial, adults received tapinarof for 12 weeks. Patients had plaque psoriasis affecting the head and neck (stable for ≥3 months), and a target lesion Physician Global Assessment (tPGA) score of 2 (mild), 3 (moderate), or 4 (severe). The primary endpoint was the proportion achieving a tPGA response (tPGA score of clear [0], or almost clear [1] and ≥2-grade improvement from baseline at Week 12). Additional endpoints included time to achieve tPGA response; proportion with complete clearance (tPGA score=0); and with ≥75% and ≥90% improvement in Psoriasis Area and Severity Index score (PASI; head and neck region). Safety and tolerability evaluations included adverse events (AEs) and investigator-assessed Local Tolerability Scale (LTS) scores.
**RESULTS:** 31 patients with mild to severe plaque psoriasis affecting the head and neck region received tapinarof. At baseline, 54.8% had a tPGA score of 3 and 58.1% (18/31) had the target lesion on the scalp. At Week 12, 88.5% (n=23/26) achieved a tPGA response and 80.8% (n=21/26) achieved complete clearance (tPGA=0). There was rapid onset of efficacy, with both tPGA response and complete clearance achieved as early as Week 1, the first assessment, in some patients. Median times to tPGA response and complete clearance were ~4 and 8 weeks, respectively. At Week 12, 96.2% (n=25/26) and 84.6% (n=22/26) achieved a ≥75% and ≥90% improvement in PASI (head and neck region), respectively. Most AEs were mild or moderate, consistent with previous trials; the most frequent were contact dermatitis, folliculitis, and headache. Most patients had no irritation of the head and neck region (LTS score=0) at all visits.
**CONCLUSIONS:** Tapinarof cream 1% QD demonstrated rapid onset of clinically meaningful efficacy as early as Week 1 in patients with plaque psoriasis affecting the head and neck region, including for scalp lesions. Tapinarof cream is a cosmetically elegant, well-tolerated, non-steroidal treatment option in adults with mild to severe plaque psoriasis, including in the head and neck region.
**FUNDING:** Dermavant Sciences, Inc.
**DISCLOSURES:** LSG has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from: Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly and Company, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB Pharma. GML has served as a consultant, speaker, investigator, or advisory board member for and/or has received grants from: AbbVie, Amgen, Inc., Bristol Myers Squibb, Dermavant Sciences, Inc., DermTech, Eli Lilly and Company, Galderma, LEO Pharma, Janssen, Novan, Inc., Pfizer, Orthodermatologics, and UCB Pharma. BL has served as a consultant, speaker, or investigator for: AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Castle, Celgene, CorronaRegistry, Dermavant Sciences, Inc., Dermira, DermTech, Eli Lilly and Company, Franklin Bioscience, Galderma, Incyte, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, Strata Skin Sciences, Trevi Therapeutics, Inc., UCB Pharma, and Vanda. PMB, KT, NF, BK, and AMT are employees of: Dermavant Sciences, Inc., with stock options. ADJ has received research funding from: Dermavant Sciences Inc. as an investigator on this trial.

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