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SDPA Presents Summer 2023 Digital Abstracts

CONTENTS

1. Assessing Humanistic Burden among Patients with Moderate to Severe Psoriasis in the United States

2. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase 2 Inhibitor, in Moderate to Severe Plaque Psoriasis: Correlations Between Patient-Reported Outcomes and Clinical Responses in the Phase 3 Clinical Trials Psoyky Pso-1 and Psoyky Pso-2

3. Quality of Life and Mental Health of Patients Stratified by Prior Biologic Exposure: Post hoc Analysis of Brodalumab

4. Treat-to-Target Outcomes and Measures of Treatment Success in Three Phase 3 Trials of Tapinarof Cream 1% Once Daily for Mild to Severe Plaque Psoriasis

5. Real-World Effectiveness of Dupilumab in Atopic Dermatitis: Consistency in Rate and Magnitude of Improvement Across Observational Study Methodologies

6. Real-World Effectiveness and Safety in a Phase 4 Study of Tildrakizumab in Patients with Moderate-to-Severe Plaque Psoriasis

7. Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Seborrheic Dermatitis in a Phase 3 Trial: Assessment of Pruritus

8. Long-Term Safety in Adults with Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab up to 4 years

9. Challenges in Diagnosing and Managing Generalized Pustular Psoriasis: Learnings from 4 Cases in Clinical Practice

10. Safety of Tazarotene 0.045% Lotion and Hyperpigmentation Improvements in Black Participants with Moderate-to-Severe Acne

11. The Impact of Abrocitinib on Vaccine-Induced Immune Responses in Adolescents With Moderate-to-Severe Atopic Dermatitis Undergoing Routine Tetanus, Diphtheria, and Pertussis Vaccination in Phase 3 JADE TEEN

12. Long-Term Safety and Efficacy of Clascoterone Cream 1% in Patients ≥12 Years Old with Acne Vulgaris

13. Treatment of Onychomycosis in an Era of Antifungal Resistance: Role for Antifungal Stewardship and Topical Antifungal Agents

14. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase 2 Inhibitor, in Moderate to Severe Plaque Psoriasis: Efficacy by Baseline Demographic and Disease Characteristics in the Phase 3 POETYK PSO-1 and PSO-2 Trials

15. Patients’ Quality of Life in a Phase 4 Real-World Study of Tildrakizumab in Moderate-to-Severe Plaque Psoriasis

16. Secukinumab in Moderate to Severe Hidradenitis Suppurativa: A Pooled Subgroup Analysis from the SUNSHINE and SUNRISE Phase 3 Trial

17. Bimekizumab in Patients With Moderate-to-Severe Hidradenitis Suppurativa: 48-Week Efficacy and Safety from Be Heard I & II, Two Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Studies

18. Efficacy and Safety of Halobetasol Propionate 0.01% and Tazarotene 0.045% Lotion in Combination With a Ceramide-Containing Moisturizer

19. Rapid Improvements in Itch with Tapinarof Cream 1% Once Daily in Two Phase 3 Trials in Adults with Mild to Severe Plaque Psoriasis

20. Deucravacitinib in Plaque Psoriasis: 2-Year Laboratory Results From the Phase 3 POETYK PSO Program

21. Development of a patient-centered conceptual disease model for prurigo nodularis: a qualitative content analysis

22. Dupilumab Improves Itch, Skin Pain, and Sleep in Adult Patients With Prurigo Nodularis (LIBERTY PN-PRIME and PRIME2)
SDPA Presents Summer 2023 Digital Abstracts

CONTENTS

23. 24-Month Drug Persistence of Guselkumab as Compared to Other Biologic Therapies in Biologic-Experienced Patients With Plaque Psoriasis
24. Brodalumab: 4-Year US Pharmacovigilance Report
25. Durability of Efficacy and Safety of Roflumilast Cream 0.3% in Adults with Chronic Plaque Psoriasis From a 52-Week, Phase 2 Open-Label Safety Trial
26. Effectiveness and Safety of Guselkumab in Patients with Facial and/or Genital Psoriasis: Interim Analysis Results at Week 12 from GULLIVER Study
27. Dupilumab Improves Urticaria Signs and Symptoms and Quality of Life in Patients With Chronic Spontaneous Urticaria (CSU)
28. Bimekizumab (Bkz) Efficacy and Safety in Biologic Dmard-Naïve Patients with Psoriatic Arthritis (PsA) Was Consistent with or Without Methotrexate (Mtx): 52-Week Results from the Phase 3 Active-Reference Study Be Optimal
29. Cytokine Targeting Activity of Halobetasol Propionate/Tazarotene Lotion For Difficult-to-Treat Psoriasis
30. Dupilumab Treatment Results in Rapid, Sustained and Clinically Meaningful Improvement in Itch in Patients Aged 6 Months to 5 Years with Moderate-to-Severe Atopic Dermatitis
31. Efficacy of Dupilumab in Infants and Preschoolers With Atopic Dermatitis up to 1 Year
32. Tapinarof Cream 1% Once Daily for the Treatment of Extensive Atopic Dermatitis in Adolescents and Children: Outcomes from the 4-week Maximal Usage Trial
33. Nonulcerated Necrobiosis Lipoidica Successfully Treated with Tapinarof
34. Association of Patient-Reported Disease Burden and Treatment Switching Among Patients with Plaque Psoriasis on Nonbiologic Systemic Therapy
35. The 31-Gene Expression Profile Outperforms Ajcc And Cp-Gep in Stratifying Risk of Recurrence in Patients with Stage I Cutaneous Melanoma
36. Aesthetic Outcomes of Combining a Series of In-Office Chemical Peels With an At-Home Topical Pigmentation Control Regimen to Treat Facial Hyperpigmentation
37. A Case Series of Live Attenuated Vaccine Administration in Dupilumab-Treated Children with Atopic Dermatitis
38. Efficacy and Safety of Roflumilast Cream 0.15% in Adults and Children Aged ≥6 with Mild to Moderate Atopic Dermatitis in Two Phase 3 Trials (INTEGUMENT-1 and INTEGUMENT-2)
39. Integrated Safety Analysis of Abrocitinib in 3802 Patients With Moderate-To-Severe Atopic Dermatitis With Over 5000 Patient-Years of Exposure
40. The 40-gene expression profile (40-GEP) test allows for an improved prognostication of the likelihood of metastasis in patients with T1 cutaneous squamous cell carcinoma (cSCC) with high-risk factors
41. Efficacy and Safety of a Fixed-Dose Clindamycin Phosphate 1.2%, Benzoyl Peroxide 3.1%, and Adapalene 0.15% Gel for Moderate-to-Severe Acne: Randomized Phase 2 and Phase 3 Studies of the First Triple-Combination Drug
42. 24 Month Drug Persistence of Guselkumab in Biologic-Naïve Plaque Psoriasis Patients
43. Bimekizumab Maintenance of Response And Safety in Patients with Moderate to Severe Plaque Psoriasis: Results from the Open-Label Extension Period (Weeks 48–144) of the Be Radiant Phase 3b Trial
44. Improvement in Patient-Reported Outcomes with Deucravacitinib in Moderate to Severe Psoriasis: Results from the Poetyk Pso-1 and Poetyk Pso-2 Randomized Phase 3 Clinical Trials
45. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase 2 Inhibitor, in Moderate to Severe Plaque Psoriasis: 2-Year Efficacy by Prior Biologic Treatment in the Phase 3 POETYK PSO Program
1. Assessing Humanistic Burden among Patients with Moderate to Severe Psoriasis in the United States

April W. Armstrong,1 Lauren Seigel,2 Sayeli Jayade,3 Sanika Rege,3 Hannah Penton,1 Vardhaman Patel,2 David Davidson,2 Samaneh Kalirai,2 Daniel Wolin,3 Kimberly Boyle,4 Tina Bhutani5

1Keck School of Medicine, USC, Los Angeles, CA; 2Bristol Myers Squibb, Lawrenceville, NJ; 3OPEN Health Evidence & Access, Parsippany, NJ; 4RTI Health Solutions, Research Triangle Park, NC; 5UCSF, San Francisco, CA

Introduction: Various treatments for psoriasis are available, yet evidence reveals substantial humanistic burden remains. This study assessed the humanistic burden in patients with moderate to severe psoriasis.

Methods: This non-interventional, cross-sectional survey study in adults in the US with moderate to severe psoriasis grouped patients based on current treatment. The survey collected demographics, clinical characteristics, and outcomes associated with humanistic burden via the Dermatology Life Quality Index (DLQI), Work Productivity and Activity Impairment Questionnaire–Psoriasis (WPAI-PSO), and questions on disease-related anxiety and depression.

Results: Within this study population of 882 patients, 92.8% were currently receiving treatment (mean duration≈2.9 years). Over the past 30 days, 76.8% reported anxiety and 57.4% reported depression due to psoriasis. Of 677 patients with anxiety due to psoriasis, 58.6% had anxiety for several days. Among 506 patients with depression due to psoriasis, 67.2% experienced it for several days over the past 30 days. Compared with other treatment groups, untreated/nonprescription group patients experienced more depression (78.0%) and anxiety (94.0%). Topical/phototherapy and untreated/nonprescription groups had the smallest percentage of patients who believed their anxiety decreased (definitely yes/probably yes) since initiating their current treatment (26.5% and 27.8%, respectively). Similar results were seen for depression: 23.4% of topical/phototherapy users and 27.7% of the exploratory group reported that their depression decreased since starting treatment. Compared with TNFi and ustekinumab users, apremilast users reported lower reduction in depression (50.4% vs 52.1%, 43.6% respectively; all P <0.001). Mean DLQI global score overall was 8.9. Ustekinumab users had the lowest DLQI score (7.6), indicating better quality of life (QoL), compared with 8.1 for apremilast users, 8.8 for TNFi users, 10.3 for topical/phototherapy users, and 11.3 for the untreated/nonprescription group (P<0.001). DLQI scores increased with psoriasis severity (P<0.001). Of 528 employed patients, mean absenteeism score was 6.0, presenteeism score 25.4, total work productivity impairment score 27.9, and activity impairment score 29.3. Patients in the topological/phototherapy and exploratory groups and those receiving TNFis had greater presenteeism and activity impairment scores, indicating worse productivity, than those receiving apremilast or ustekinumab.

Conclusions: Patients’ current treatment, or lack thereof, influences how psoriasis impacts QoL, anxiety and depression, and productivity. We recommend that physicians consider QoL in addition to symptom management when making treatment decisions.

2. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase 2 Inhibitor, in Moderate to Severe Plaque Psoriasis: Correlations Between Patient-Reported Outcomes and Clinical Responses in the Phase 3 Clinical Trials Poetyk Pso-1 and Poetyk Pso-2

April W. Armstrong1, Kim A. Papp,2 Joe Zhuo,3 Brandon Becker,1 Yichen Zhong,5 Jennifer L. Beaumont,1 Michael DeRosa,4 Renata M. Kisa,5 Subhashis Banerjee,1 Bruce Strober5,6

1Keck School of Medicine, University of Southern California, Los Angeles, CA; 2Probity Medical Research Inc., Waterloo, ON, Canada; 3Bristol Myers Squibb, Princeton, NJ; 4Clinical Outcomes Solutions, Chicago, IL; 5Yale School of Medicine, Yale University, New Haven, CT; 6Central Connecticut Dermatology, Cromwell, CT

Introduction: The phase 3 clinical trials POETYK PSO-1 (N = 666) and PSO-2 (N = 1020) randomized adult patients with moderate to severe plaque psoriasis 2:1 to deucravacitinib, placebo, or apremilast. Using data pooled from both trials, this post hoc analysis evaluated the correlation between clinical outcomes, as assessed by the Psoriasis Area and Severity Index (PASI) and static Physician’s Global Assessment (sPGA), and patient-reported outcomes (PROs), as assessed by the Psoriasis Symptom and Signs Diary (PSSD) and Dermatology Life Quality Index (DLQI).

Methods: With all treatment groups combined, Spearman correlation coefficients were calculated for score changes from baseline to Week 16 for PASI with PSSD and DLQI total scores. Mean PRO scores were determined within clinical response subgroups. The proportions of patients achieving meaningful improvements (ie, response) in total score for PSSD (≥25 points) and DLQI (≥4 points) were summarized by whether they did or did not achieve 75% reduction from baseline PASI score (PASI 75), analyzed by deucravacitinib and placebo treatment arms.

Results: Score change from baseline to Week 16 was correlated between PASI and PSSD total score (rs = 0.536), and between PASI and DLQI total score (rs = 0.421). In each trial, significantly greater proportions of patients who received deucravacitinib achieved PASI 75 than those who received placebo. Greater clinical response was associated with greater PRO response. In addition, PSSD and DLQI responses were reported by greater proportions of deucravacitinib-treated patients than placebo-treated patients, in patients both with and without PASI 75 response. Among patients who achieved PASI 75, 68.6% of deucravacitinib patients reported PSSD response vs 31.3% of patients who received placebo. Among patients who did not achieve PASI 75, 41.8% of deucravacitinib patients reported PSSD response vs 10.4% of patients who received placebo. Greater proportions of deucravacitinib patients reported DLQI response vs those who received placebo in patients both with and without PASI 75 response.

Conclusions: The correlation between PROs and clinical
endpoints in the POETYK PSO-1 and PSO-2 trials was consistent with that reported in other studies. Higher rates of PRO response were observed in the deucravacitinib arm than in the placebo arm for patients both with and without PASI 75 response.

3. Quality of Life and Mental Health of Patients Stratified by Prior Biologic Exposure: Post hoc Analysis of Brodalumab

April Armstrong,1 Brad Glick,2 Tina Bhutani,3 Abby Jacobson4
1University of Southern California, Los Angeles, CA; 2Glick Skin Institute, Margate, FL; 3UCSF Psoriasis and Skin Treatment Center, San Francisco, CA; 4Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

Introduction: Psoriasis is associated with high rates of depression, anxiety, and difficulties with interpersonal relationships. Several clinical trials show that treatment with biologic agents is associated with a decreased incidence of depressive symptoms vs conventional systemic therapies. The dysregulation of several interleukin-17 (IL-17) cytokines promotes psoriasis pathogenesis; however, many systemic biologics target individual cytokines. Brodalumab, a human IL-17 receptor antagonist efficacious for the treatment of moderate-to-severe psoriasis in adults, has a unique mechanism of action that blocks multiple inflammatory cytokines, including IL-17A, IL-17C, IL-17E, and IL-17F. Treatment failure can lead to increased disease severity, which can exacerbate depression and anxiety symptoms in patients with psoriasis. Thus, this post hoc analysis of the AMAGINE-1 trial evaluates patient-reported quality of life (QOL) and symptoms of anxiety and depression in patients with psoriasis stratified by prior exposure to biologics.

Methods: In AMAGINE-1, patients (n=305) or without (n=356) biologic exposure before entering the study received brodalumab 210 mg every 2 weeks or placebo. The dermatology life quality index (DLQI) was used to measure patient-reported QOL (total score range: 0 [no impairment to QOL] to 30 [maximum impairment to QOL]); the hospital anxiety and depression scale (HADS) was used to measure symptoms of anxiety and depression (total score range for each: 0 [normal] to 21 [severe]).

Results: Mean DLQI at baseline was 14.2 and 14.1 for patients with or without prior biologic exposure, respectively. For patients with prior biologic exposure, those receiving brodalumab vs placebo exhibited a significant reduction in mean DLQI at week 12 (2.3 vs 15.2, respectively; P=0.0001); similar results were seen in patients without prior biologic exposure (3.2 vs 11.0, respectively; P<0.0001). Mean HADS anxiety scores at baseline were similar for the brodalumab group regardless of prior biologic exposure; in the placebo group, HADS anxiety scores were lower in patients with vs without prior biologic exposure (5.8 vs 6.9, P=0.04). Regardless of prior biologic exposure, there was a numeric reduction in mean HADS anxiety scores with brodalumab from baseline (range, 6.3-7.0) to week 12 (range, 4.6-5.1); in the placebo group, mean HADS anxiety scores were unchanged from baseline (range, 5.8-6.9) to week 12 (range, 5.8-6.6). A similar trend was seen in mean HADS depression scores, with the brodalumab group exhibiting a numeric reduction from baseline (range, 5.0-5.8) to week 12 (range, 3.2-3.6) and the placebo group exhibiting unchanged scores from baseline (range, 5.0-5.6) to week 12 (range, 5.4-5.5).

Conclusion: Patients with psoriasis can experience a profound psychosocial burden that may negatively influence QOL. Brodalumab demonstrated improvements in QOL and symptoms of mental health in patients with psoriasis regardless of prior biologic exposure.

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4. Treat-to-Target Outcomes and Measures of Treatment Success in Three Phase 3 Trials of Tapinarof Cream 1% Once Daily for Mild to Severe Plaque Psoriasis

April W. Armstrong1, Robert Bissonnette2, Philip M. Brown1, Anna M. Tallman3, Kim A. Papp4
1Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; 2Innovaderm Research Inc., Montreal, QC, Canada; 3Dermavant Sciences, Inc., Morrisville, NC, USA; 4Probity Medical Research Inc., Waterloo, ON, Canada

Introduction: Treat-to-target strategies are used in several chronic diseases to improve outcomes. Treatment goals for psoriasis have been recommended by the US National Psoriasis Foundation (e.g., achieving a percent body surface area [%BSA] affected of ≤1% at 3 months) and the European S3-Guidelines on the Systemic Treatment of Psoriasis (e.g., a ≥75% decrease in Psoriasis Area and Severity Index [PASI] within 3–4 months). Current topical treatments alone are generally insufficiently efficacious to achieve these goals. Tapinarof cream 1% once daily (QD), a non-steroidal, topical, aryl hydrocarbon receptor agonist, demonstrated statistically significant efficacy versus vehicle and was well-tolerated in adults with mild to severe plaque psoriasis in PSOARING 1 and 2, two 12-week, phase 3 trials. Efficacy continued to improve, beyond the 12-week trials in PSOARING 3, the long-term extension trial, with a high rate (40.9%; n=312) of complete disease clearance (Physician Global Assessment [PGA]=0), ~4-month remittive effect off therapy, and durability on therapy for up to 52 weeks.

Objective: To present analyses of treat-to-target outcomes for patients treated with tapinarof in the PSOARING trials.

Methods: Pooled analyses explored more-aggressive
targets, including patients achieving a %BSA affected of ≤1.0% or ≤0.5%, or an absolute PASI score of ≤1, ≤2 or ≤3. Time-to-event analyses are based on Kaplan–Meier estimates using observed cases among all patients in the PsoAring trials with a baseline PGA≥2 before tapinarof treatment. Safety analyses are based on all patients who received tapinarof in the PsoAring trials.

**Results:** Efficacy analyses included 915 patients. At baseline, 78.1% had PGA=3 (moderate), mean PASI was 8.7, and mean %BSA was 7.8%. The analyses indicated that 61.3% of patients (n=561) achieved %BSA ≤1.0%, median time to target of 120 days (95% confidence interval [CI], 113–141), while 49.7% (n=455) achieved %BSA ≤0.5%, median time to target of 199 days (172–228). A %BSA ≤1.0% was achieved by 40% (95% CI, 37–43%) of patients at 90 days (3 months). In addition, 75.0% (n=686) achieved PASI≤3, with mean time to target of 58 days (95% CI, 57–63); 66.9% (n=612) achieved PASI≤2, median time to target of 87 days (85–110); and 50.3% (n=460) achieved PASI≤1, median time to target of 185 days (169–218). Among all patients who received tapinarof in the PsoAring trials (N=936), most treatment-emergent adverse events (TEAEs) were mild to moderate. Most common TEAEs (≥5%) were folliculitis, contact dermatitis, and nasopharyngitis.

**Conclusion:** Together with previously reported tapinarof efficacy and safety, these findings demonstrate that a high percentage of patients treated with tapinarof cream 1% QD alone can achieve and exceed ambitious treatment targets.

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5. **Real-World Effectiveness of Dupilumab in Atopic Dermatitis: Consistency in Rate and Magnitude of Improvement Across Observational Study Methodologies**

Jerry Bagel1, Tien Q. Nguyen2, Eric Simpson1, Hermenio Lima3, Haixin Zhang3, Chien-Chia Chuang4, Debra Sierka5, Dimitri Delevry5, Moataz Daoud4, Andrew Korotzer6

1Eczema Treatment Center of New Jersey, East Windsor, NJ, USA; 2The First OC Dermatology, Fountain Valley, CA, USA; 3Oregon Health and Science University, Portland, OR, USA; 4LEADER Research and the Division of Dermatology, McMaster University, Hamilton, Ontario, Canada; 5Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; 6Sanofi, Cambridge, MA, USA

**Introduction:** Results from real-world (RW) observational studies may be influenced by differences in study recruitment, design, and clinical practice. Consistent results across RW studies support generalizability of findings. The objective of this study is to summarize patient-reported outcomes in the RELIEVE-AD (DOI:10.1001/jamadermatol.2021.4778) and PROSE (NCT03428646) RW studies of dupilumab in atopic dermatitis (AD).

**Method:** RELIEVE-AD was a prospective, observational, RW study of dupilumab effectiveness in patients with moderate-to-severe AD recruited from a US patient support program. PROSE is a prospective, observational, multicenter registry of AD patients initiating dupilumab in the US and Canada. Skin pain, heat/burning, and skin sensitivity numeric rating scale (NRS; each scale 0–10) and Dermatology Life Quality Index (DLQI; 0–30) were compared between studies.

**Results:** In RELIEVE-AD (N=698)/PROSE (N=764), mean age was 46.41 years, 62%/59% female, 74%/55% white. Trajectory of improvement with dupilumab was similar between RELIEVE-AD/PROSE: mean skin pain NRS improved from 5.9/5.4 at baseline to 2.3/2.3 at Month 2, and 1.7/1.7 at month 12; heat/burning NRS improved from 5.2/4.7 at baseline to 1.9/2.0 at month 2, and 1.5/1.6 at month 12; skin sensitivity NRS improved from 5.5/5.2 at baseline to 2.0/2.3 at month 2, and 1.5/1.8 at month 12; and DLQI improved from 14.4/13.3 at baseline to 4.8/5.9 at month 3, and 3.5/5.1 at month 12.

**Conclusions:** Two RW studies utilizing different methodologies yielded similar findings regarding time course and extent of dupilumab effectiveness in AD across multiple patient-reported outcomes.
Conclusion: These real-world data demonstrated the significant effectiveness of tildrakizumab beginning as early as Week 4 and showed a favorable safety profile in patients with moderate-to-severe plaque psoriasis.

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7. Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Seborrheic Dermatitis in a Phase 3 Trial: Assessment of Pruritus

Andrew Blauvelt1, Zoe D. Draelos2, Melinda Gooderham3, Edward Lain3, Angela Y. Moore4, Kim A. Papp5, Matthew Zirwas3, David Krupa3, Patrick Burnett6, David R. Berk6, David H. Chu8
1Oregon Medical Research Center, Portland, OR, USA; 2Dermatology Consulting Services, High Point, NC, USA; 3SKIN Centre for Dermatology, Proby Medical Research and Queen’s University, Peterborough, ON, Canada; 4Sanova Dermatology, Austin, TX, USA; 5Arlington Research Center, Arlington, TX, and Baylor University Medical Center, Dallas, TX, USA; 6Probity Medical Research and K Papp Clinical Research, Waterloo, ON, Canada; 7Dermatologists of the Central States, Proby Medical Research, and Ohio University, Bexley, OH, USA; 8Arcticus Biotherapeutics, Inc., Westlake Village, CA, USA.

Introduction: Itch is a major complaint among patients with seborrheic dermatitis (SD). Roflumilast is a selective, nonsteroidal, highly potent phosphodiesterase-4 inhibitor under investigation as a once-daily foam for treatment of SD.

Methods: This phase 3 randomized, parallel-group, double-blind, vehicle-controlled trial (NCT04973228) was conducted in patients ≥9 years old with at least moderate SD affecting scalp and/or non-scalp areas. Patients were randomized 2:1 to apply once-daily roflumilast foam 0.3% (n=304) or vehicle (n=153) for 8 weeks. The primary efficacy endpoint was Investigator Global Assessment (IGA) success (IGA of Clear or Almost Clear plus ≥2-grade improvement from baseline) at Week 8. Secondary efficacy endpoints included Worst Itch Numeric Rating Scale (WI-NRS), which was completed daily by patients. Safety and local tolerability were also evaluated.

Results: Overall, significantly more roflumilast-treated patients than vehicle-treated patients achieved IGA success (79.5% vs. 58.0%; P=0.0001) and IGA status of Clear (50.6% vs. 27.7%; P=0.0001) at Week 8. Significantly greater percentages of roflumilast- than vehicle-treated patients had ≥4-point improvement on WI-NRS at Weeks 2 (32.7% vs. 15.5%; P=0.0016), 4 (47.6% vs. 29.1%; P=0.0007), and 8 (62.8% vs. 40.6%; P=0.0001). Greater improvement in itch was observed among roflumilast-treated patients as early as 48 hours after the first application (mean percent change from baseline: -27.87% vs. -13.11%; nominal P=0.0024). Local tolerability and safety were favorable.

Conclusion: Once-daily roflumilast foam provided improvement across multiple efficacy endpoints including rapid itch improvement, while demonstrating favorable safety and tolerability.

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9. Challenges in Diagnosing and Managing Generalized Pustular Psoriasis: Learnings from 4 Cases in Clinical Practice

E. Christianson1, J. Heim2, L.A. Pansch3, H. Yu4

1Brookside Dermatology Associates, Bridgeport, Connecticut
2West Michigan Dermatology, Grandville, Michigan
3Dermatologists of Central States, Cincinnati, Ohio 4West Derm Center, Bronx, New York

Introduction: Generalized pustular psoriasis (GPP) is a rare autoinflammatory skin disease characterized by small, sterile pustules and is often accompanied by systemic symptoms.

Description of the procedure: We present 4 cases from our respective clinical practices that highlight the physical and psychological burden of GPP, and the challenges of diagnosing and managing the disease.

Results: Case 1 is a 14-year-old White male with autism who presented with a rash on his feet that worsened and spread to his entire body. The patient was initially misdiagnosed and mistreated for skin eruptions on his feet and a staphylococcus aureus infection; a biopsy confirmed the GPP diagnosis. Personalized care was administered to the patient to facilitate timely and appropriate care. This case highlights the importance of recognizing and diagnosing GPP to reduce disease burden.

Case 2 is a 55-year-old White male with a 20-year history of plaque psoriasis (PsO). The patient presented to an urgent care center with an upper respiratory tract infection and was treated with oral corticosteroids. After stopping treatment, he returned to urgent care with a pustular rash (scalp/hands/feet/trunk) and was given another course of corticosteroids to treat the rash. He later presented to us with a hyperkeratotic rash that consisted of pustules on the scalp, trunk, hands, and feet. A GPP diagnosis was confirmed by skin biopsy. This case highlights that GPP flares can often present in an emergency setting.

Case 3 is a 33-year-old White female who was diagnosed with GPP after being hospitalized due to a flare. Despite being treated with multiple topical and systemic treatments over a 7-year period since diagnosis, her GPP was never fully controlled. She was hospitalized 2 more times for GPP flares with painful pustules on 20–40% of her body. This case highlights the difficulty in finding the right treatment, which can cause substantial psychological burden and distress.

Case 4 is a 59-year-old Hispanic male who presented with a 1-year history of mild PsO and multiple comorbidities. Certolizumab, ixekizumab, and secukinumab were sequentially used to treat PsO but subsequently stopped due to adverse reactions assumed to be related to the different drugs. A provisional pustular psoriasis diagnosis was indicated by a skin biopsy; however, the patient was lost to follow-up due to COVID-19 pandemic. He presented 2 years later with a worsened condition. This case highlights that GPP flares may be misdiagnosed as drug-induced reactions.

Conclusion: GPP flares are associated with substantial physical and psychosocial disease burden and deteriorating quality of life. The severity and consequences of untreated GPP highlight the importance of prompt diagnosis and effective treatment.
0 [none] to 3 [severe]). Post hoc analyses were based on participants’ self-identification of race, including ‘Black or African American’ (herein referred to as Black).

**Results:** Of 1,614 participants randomized in the two phase 3 studies, 262 (16%) self-identified as Black. The safety population comprised 253 Black participants. The most common TEAEs with tazarotene 0.045% lotion were at the application site: pain (6.6%), exfoliation (5.0%), and dryness (3.3%). No participants reported application site irritation or dermatitis with tazarotene lotion.

**Methods:** Adolescents (aged 12-17 years) received abrocitinib 200 mg, 100 mg, or placebo orally once-daily for 12 weeks with medicated topical therapy; a subset of patients (n=25) received the Tdap vaccine at week 8. The proportion of patients who achieved a ≥4-fold increase in IgG concentrations to vaccine antigens from baseline (week 8) to 4 weeks post-vaccination (week 12), routinely considered a satisfactory response, was assessed for each treatment arm.

**Results:** Six patients receiving abrocitinib 200 mg, 9 patients receiving abrocitinib 100 mg, and 10 patients receiving placebo were administered Tdap booster vaccination (as per local guidelines). Serum samples were available before vaccination for 5, 8, and 10 patients, respectively, and at 4 weeks post-vaccination for 4, 8, and 10 patients, respectively. A ≥4-fold increase in antibody concentration to tetanus toxoid was achieved in 100% (4/4), 75% (6/8), and 50% (5/10) of patients in the abrocitinib 200 mg, 100 mg, and placebo groups, respectively; in 100% (4/4), 62.5% (5/8), and 80% (8/10) of patients to diphtheria toxoid; and for acellular pertussis antigens, in 100% (4/4), 75% (6/8), and 70% (7/10) of patients to pertussis toxin; in 100% (4/4), 62.5% (5/8), and 70% (7/10) of patients to filamentous hemagglutinin; in 0% (0/4), 0% (0/8), and 10% (1/10) of patients to fimbriae types 2/3; and in 100% (4/4), 87.5% (7/8), and 80% (8/10) of patients to pertactin. Among Tdap vaccinated patients, treatment-emergent adverse events (AEs) that started at or after week 8 (date of Tdap vaccination) were reported in 16.7% (1/6), 33.3% (3/9), and 10.0% (1/10) patients in the abrocitinib 200 mg, 100 mg, and placebo groups, respectively; none of those AEs were severe, serious, or led to discontinuation.

**Conclusion:** There were no appreciable differences in immune responses to Tdap vaccination in adolescents receiving abrocitinib compared to placebo. Despite the limited sample size of the current study, the results suggest adequate immune responses to the Tdap vaccine.

**Funding:** Pfizer Inc.

11. **The Impact of Abrocitinib on Vaccine-Induced Immune Responses in Adolescents With Moderate-to-Severe Atopic Dermatitis Undergoing Routine Tetanus, Diphtheria, and Pertussis Vaccination in Phase 3 JADE TEEN**

Michael Cork,1 Lawrence Eichenfield,2 Carsten Flohr,3 Christine Bangert,4 Sebastien Barbarot,5 Gary Chan,6 Ricardo Rojo,7 Fan Zhang,7 Claire Feeney,7 Herman Valdez7
1Sheffield Dermatology Research, IICC, University of Sheffield, Sheffield, UK; 2University of California San Diego and Rady Children’s Hospital-San Diego, San Diego, CA, USA; 3Unit for Population-Based Dermatology Research, St John’s Institute of Dermatology, Guy’s and St Thomas’ NHS Foundation Trust, King’s College London, London, UK; 4Department of Dermatology, Medical University of Vienna, Vienna, Austria; 5Nantes Université, CHU Nantes, France; 6Pfizer Inc., Collegeville, PA, USA; 7Pfizer Inc., Groton, CT, USA; 8Pfizer Ltd, Surrey, UK; 9Pfizer Inc., New York, NY, USA

**Introduction:** It is currently unclear whether abrocitinib has an impact on the immunogenicity of routine vaccinations in adolescents with moderate-to-severe atopic dermatitis. This study investigated the effect of abrocitinib on mounting immune responses to the tetanus, diphtheria, and acellular pertussis (Tdap) booster vaccination in adolescent patients from the JADE TEEN trial (NCT03796676).

**Methods:** Adolescents (aged 12-17 years) received abrocitinib 200 mg, abrocitinib 100 mg, or placebo orally once-daily for 12 weeks with medicated topical therapy; a subset of patients (n=25) received the Tdap vaccine at week 8. The proportion of patients who achieved a ≥4-fold increase in IgG concentrations to vaccine antigens from baseline (week 8) to 4 weeks post-vaccination (week 12), routinely considered a satisfactory response, was assessed for each treatment arm.

**Results:** Six patients receiving abrocitinib 200 mg, 9 patients receiving abrocitinib 100 mg, and 10 patients receiving placebo were administered Tdap booster vaccination (as per local guidelines). Serum samples were available before vaccination for 5, 8, and 10 patients, respectively, and at 4 weeks post-vaccination for 4, 8, and 10 patients, respectively. A ≥4-fold increase in antibody concentration to tetanus toxoid was achieved in 100% (4/4), 75% (6/8), and 50% (5/10) of patients in the abrocitinib 200 mg, 100 mg, and placebo groups, respectively; in 100% (4/4), 62.5% (5/8), and 80% (8/10) of patients to diphtheria toxoid; and for acellular pertussis antigens, in 100% (4/4), 75% (6/8), and 70% (7/10) of patients to pertussis toxin; in 100% (4/4), 62.5% (5/8), and 70% (7/10) of patients to filamentous hemagglutinin; in 0% (0/4), 0% (0/8), and 10% (1/10) of patients to fimbriae types 2/3; and in 100% (4/4), 87.5% (7/8), and 80% (8/10) of patients to pertactin. Among Tdap vaccinated patients, treatment-emergent adverse events (AEs) that started at or after week 8 (date of Tdap vaccination) were reported in 16.7% (1/6), 33.3% (3/9), and 10.0% (1/10) patients in the abrocitinib 200 mg, 100 mg, and placebo groups, respectively; none of those AEs were severe, serious, or led to discontinuation.

**Conclusion:** There were no appreciable differences in immune responses to Tdap vaccination in adolescents receiving abrocitinib compared to placebo. Despite the limited sample size of the current study, the results suggest adequate immune responses to the Tdap vaccine.

**Funding:** Pfizer Inc.

12. **Long-Term Safety and Efficacy of Clascoterone Cream 1% in Patients ≥12 Years Old with Acne Vulgaris**

Lawrence F. Eichenfield1, Adelaïde A. Hebert1, Linda Stein Gold2, Martina Cartwright3, Luigi Moro4, Jenny Han5, Nicholas Squittieri5, Alessandro Mazzetti3
1University of California San Diego School of Medicine, La Jolla, CA, USA; Rady Children’s Hospital San Diego, San Diego, CA, USA; 2UTH Health McGovern Medical School, Houston, TX, USA; 3Henry Ford Medical Center, Detroit, MI, USA; 4Cassiopea, Inc., San Diego, CA, USA; 5Cassiopea S.p.A., Lainate, Italy; 6Pharmapace, Inc., San Diego, CA, USA; 7Sun Pharmaceutical Industries Inc., Princeton, NJ, USA

**Background:** Clascoterone cream 1% is approved for the treatment of acne vulgaris in patients aged ≥12 years based on results in two 12-week, randomized, double-blind, vehicle-controlled, Phase 3 studies in patients with moderate-to-severe acne. Patients who completed one of these pivotal studies could enter an open-label long-term extension study and receive treatment for up to 9 additional months. Long-term safety and efficacy of clascoterone for up to 12 months in patients aged ≥12 years from the extension study are presented.

**Methods:** All patients who continued into the open-label, long-term extension study (NCT02682264) applied
clascoterone twice daily to the entire face and, if desired, any truncal acne, for up to 9 months. Patients achieving Investigator’s Global Assessment score of 0 or 1 (IGA 0/1) could stop treatment and resume if/when acne worsened. Safety was assessed from treatment-emergent adverse events (TEAEs) and local skin reactions (LSRs [telangiectasia, skin atrophy, striae rubrae, erythema, edema, scaling/dryness, stinging/burning, and pruritus]) in all treated patients. Efficacy was assessed from percentage of patients with IGA 0/1 among those who completed the extension study without significant protocol deviations (per-protocol [PP] population).

**Results:** Of 598 patients treated in the extension study, 108 (18.1%) experienced 187 TEAEs, with similar frequency between patients previously treated with vehicle (52/287 [18.1%]) vs clascoterone (56/311 [18.0%]). Frequency of LSRs was low throughout the study. Percentage of PP patients with facial and truncal IGA 0/1 increased over time to 48.9% (156/319) and 52.4% (65/124), respectively, at end of study and was greatest in patients applying clascoterone for 12 months (face, 67/119 [56.3%]).

**Conclusion:** Clascoterone cream 1% maintained a favorable safety and efficacy profile for up to 12 months in patients aged ≥12 years.

**Sponsorship:** The studies were funded by Cassiopeia S.p.A. and medical writing support for this abstract by Sun Pharma.

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**13. Treatment of Onychomycosis in an Era of Antifungal Resistance: Role for Antifungal Stewardship and Topical Antifungal Agents**

Boni Elewski, MD; Aditya K Gupta, MD, PhD1,2; Warren S Joseph, DPM3; Shari R Lipner, MD, PhD; C Ralph Daniel, MD3; Antonella Tosti, MD3; Eric Guenin, PharmD, PhD, MPH4; Mahmoud Ghannoum, PhD5,6

**Introduction:** A growing body of literature has marked the role of topical antifungals in overcoming antifungal resistance among species of *Trichophyton*—the two most common oral treatments for onychomycosis and other superficial fungal infections caused by dermatophytes—has been detected around the globe. Fungal adaptations, patient characteristics (e.g., immunocompromised status; drug-drug interactions), and empirical diagnostic and treatment patterns may contribute to reduced antifungal efficacy and the development of antifungal resistance. Antifungal stewardship efforts aim to ensure proper antifungal use to limit antifungal resistance and improve clinical outcomes. In the treatment of onychomycosis, critical aspects of antifungal stewardship include proper identification of the fungal infection and conducting antifungal susceptibility testing, along with efforts to improve clinician and patient education. Topical ciclopirox, efinaconazole, and tavaborole, delivered either alone or in combination with oral antifungals, have demonstrated efficacy in vitro against susceptible and/or resistant isolates of *Trichophyton* species, and low potential for development of antifungal resistance.

**Conclusions:** The rise and spread of antifungal resistance presents a growing threat to the management of onychomycosis and other superficial fungal infections. Real-world long-term data are needed to monitor global rates of antifungal resistance and the efficacy of oral and topical antifungals, alone or in combination, in counteracting antifungal resistance in the treatment of onychomycosis.

**Funding:** Ortho Dermatologics

**References**


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**14. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase 2 Inhibitor, in Moderate to Severe Plaque Psoriasis: Efficacy by Baseline Demographic and Disease Characteristics in the Phase 3 POETYK PSO-1 and PSO-2 Trials**

Melinda Gooderham,1 Lynda Spelman,2 Shinichi Imafuku,3 Marco Romanelli,4 Joseph F. Merola,5 April W. Armstrong,6 Elizabeth Colston,7 Subhashis Banerjee,7 Thomas Schramnit,7 Andrew Blauvelt8

**Introduction:** Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate- to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In the POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials, deucravacitinib was superior to placebo and apremilast.
in patients with moderate to severe plaque psoriasis. This analysis evaluated deucravacitinib efficacy by baseline characteristics.

**Methods:** Efficacy endpoints, including ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and static Physician’s Global Assessment score of 0 (clear) or 1 (almost clear) (sPGA 0/1), were evaluated at Week 24 by baseline subgroups including weight, sex, and PASI in the pooled PSO-1 and PSO-2 population, and at Week 52 in PSO-1 patients who received continuous deucravacitinib treatment from Day 1.

**Results:** In the pooled PSO-1 and PSO-2 population, deucravacitinib (n=483) was more efficacious than apremilast (n=422) at Week 24 across subgroups defined by baseline weight (<90 kg: PASI 75, 69.8% vs 43.8%, sPGA 0/1, 60.2% vs 34.2%; ≥90 kg: PASI 75, 55.4% vs 31.5%, sPGA 0/1, 45.9% vs 25.6%), sex (male: PASI 75, 59.3% vs 33.7%, sPGA 0/1, 49.6% vs 24.7%; female: PASI 75, 70.4% vs 45.2%, sPGA 0/1, 60.9% vs 39.4%), and PASI ≤20: PASI 75, 61.6% vs 38.6%, sPGA 0/1, 53.5% vs 32.4%; >20: PASI 75, 64.7% vs 37.0%, sPGA 0/1: 53.2% vs 27.1%). Consistent efficacy was observed through Week 52 in patients who received continuous deucravacitinib treatment in PSO-1 (n=332), regardless of baseline characteristics.

**Conclusion:** Deucravacitinib demonstrated consistent efficacy for up to 52 weeks regardless of baseline characteristics in patients with moderate to severe plaque psoriasis.

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**MR:** Nothing to disclose

**15. Patients’ Quality of Life in a Phase 4 Real-World Study of Tildrakizumab in Moderate-to-Severe Plaque Psoriasis**

Jayme Heim1, J Gabriel Vasquez2, Ranga Gogineni2, Brad Schenkel3, Neal Bhatia4

1West Michigan Dermatology, Grandville, MI, USA; 2Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA; 3Therapeutics Clinical Research, San Diego, CA, USA

**Background:** Tildrakizumab is an anti–interleukin-23p19 monoclonal antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis. We describe the primary outcome of improvement in health-related quality of life (HRQoL) from a real-world study of tildrakizumab.

**Methods:** In this Phase 4, uncontrolled, open-label, real-world study (NCT03718299), adult patients with moderate-to-severe plaque psoriasis received tildrakizumab 100 mg at Week (W)0, W4, and every 12 weeks thereafter up to W52. The primary outcome was Psychological General Well-Being Index (PGWBI) total score through W64 (higher scores indicate improvement); Dermatology Life Quality Index (DLQI) was also assessed (higher scores indicate greater impairment). Missing data were not imputed.

**Results:** Of 55 patients enrolled, 45 were assessed at W64; 50.9% were male, and 94.5% were White, with a
mean (standard deviation [SD]) age of 48.6 (15.3) years. The mean (SD) PGWBI total score increased significantly beginning at W4, from 78.1 (14.1) at baseline to 83.2 (13.5) at W64 (P = 0.01), as did positive well-being (12.6 [3.3] to 13.8 [3.2]; P = 0.008) and general health (9.9 [2.5] to 11.5 [2.2]; P < 0.001) component scores. The DLQI score (mean [SD]) improved from 9.4 [5.2] at baseline to 2.0 [2.6] at W64 (P < 0.001); 62.2%, 93.3%, and 78.9% of patients had a DLQI score of 0 or 1, ≤5, and reduction by ≥5 points, respectively.

Conclusion: Treatment with tildrakizumab in a real-world setting significantly improved HRQoL in patients with psoriasis as measured by the PGWBI and DLQI.

Sponsorship: The study and medical writing support for this abstract were funded by Sun Pharma.

16. Secukinumab in Moderate to Severe Hidradenitis Suppurativa: A Pooled Subgroup Analysis From the SUNSHINE and SUNRISE Phase 3 Trials

Jennifer L. Hsiao,1 Vivian Y. Shi,2 Stephanie Mehlis,2 Julia M. Riley,3 John Darcy II,4 Xiaoling Wei,6 Elisa Muscianisi7
1 Department of Dermatology, University of Southern California, Los Angeles, CA; 2 Department of Dermatology, University of Arkansas for Medical Sciences, Little Rock, AR; 3 NorthShore University HealthSystem, Skokie, IL; 4 Northwestern Medicine, Chicago, IL; 5 Novartis Pharmaceuticals Corporation, East Hanover, NJ; 6 Novartis Pharma AG, Shanghai, China; 7 Novartis Gene Therapies, Bannockburn, IL

Introduction: This post hoc analysis assessed the efficacy of secukinumab through 16 weeks in a population of patients with moderate to severe hidradenitis suppurativa (HS) pooled from 2 phase 3 trials.

Methods: This analysis included patients from the phase 3 SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials that evaluated subcutaneous secukinumab 300 mg every 2 weeks (Q2W) and every 4 weeks (Q4W) vs placebo in patients with moderate to severe HS. Included patients were aged ≥18 years, had ≥5 inflammatory lesions affecting ≥2 distinct anatomical areas, and had an HS diagnosis ≥1 year prior to baseline. Patients were pooled by treatment and dose regimen received in SUNSHINE and SUNRISE. Efficacy was assessed by achievement of HS Clinical Response (HiSCR50), defined as ≥50% decrease in abscess and inflammatory nodule (AN) count without increase in the number of abscesses or draining fistulas from baseline, and by percent change in AN count from baseline. Associations between proportions of HiSCR50 responders and patient subgroups (age, sex, and race) were assessed using logistic regression analysis with treatment group, Hurley stage, baseline AN count, geographic region, antibiotic use, baseline body weight, and study as explanatory variables in the model. Data based on multiple imputation are reported. Descriptive statistics were reported for patient demographics.

Results: Overall, 361, 360, and 363 patients who received secukinumab Q2W, secukinumab Q4W, and placebo, respectively, were included; similar proportions of patients in each subgroup were included across treatment groups. Most patients were White and aged <40 years. Secukinumab efficacy was independent of subgroup, with a significantly increased likelihood (OR [95% CI]) of achieving HiSCR50 vs placebo among patient age (<40 years Q2W, 1.77 [1.20-2.61]; P <.01 and Q4W, 1.53 [1.04-2.23]; P=.03; ≥40 years Q4W 1.88 [1.09-3.24]; P=.02), sex (female Q4W, 1.92 [1.28-2.90] and male Q2W, 2.05 [1.27-3.32]; both P<.01), and race subgroups (White Q2W, 1.97 [1.37-2.82]; White Q4W, 1.83 [1.28-2.61]; P<.01). Increased HiSCR rates were achieved in both secukinumab groups vs placebo from week 2 through 16 across age, sex, and race subgroups. Greater improvements in AN counts from baseline were achieved with secukinumab vs placebo, irrespective of subgroup, and were sustained through week 16.

Conclusions: In patients with moderate to severe HS, secukinumab treatment led to higher proportions of HiSCR50 responders and greater improvements in percent change in AN counts from baseline vs placebo through week 16, with efficacy demonstrated independent of patient subgroup. Findings on the efficacy of secukinumab for HS from this subgroup analysis were consistent with findings from the primary analyses in SUNSHINE and SUNRISE trials.

17. Bimekizumab in Patients with Moderate-to-Severe Hidradenitis Suppurativa: 48-Week Efficacy and Safety from Be Heard I & II, Two Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Studies

Alexa B. Kimball,1 Christos C. Zouboulis,2,3 Christopher Sayed,2,4 Joslyn S. Kirby,5 Errol Prens,6,7 John R. Ingram,5,7 Amit Garg,8 Robert Roberi,9 Edward Muller,10 Paulatsya Joshi,10 Gregor Jemeck,2,7,12
1 Beth Israel Deaconess Medical Center and Harvard Medical School, USA, 2 European Hidradenitis Suppurativa Foundation (EHSF), Germany, 3 Departments of Dermatology, Venereology, Allergology and Immunology, Dessau Medical Center, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences, Germany, 4 Department of Dermatology, University of North Carolina School of Medicine, USA, 5 Department of Dermatology, Penn State University, USA, 6 Department of Dermatology, Erasmus University Medical Center Rotterdam, The Netherlands, 7 Department of Dermatology and Academic Wound Healing, Division of Infection & Immunity, Cardiff University, UK, 8 Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, USA, 9 UCB Pharma, USA, 10 UCB Pharma, UK, 11 Department of Dermatology, Zealand University Hospital, Denmark, 12 Department of Clinical Medicine, Faculty of Health and Medical Science, University of Copenhagen, Denmark

Introduction: IL-17F and IL-17A are elevated in hidradenitis suppurativa (HS) tissue[1], highlighting their role in the immunopathogenesis of this disease. Bimekizumab (BKZ) selectively inhibits both IL-17F and IL-17A. This is the first disclosure of positive trial results from the pivotal BKZ 48-week phase 3 BE HEARD I and II (BHI/II) studies, reporting both the efficacy and safety of BKZ in study participants with moderate-to-severe HS.
**Methods:** BE HEARD I and II comprised double-blind 16-week (wk) initial and 32-wk maintenance treatment periods[2–3]. Participants with moderate-to-severe HS were randomized 2:2:2:1 to (initial/maintenance) BKZ 320mg every 2 weeks (Q2W)/Q2W, BKZQ2W/Q4W, BKZQ4W/Q4W, placebo/BKZQ2W. Until Wk16, BKZQ2W/ Q2W and BKZQ2W/Q4W were combined to BKZQ2W. The primary endpoint was HS 50% Clinical Response (HiSCR50) at Wk16; secondary endpoints included HiSCR75. Participants who received systemic antibiotics were also considered non-responders in the pre-specified imputation method.

**Results:** 1,014 participants were randomized (BHI n=505; BHII n=509). BKZQ2W/Q2W=143 (BHI), 145 (BHII); BKZQ2W/ Q4W=146 (both); BKZQ4W/Q4W=144 (both); placebo/ BKZQ2W=72 (BHI), 74 (BHII). More participants achieved HiSCR50 with BKZ at Wk16 than with placebo (BHI: BKZQ2W [47.8%] or BKZQ4W [45.3%] vs placebo [28.7%] p=0.006, p=0.030; BHII: BKZQ2W [52.0%] or BKZQ4W [53.8%] vs placebo [32.2%] p=0.003, p=0.004). A greater proportion of participants achieved HiSCR75 with BKZ at Wk16 than with placebo with statistical significance in BHII (both dosing regimens) and BHII (Q2W). Responses were maintained to Wk48 with BKZ for HiSCR50 and HiSCR75 across dosing regimens and both studies. Safety profile of BKZ across BHI/BHII was consistent with previous studies; no new safety signals were observed.

**Conclusion:** BKZ achieved the primary endpoint, providing higher response rates vs placebo using this conservative imputation method and indicating that blocking IL-17F plus IL-17A was efficacious in moderate-to-severe HS. BKZ was generally well tolerated with no unexpected safety findings.

**References:**
1. Marooj A et al. Translational data suggesting a pivotal role for IL-17A and IL-17F in hidradenitis suppurativa. Poster 3776; SHSA 2022.

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**Disclosures:**
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18. **Efficacy and Safety of Halobetasol Propionate 0.01% and Tazarotene 0.045% Lotion in Combination With a Ceramide-Containing Moisturizer**

Leon Kiricik,
Abby Jacobson

1Icahn School of Medicine at Mount Sinai, New York, NY;
2Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

**Background:** Moisturizers are important components of psoriasis treatment regimens, as they contribute to rehydration and repair of skin barrier function.\(^2\) Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is indicated for the treatment of plaque psoriasis in adults,\(^3\) with a demonstrated clinical profile from two phase 3 clinical trials and a long-term open-label study.\(^4,5\) However, the efficacy of HP/TAZ used alongside a ceramide-containing moisturizer has not been demonstrated, and it is unclear if the order of application affects treatment outcomes. This analysis investigated the efficacy and safety of HP/TAZ applied before or after adjuvant moisturizer (CeraVe®, L’Oreal Group) in adults with mild-to-moderate psoriasis.
Methods: Sixteen participants were randomized (1:1) to receive once-daily HP/TAZ followed by moisturizer on the right side of the body and moisturizer followed by HP/TAZ on the left or vice versa. The assigned treatment protocol was followed for 12 continuous weeks. Endpoints included Investigator’s Global Assessment (IGA) score, Dermatology Life Quality Index (DLQI), visual analog scale (VAS) for itching, tolerability assessments (itching, dryness, and burning/stinging), and adverse events (AEs). Participants were assessed at weeks 2, 4, 8, and 12. A Wilcoxon signed rank test was utilized to calculate P values compared with baseline; 1 participant was lost to follow-up before the week 12 visit, and values were imputed for this visit by last observation carried forward.

Results: Significant improvements from baseline in IGA score were observed at all study visits (P<0.003 for all) regardless of the order in which HP/TAZ and moisturizer were applied (P>0.14). By week 12, 56% of the HP/TAZ-first regimen and 44% of the moisturizer-first regimen achieved an IGA of 0 or 1 (clear or almost clear). IGA improvement was similar regardless of application order. DLQI total score also improved significantly from baseline at each time point (P<0.003 for all). Significant improvements in VAS itch were seen as early as week 4 (P=0.007) and were maintained through week 12. Four moderate AEs were experienced by 3 participants. Two participants reported itching/irritation, which was worse when HP/TAZ was applied first. No serious AEs were reported.

Conclusions: HP/TAZ treatment in combination with ceramide-containing moisturizer had a similar efficacy and safety profile as that seen in clinical trials of HP/TAZ alone, including improvements in disease severity and quality of life. Moisturizer applied immediately before or after HP/TAZ did not decrease therapeutic efficacy in adults with mild-to-moderate psoriasis. However, use of moisturizer before HP/TAZ may reduce incidence of application site AEs associated with treatment and may increase tolerability of treatment.

References:

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19. Rapid Improvements in Itch with Tapinarof Cream 1% Once Daily in Two Phase 3 Trials in Adults with Mild to Severe Plaque Psoriasis
Leon Kiricik1, Matthew Zirwas2, Shawn G. Kwatra3, G. Michael Lewitt4, Holly Glover5, Tomas Chao6, Philip M. Brown7, David S. Rubenstein7, Anna M. Tallman2
1Icahn School of Medicine & Skin Science PLLC, New York, NY; 2Bexley Dermatology, Bexley, OH; 3Johns Hopkins University School of Medicine, Baltimore, MD; 4Illinois Dermatology Institute, Chicago, IL; 5Dermatology and Skin Cancer Surgery Center, Waxahachie, TX; 6Atlanta North Dermatology, Woodstock, GA; 7Dermavant Sciences, Inc, Morrisville, NC

Introduction: Itch has a significant impact on health-related quality of life (HRQoL) for many patients with psoriasis and is reported to be the most bothersome psoriasis symptom. Tapinarof cream 1% once daily (QD), a non-steroidal, topical, aryl hydrocarbon receptor agonist, demonstrated statistically significant efficacy versus vehicle and was well-tolerated in adults with mild to severe plaque psoriasis in two 12-week phase 3 trials, PSOARING 1 and 2.

Objective: To present patient-reported itch outcomes from PSOARING 1 and 2. Methods: Itch was assessed by the proportion of patients achieving a Peak Pruritus Numerical Rating Scale (PP-NRS) score of 0 or 1, indicating an itch-free state, at Week 12 on an 11-point scale (0=not at all; 3=very much); and the Psoriasis Symptom Diary (PSD) items 1 (itching severity) and 2 (bothered by itching), each rating itch on an 11-point scale (0=absent; 10=worst imaginable).

Results: The analysis included 683 tapinarof- and 342 vehicle-treated patients from PSOARING 1 and 2. Mean baseline itch scores were similar in the tapinarof and vehicle groups in both trials: PP-NRS=5.7–6.1; DLQI itch item=1.8–1.9; PSD item 1=5.6–6.0; PSD item 2=5.5–5.7. Improvements in itch were apparent as early as Week 2, the first clinical assessment, and were significantly greater at Week 12 across all measures with tapinarof versus vehicle. A higher proportion of tapinarof-treated patients achieved a PP-NRS score of 0 or 1 (itch-free state) at Week 12 than vehicle in PSOARING 1 and 2, respectively: 49.6% (136/274) vs 32.1% (42/131; P=0.0007), and 50.3% (144/286) vs 27.3% (39/143; P<0.0001). Mean itch scores improved significantly more with tapinarof compared with vehicle at Week 12 in PSOARING 1 and 2, respectively (least squares mean difference): DLQI itch item=–0.3 (P=0.0026) and –0.5 (P<0.0001); PSD item 1=–1.0 and –1.8 (both P<0.0001); PSD item 2=–1.1 and –1.9 (both P<0.0001); and PP-NRS=–1.0 (P=0.0002) and –1.7 (P<0.0001).

Conclusions: Tapinarof cream 1% QD was superior to vehicle in improving itch across multiple patient-reported outcome measures, with rapid, statistically significant, and clinically meaningful reductions in itch and achievement of an itch-free state. Tapinarof cream is an effective, well-tolerated treatment option for patients with mild to severe plaque psoriasis.

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20. Deucravacitinib in Plaque Psoriasis: 2-Year Laboratory Results From the Phase 3 POETYK PSO Program

Neil J. Korman,1 Thierry Passeron,2 Kenneth B. Gordon,3 Yukari Okubo,4 Jerry Bagel,5 Howard Sofen,6 Richard B. Warren,7 Neal Bhatia,8 Lynda Spelman,9 Kevin Winthrop,10 Lauren Hippeli,11 Renata M. Kisa,11 Subhashis Banerjee,11 Diamant Thaci12

1Case Western Reserve University, University Hospitals of Cleveland, Cleveland, OH, USA; 2Côte d’Azur University, University Hospital of Nice, Nice, France; 3Medical College of Wisconsin, Milwaukee, WI, USA; 4Tokyo Medical University, Tokyo, Japan; 5Psoriasis Treatment Center of New Jersey, East Windsor, NJ, USA; 6UCLA School of Medicine, Los Angeles, CA, USA; 7Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; 8Therapeutics Clinical Research, San Diego, CA, USA; 9Veracy Clinical Research, Brisbane, QLD, Australia; 10Oregon Health & Science University, Portland, OR, USA; 11Bristol Myers Squibb, Princeton, NJ, USA; 12University of Lübeck, Lübeck, Germany

Introduction: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 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 or phototherapy. In POETYK PSO-1 and PSO-2, deucravacitinib was significantly more efficacious than placebo or apremilast and well tolerated. PSO-1/PSO-2 completers could enroll in the ongoing long-term extension (LTE) trial. This study examined changes in blood laboratory parameters with deucravacitinib in the 3 trials and compared them with signature changes seen with JAK 1/2/3 inhibitors.

Methods: PSO-1 and PSO-2 randomized patients with moderate to severe plaque psoriasis 1:1:2 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. At Week 52, all eligible patients enrolled in the LTE and received open-label deucravacitinib. Changes from baseline in hematologic parameters (lymphocytes, neutrophils, platelets, hemoglobin) and lipid/chemistry parameters (cholesterol, creatinine, CPK, ALT) known to be impacted by JAK 1/2/3 inhibitors were assessed through Week 100 (LTE Week 48). CTCAE grade ≥3 laboratory abnormalities and treatment discontinuations due to laboratory abnormalities were evaluated.

Results: 1519 patients received ≥1 deucravacitinib dose in PSO-1, PSO-2, and/or the LTE through the cutoff date (October 1, 2021). In total, 1179 (77.6%) and 584 (38.4%) patients had ≥52 and ≥104 weeks, respectively, of continuous deucravacitinib exposure at the cutoff date; median duration of exposure was 97 weeks. Consistent with PSO-1, no trends of clinically meaningful changes from baseline were observed in any of the laboratory parameters from Weeks 0-52 or in the LTE. Grade 3/4 abnormalities over 100 weeks of deucravacitinib treatment were rare, with incidence rates comparable to placebo and apremilast through Week 52; no increases were seen in the LTE. Two patients discontinued deucravacitinib due to laboratory abnormalities (lymphopenia and abnormal hepatic function).

Conclusion: No trends of clinically meaningful changes from baseline were observed with deucravacitinib in hematologic, lipid, or chemistry parameters, including signature changes associated with JAK 1/2/3 inhibitors, for up to 100 weeks. Discontinuations and grade 3/4 laboratory abnormalities were rare and consistent with those in PSO-1/PSO-2, which were comparable to incidence rates seen with placebo and apremilast. Results suggest deucravacitinib does not warrant laboratory monitoring.

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Prurigo nodularis (PN) is characterized by chronic pruritus and multiple localized lesions and an intractable itch-scratch cycle. Breaking this cycle is difficult because of a lack of treatment options. Importantly, patients’ perspectives on the symptoms and impacts of PN, and the treatment outcomes that are most important, are not well understood. We sought to capture patient experiences of living with PN to develop a conceptual disease model (CDM) as a resource for integrating the patient perspective into drug development and guiding the selection of relevant outcome measures for future clinical trials.

Materials and methods: The initial conceptual model was informed by a targeted literature review (which included scientific publications and relevant guidelines) and one-on-one concept elicitation interviews with adults diagnosed with PN who experienced severe itch (peak pruritus numerical rating scale score ≥7 at screening). The model was finalised based on clinical expert review. Interview transcripts were coded and analysed using techniques of qualitative content analysis.

Results: Of the 21 adults with PN and severe itch who were interviewed, most (81%) rated their disease as moderate or severe. All interview participants (100%) reported itching, pain related to PN, bleeding/scabbing, and dry skin; most experienced lumps/bumps (95%), a crust on their skin (95%), burning (90%), stinging (90%), lesions/sores (86%), skin discoloration (86%), raw skin (81%), rough skin (76%), a hot sensation (62%), and tingling (57%). Overall, itch was identified as their worst symptom. Furthermore, participants described substantial impacts of PN on their quality of life, including sleep disturbance (100%) and impacts on daily life (100%), feelings or mood (95%), relationships (95%), social life (81%), and work or school (71%). The CDM of PN emerging from these qualitative data illustrates how symptoms and impacts are interlinked in the minds of patients: itching causes scratching, which in turn leads to bleeding/scabbing and inflammation or infection; patients also feel that skin sensations and skin changes are directly or indirectly related to itching or to characteristic disease signs such as bumps and sores. Some impacts of PN, such as sleep disturbance and emotional impacts, are directly linked to itching in patients’ minds. Patients also link sleep disturbance resulting from night-time itching and scratching to disabling impacts on daily activities and work/school.

Discussion: The emergent CDM highlights how patients living with PN and severe pruritus process the interrelationships of core symptoms and downstream clinical and psychosocial impacts. The model confirms the relevance of different disease concepts to people with PN and identifies patient-relevant outcomes that can be used to assess treatment benefit in future PN clinical trials.
change thresholds for 3 patient-reported outcome instruments have been assessed in patients with PN: Worst Itch Numerical Rating Scale (WI-NRS), Skin Pain-NRS, and Sleep-NRS. The proportion of patients achieving clinically meaningful improvement in these scores was investigated in 2 pooled randomized, double-blind, placebo-controlled, phase 3 trials of dupilumab in adults with PN uncontrolled on topical therapies, LIBERTY-PN PRIME (NCT04183335) and PRIME2 (NCT04202679).

Methods: Adults with PN inadequately controlled on topical prescription therapies or when those therapies are not advisable were randomized 1:1 to dupilumab 300 mg every 2 weeks or matched placebo. Here we report the proportion of patients with a ≥4-, ≥4-, and ≥2-point improvement (within-patient meaningful improvement) in weekly average WI-NRS, Skin Pain-NRS, and Sleep-NRS (ranges 0–10), respectively, from baseline to Week 24.

Results: 311 patients were randomized (dupilumab/placebo, n=153/n=158). Baseline characteristics for WI-NRS, Skin Pain-NRS, and Sleep-NRS were balanced between treatment groups. Significantly more patients treated with dupilumab vs placebo achieved within-patient meaningful improvement in WI-NRS (58.8% vs 19.0%; P<0.0001), Skin Pain-NRS (49.7% vs 20.9%; P<0.0001), and Sleep-NRS (42.5% vs 23.4%; P<0.0001) from baseline to Week 24. The safety profile of dupilumab was consistent with the known safety profile in its approved indications.

Conclusion: Adults with PN uncontrolled on topical therapies treated with dupilumab achieved statistically significant and clinically meaningful improvement in itch, skin pain, and sleep quality.

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23. 24-Month Drug Persistence of Gusekumab as Compared to Other Biologic Therapies in Biologic-Experienced Patients With Plaque Psoriasis

Mark Lebwohl, MD,1 Timothy Fitzgerald, PhD,2 Rachel Teneralli, PhD,3 Judson Janak, PhD,4 Maya Marchese, MS,5 Katelyn Rowland, MS, ARNP,2 Olivia Choi, MD, PhD,2 Daphne Chan, PhD,2 Elizabeth Lesser, MS,3 Michael Cameron, MD,1 Bruce Strober, MD, PhD6

1Icahn School of Medicine at Mount Sinai, New York, NY, USA; 2Janssen Scientific Affairs, Horsham, PA, USA; 3Janssen Global Services, LLC, Horsham, PA, USA; 4CorEvitas, LLC, Waltham, MA, USA; 5Yale University School of Medicine, New Haven, CT, USA; Central Connecticut Dermatology, Cromwell, CT, USA

Introduction: Clinical trials show that high levels of clinical response and improvement in patient-reported outcomes of plaque psoriasis through five years can be achieved by treatment with gusekumab (GUS). Although several biologic therapies are approved for the treatment of moderate-to-severe disease, challenges remain for addressing long-term control in those with prior biologic use. The objective of this study was to compare treatment persistence over a 24-month follow-up period of biologic-experienced patients initiating GUS versus three biologic therapies: ixekizumab (IXE), secukinumab (SEC), and adalimumab (ADA).

Methods: This was a retrospective cohort study of bio-experienced patients with plaque psoriasis from the CorEvitas Psoriasis Registry initiating either GUS or a comparator biologic therapy between 7/13/2017 and 1/10/2022. Patient characteristics were collected at biologic treatment initiation. To estimate the average treatment effect on the treated, standardized mortality ratio weighting (SMR-W) was used to adjust for potential confounding between patients initiating GUS and each comparator separately by reweighting comparator patients to be representative of the GUS population.

Results: The study included 1584 biologic-experienced patients with plaque psoriasis (GUS [n=546]; IXE [n=485]; SEC [n=466]; ADA [n=87]). The 24-month SMR-W average treatment persistence for initiators ranged from approximately 14 to 18 months: GUS, 18 months (95% confidence interval [CI]: 17, 18); IXE, 17 months (16, 18); SEC, 17 months (16, 17); ADA, 14 months (12,16). GUS initiators had a significantly longer 24-month SMR-W average treatment persistence compared to patients initiating SEC or ADA: GUS vs. SEC (5 weeks [95% CI: 0.2,10]) and GUS vs. ADA (18 weeks [59,27]). Similarly, GUS initiators had significantly lower relative rates of discontinuation: GUS vs. SEC, hazard ratio (HR) 0.8 (95% CI: 0.6, 0.9) and GUS vs. ADA, HR 0.5 (0.3, 0.7).

GUS initiators had numerically longer 24-month SMR-W average treatment persistence than IXE: GUS vs. IXE, (3 weeks [95% CI: –1.9, 8]); and lower relative rates of discontinuation: GUS vs. IXE, (HR: 0.9 [0.7, 1.1]).

Conclusion: This real-world study demonstrated that biologic-experienced GUS initiators had the longest treatment persistence and lowest rate of discontinuation within a 24-month treatment period vs. SEC and ADA and similar treatment persistence vs. IXE in a large US registry. As prior biologic use can impact the success of subsequent biologics examining persistence in this population may inform treatment sequencing.

24. Brodalumab: 4-Year US Pharmacovigilance Report

Mark Lebwohl,1 Andrea Murina,2 George Han,3 Abby Jacobson4

1Icahn School of Medicine at Mount Sinai, New York, NY; 2Tulane University School of Medicine, New Orleans, LA; 3Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY; 4Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

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

Methods: Here, we review the pharmacovigilance data over a 4-year reporting period to provide insight into the safety of brodalumab for the treatment of moderate-to-severe psoriasis in adults. Pharmacovigilance data for brodalumab were compiled from August 15, 2017, to August 14, 2021, from US patients and healthcare providers. The most common AEs listed in the brodalumab package insert (incidence ≥1%; arthralgia, headache, myalgia, influenza, diarrhea, oropharyngeal pain, nausea, injection-site reactions, fatigue, neutropenia, and Tinea infections) and AEs of special interest were assessed as exposure-adjusted rates per 100 patient-years (PYs). Exposure was estimated as the time between first and last prescription-dispensing authorization dates. Patients with the same initial and last prescription-dispensing authorization date were excluded.

Results: Data were collected from 4019 US patients and exposure was estimated as 4563 PYs. There were 2188 unique AE cases reported, 22% of which were reported by healthcare providers and 78% by patients. The most common AE was arthralgia (115 reports, 2.52 events/100 PYs). Since the 3-year report, 2 new cases of headache, 3 new cases of myalgia, 1 new case of influenza, 1 new case of diarrhea, and 1 new case of oropharyngeal pain were reported; no new cases of fatigue, injection-site reactions, neutropenia, or Tinea infections were reported. No new suicide attempts or completed suicides were reported. Within the 4-year reporting period, 102 serious infections (prolonged or requiring intervention) occurred, 3 of which were considered as related to brodalumab. There were 24 patients with confirmed COVID-19. No new cases of Crohn’s disease were reported since the 2-year report (1 case), and there was 1 new case of ulcerative colitis (most likely unrelated to brodalumab). Of 37 malignancies reported in 32 patients (0.81 events/100 PYs), including 30 cases previously reported in the 3-year analysis, none were related to brodalumab.

Conclusion: These pharmacovigilance data are consistent with previous pharmacovigilance data and the safety profile of brodalumab established in pivotal clinical trials. No trends or safety signals emerged.

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26. Effectiveness and Safety of Guselkumab in Patients with Facial and/or Genital Psoriasis: Interim Analysis Results at Week 12 from GULLIVER Study

Claudio Bonifati1, Concetta Potenza2, Federico Bardazzi3, Luca Bianchi4, Claudia Lasagni5, Gabriella Fabbrocin6, Vito Di Lernia7, Sabatino Pallotta8, Marco Romanelli9, Francesco Loconsole9, Aurora Parodi10, Carlo G. Carrera10, Maria Rita Bongiorno13, Talia Gramiccia14, Giuseppe Argenziano15

1San Gallicano Dermatological Institute, Italy; 2Sapienza University of Rome, Italy; 3University of Bologna, Italy; 4University of Rome, Italy; 5AOU Policlinico di Modena, Italy; 6University of Naples Federico-II, Italy; 7Arcispedale S. Maria Nuova, Azienda ULSS-IRCCS, Italy; 8Fondazione Luigi M. Monti, Italy; 9University of Pisa, Italy; 10University of Bari, Italy; 11University of Genoa, Italy; 12Fondazione IRCCS Ca’Granda Ospedale Maggiore Policlinico, Italy; 13University of Palermo, Italy; 14Medical Affairs Department, Janssen-Cilag SpA, Italy; 15University of Campania Luigi Vanvitelli, Italy.

Introduction: Guselkumab, an interleukin-23 inhibitor, demonstrated efficacy in patients with moderate-to-severe plaque psoriasis. GULLIVER study, a non-interventional study is evaluating the effectiveness and safety of guselkumab in patients with psoriasis, with a significant involvement (defined as sPGA score≥3) of genital and/or facial area. This interim analysis evaluated the effectiveness and safety of guselkumab at week 12 among patients with moderate-to-severe psoriasis (defined as PASI score>10) enrolled in GULLIVER study.

Methods: Effectiveness of guselkumab was evaluated by calculating percentage of participants achieving PASI 100, PASI 90 and PASI 75 responses through first 12 weeks treatment. Additionally, an in-depth analysis was conducted, calculating improvements by individual PASI components (erythema, thickness, and scaling) of each body region (head, trunk, upper extremities, and lower extremities). To date, 270 patients have been enrolled in the study. An interim analysis including 172 patients was conducted among patients enrolled in the study who completed 12 weeks of guselkumab treatment on 31-Dec, 2021.

Results: Of the 172 selected patients (male, 57.8%; mean BMI, 28.0; mean disease duration from diagnosis to first guselkumab dose, 12.7±12.9 years; received at least one biologic agent, 38.6%), 83 (48.3%), presented a PASI score >10 at baseline. Patients achieving PASI 100/90/75 at week 12 was 45.8% (n=38), 73.5% (n=61) and 88.0% (n=73), respectively. Overall mean PASI markedly decreased from baseline to week 12: mean (±SD) change of total score was –16.9±7.7. Improvements from baseline to week 12 in erythema, thickness, and scaling were observed across all body regions. Percentage of patients with moderate-to-severe score at baseline achieving score 0/1 (none/slight) for erythema, thickness, and scaling, respectively, was as follows: head (84.2%, 90.6%, 91.7%), trunk (83.3%, 89.6%, 92.3%), upper extremities (85.4%, 90.7%, 91.3%), and lower extremities (84.3%, 89.6%, 93.8%). Twelve TEAEs were reported in 7 (8.4%) patients (1 patient: treatment-related in [worsening of psoriasis leading to study discontinuation]; none: serious).

Conclusions: This interim analysis showed guselkumab was effective for treating moderate-to-severe chronic plaque psoriasis in real-life clinical practice through 12 weeks of treatment. PASI responses obtained in this analysis were in line with results observed for VOYAGE 1, VOYAGE 2 and ECLIPSE trials but showing a higher proportion of patients reaching a complete resolution (PASI 100) after 12 weeks of treatment (45.8% vs 21.6%, 23.8% and 37.8%, respectively).

27. Dupilumab Improves Urticaria Signs and Symptoms and Quality of Life in Patients With Chronic Spontaneous Urticaria (CSU)

Marcus Maurer1,2, Thomas B. Casale3, Sarbjit S. Saini4, Moshe Ben-Shoshan5, Allen Radin6, Deborah Bauer7, Ryan B. Thomas8

1Institute of Allergology, Charité – Universitätsmedizin Berlin, corporate member of Free University, Berlin and Humboldt-University of Berlin, Berlin, Germany; 2Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Allergology and Immunology, Berlin, Germany; 3Division of Allergy and Immunology, University of South Florida, Tampa, FL, USA; 4Johns Hopkins Asthma and Allergy Center, Baltimore, MD, USA; 5Department of Pediatrics, Division of Allergy/Immunology/Dermatology, McGill University Health Centre, Montreal, QC, Canada; 6Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; 7Sanoﬁ, Bridgewater, NJ, USA

Background: Chronic spontaneous urticaria (CSU) is a chronic inflammatory disease characterized by wheals and/or angioedema recurring for >6 weeks that impacts quality of life (QoL) through itch and disruptions in emotional wellbeing, daily activities, and work/school performance. Many patients continue to experience disease burden despite treatment with H1-antihistamines. The purpose of this study was to report the effect of dupilumab treatment on disease burden and QoL in patients with CSU from LIBERTY-CSU CUPID Study A.

Methods: LIBERTY-CSU CUPID Study A (NCT04180488) was a randomized, placebo-controlled, phase 3 trial of dupilumab treatment for 24 weeks in adults, adolescents, and children (≥6 years) with CSU who remain symptomatic despite use of standard-of-care H1-antihistamines. Patients receiving H1-antihistamine (up to fourfold approved dose) were randomized to receive add-on dupilumab 300 mg (adults/adolescents ≥60 kg) or 200 mg (adolescents <60 kg, children ≥30 kg) (n=70) or matching placebo (n=68) subcutaneously every 2 weeks. Efficacy endpoints included the Urticaria Activity Score over 7 days (UAS7; range 0–42). Health-related QoL outcomes included the Chronic Urticaria Quality of Life Questionnaire (CU-QoL; range 0–100 [higher scores indicate greater QoL impairment]).

Results: Mean UAS7 and CU-QoL scores at baseline...
were 31.9/30.8 (dupilumab [n=70]/placebo [n=68]) and 41.0/46.7, respectively. UAS7 improved significantly in dupilumab-treated patients; at Week 24, least squares (LS) mean change from baseline was −20.5/−12.0 for dupilumab/placebo, respectively (difference −8.5, \( P=0.0003 \)).

Similar results were seen in CU-Q2oL scores at Week 24; LS mean change from baseline was −29.6/−21.0 for dupilumab/placebo, respectively (difference −8.6; nominal \( P=0.0049 \)).

Conclusions: Patients with CSU treated with dupilumab experienced reduction in urticaria activity, as measured by UAS7, and improvement in quality of life, as measured by CU-Q2oL.

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28. Bimekizumab (Bkz) Efficacy and Safety in Biologic DmARD-Naïve Patients with Psoriatic Arthritis (Psa) Was Consistent Without or With Methotrexate (MtX): 52-Week Results from the Phase 3 Active-Reference Study Be Optimal

Iain B. McNenes,1 Philip J. Mease,2 Yoshiya Tanaka,3 Frank Behrens,4 Laure Gossec,5 M. Elaine Husni,6 Lars E. Kristensen,7 Richard B. Warren,8 Barbara Ink,9 Rajan Bajracharya,9 Jason Coarse,9 Jason Eells,10 Alice B. Gottlieb11

1College of Medical Veterinary and Life Sciences, University of Glasgow, UK. 2Swedish Medical Center and Providence St. Joseph Health, University of Washington, USA. 3The First Department of Internal Medicine, University of Occupational and Environmental Health, Japan. 4Division of Rheumatology, University Hospital and Fraunhofer Institute for Translational Medicine & Pharmacology ITMP, Goethe University, Germany. 5Sorbonne Université, and AP-HP, Pitié-Salpêtrière Hospital, France. 6Department of Rheumatic and Immunologic Diseases, Cleveland Clinic, USA. 7The Parker Institute, Copenhagen University Hospital, Denmark. 8Dermatology Centre, Salford Royal NHS Foundation Trust, The University of Manchester, UK. 9UCB Pharma, UK. 10UCB Pharma, USA. 11Department of Dermatology, The Icahn School of Medicine at Mount Sinai, USA

Introduction: Given the chronic nature of PsA, understanding long-term efficacy and safety of biologic monotherapy or therapy in combination with ongoing MTX is of interest.1

Objectives: To report the efficacy and safety of BKZ, a monoclonal immunoglobulin G1 (IgG1), to Wk52 from the phase 3 study BE OPTIMAL in biological disease-modifying antirheumatic drug (bDMARD)-naïve patients (pts) with PsA, with or without ongoing concomitant MTX.2

Methods: BE OPTIMAL (NCT03895203) comprised a 16-wk double-blind placebo (PBO) controlled period and a 36-wk active treatment-blind period. Pts were randomized 3:2:1 subcutaneous BKZ 160mg every 4wks (Q4W):PBO:reference arm (adalimumab [ADA] 40mg Q2W). From Wk16, PBO pts received BZK 160mg Q4W. Pts could not adjust their background medication during the 16-wk PBO-controlled period. Efficacy and safety were evaluated by concomitant MTX use at baseline (BL).

Results: 761/852 (89.3%) pts completed Wk52 (+MTX: 454/497 [91.3%], −MTX:307/355 [86.5%]). BL characteristics were generally similar +/-MTX: mean age 48.1 vs 49.4 years, BMI 29.1 vs 29.4 kg/m2, 5.7 vs 6.2 years since diagnosis, 47.3% vs 46.2% male, 49.5% vs 50.4% with psoriasis affecting ≥3% body surface area. To Wk52, the proportions of BKZ-randomized pts who achieved American College of Rheumatology (ACR)50, complete skin clearance (Psoriasis Area and Severity Index [PASI]100), and minimal disease activity (MDA) were similar regardless of BL MTX use. Fewer pts receiving ADA –MTX achieved ACR50 or MDA at Wk52 compared to ADA +MTX. Other Wk52 efficacy responses on BKZ were generally of a similar magnitude +/-MTX. To Wk52, pts with ≥1 treatment-emergent adverse event +/-MTX: PBO/BKZ 124/158 (78.5%) vs 89/113 (78.8%), BKZ 214/252 (84.9%) vs 150/179 (83.8%), ADA 63/82 (76.8%) vs 50/58 (86.2%).

Conclusions: BKZ treatment demonstrated consistent sustained clinical efficacy across disease manifestations to Wk52 in bDMARD-naïve pts with PsA, irrespective of concomitant MTX. BKZ was well tolerated in pts with PsA with or without MTX.


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29. Cytokine Targeting Activity of Halobetasol Propionate/Tazarotene Lotion For Difficult-to-Treat Psoriasis

Lauren Miller,¹ Leon Kirck,² Zoe Draelos,³ Matthew M. Draelos,⁴ Linda Stein Gold,⁴ Abby Jacobson⁴
¹Dermatology Specialists of Alabama, Gadsden, AL; ²Icahn School of Medicine at Mount Sinai, New York, NY; ³Dermatology Consulting Services, PLLC, High Point, NC; ⁴Henry Ford Health System, Detroit, MI; ⁵Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

Background: Tumor necrosis factor-α (TNF-α) plays a key role in the pathogenesis of psoriasis and is a target of systemic therapies. A recent study demonstrated that fixed-combination halobetasol propionate 0.01%/tazarotene 0.045% lotion (HP/TAZ) substantially reduced TNF-α levels in psoriatic plaques at weeks 2 through 12 of treatment compared with levels in untreated plaques. The additive effect of HP and TAZ on reduction of proinflammatory mediators such as TNF-α may improve outcomes in difficult-to-treat areas, such as the palms, soles of the feet, and scalp; additionally, TAZ may mitigate the risk of skin atrophy associated with prolonged topical corticosteroid use.

Methods: In an investigator-initiated study, participants with moderate-to-severe palmoplantar psoriasis (N=17) were treated once daily with HP/TAZ for 24 weeks. In a separate study, participants with scalp psoriasis (N=21) applied HP/TAZ once daily for 8 weeks and were followed for 4 weeks posttreatment (week 12). HP/TAZ was well tolerated in both studies.

Results: In the first study, palmoplantar psoriasis significantly improved with HP/TAZ treatment (baseline mean palmoplantar Physician’s Global Assessment 3.47 vs 2.82 at week 24, P=0.0165). After 8 weeks of HP/TAZ treatment in the second study, 72% of participants had achieved clear or almost clear on the scalp Investigator’s Global Assessment, and nearly 30% were completely clear. At the 12-week follow-up, 50% of participants maintained a rating of clear or almost clear.

Conclusions: The inhibition of TNF-α by tazarotene, combined with effects of halobetasol on gene transcription, may contribute to the effectiveness of HP/TAZ in psoriasis lesions involving difficult-to-treat areas.

Prior presentations: Data in this poster have been published previously (Ozyurekoglu and Kirck. J Drugs Dermatol. 2021;20:1191-1194) and were presented at the 2022 American Academy of Dermatology Annual Meeting; March 25-29, 2022; Boston, MA, and at the Fall Clinical Dermatology Conference; October 20-23, 2022; Las Vegas, NV, and Virtual.

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30. Dupilumab Treatment Results in Rapid, Sustained and Clinically Meaningful Improvement in Itch in Patients Aged 6 Months to 5 Years with Moderate-to-Severe Atopic Dermatitis

Amy S. Paller¹², Elaine C. Siegfried¹³,⁴ Gil Yosipovitch⁵, Shawn G. Kwatra⁶, Amy Praestgaard⁷, Zhixiao Wang⁸, Randy Prescilla⁹
¹Northwestern University Feinberg School of Medicine, Chicago, IL, USA; ²Ann and Robert H. Lurie Children’s Hospital, Chicago, IL, USA; ³Saint Louis University, St. Louis, MO, USA; ⁴Cardinal Glennon Children’s Hospital, St. Louis, MO, USA; ⁵University of Miami, Miami, FL, USA; ⁶Johns Hopkins University, Baltimore, MD, USA; ⁷Sanofi, Cambridge, MA, USA; ⁸Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

Introduction: Atopic dermatitis (AD) is characterized by intense pruritus. Dupilumab treatment has demonstrated rapid onset of itch reduction in adults, adolescents, and school-age children in previous phase 3 studies.

Methods: LIBERTY AD PRESCHOOL (NCT03346434 part B) was a 16-week, randomized, double-blind, placebo-controlled phase 3 study, during which children aged 6 months to 5 years were randomized 1:1 to dupilumab 200/300mg + topical corticosteroids (TCS) every 4 weeks (q4w; n=83), or placebo + TCS (n=79). Caregiver-reported Worst Scratch/Itch NRS scores (WSI-NRS; 0–10) were assessed from baseline to Week 16.

Results: From Day 9, treatment with dupilumab 200/300mg q4w + TCS significantly improved itch compared to placebo + TCS, as measured by LS mean percent change from baseline in Daily WSI-NRS (~16.8% vs +8.0%; P=0.005)). At Week 16, patients treated with dupilumab showed a significant reduction in LS mean percentage change from baseline in Weekly PP-NRS compared to placebo (~49.4% vs −2.2%; P<0.0001). At Week 2, 10.8% of patients treated with dupilumab showed ≥4-point improvement in average Weekly WSI-NRS,
compared to 2.5% of the placebo group (P=0.04). The proportion of dupilumab-treated patients with ≥4-point improvement increased to 49.4% at Week 16, compared to 12.7% in the placebo group (P<0.0001). Overall safety was consistent with the known dupilumab safety profile.

**Conclusion:** Dupilumab treatment leads to rapid and sustained improvement in itch in children with moderate-to-severe AD aged 6 months to 5 years, with a significant effect seen as early as Day 9.

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- **Wang Z:** Regeneron Pharmaceuticals, Inc. – employee and shareholder.

**Praestgaard A, Prescilla R:** Sanofi – employees, may hold stock and/or stock options in the company.

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**31. Efficacy of Dupilumab in Infants and Preschoolers With Atopic Dermatitis up to 1 Year**

Amy S. Paller1,2, Elaine C. Siegfried3,4, Jing Xiao2, Randy Prescilla4, Ashish Bansal7

1Northwestern University Feinberg School of Medicine, Chicago, IL, USA; 2Ann and Robert H. Lurie Children’s Hospital, Chicago, IL, USA; 3Saint Louis University, St Louis, MO, USA; 4Cardinal Glennon Children’s Hospital, St Louis, MO, USA; 5Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; 6Sanofi, Cambridge, MA, USA

**Introduction:** Continuous use of several traditional systemic atopic dermatitis (AD) treatments in pediatric patients is not recommended due to safety concerns and lack of long-term efficacy data. The current study aimed to evaluate efficacy and safety of dupilumab up to 1 year in infants and preschoolers with moderate-to-severe AD.

**Methods:** Children aged 6 months to 5 years with moderate-to-severe AD who had participated in the 16-week, double-blind, phase 3 LIBERTY AD PRESCHOOL trial (NCT03346434, part B; parent study) were enrolled into an open-label extension (OLE) study (NCT02612454). Patients received subcutaneous dupilumab every 4 weeks (200 mg for children weighing 5 to <15 kg; 300 mg for 15 to <30 kg). Topical AD treatments were allowed.

**Results:** Relative to parent study baseline, mean percentage changes (± standard error) in Eczema Area and Severity Index score were −41.6 (±4.6) and −54.0 (±3.2) at OLE baseline, −74.5 (±3.7) and −81.7 (±1.8) at Week 16, and −85.6 (±3.5) and −86.4 (±2.2) at Week 52 in the 200 mg and 300 mg dupilumab groups, respectively. The number of patients (%) achieving an Investigator’s Global Assessment score of 0/1 increased from OLE baseline (6/61 [9.8%] and 15/116 [12.9%]), to Week 16 (22/58 [37.9%] and 35/115 [30.4%]), and at Week 52 (16/34 [47.1%] and 18/54 [33.3%]) in the 200 mg and 300 mg dupilumab groups, respectively. Overall safety of dupilumab treatment administered for up to 1 year was consistent with the known dupilumab safety profile.

**Conclusion:** Dupilumab treatment for 1 year provides sustained improvement in signs of AD in patients aged 6 months to 5 years with moderate-to-severe AD.

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**32. Tapinarof Cream 1% Once Daily for the Treatment of Extensive Atopic Dermatitis in Adolescents and Children: Outcomes from the 4-week Maximal Usage Trial**

Amy Paller1, Adelaide Hebert3,4, Philip M. Brown2, Victoria Butners2, Nancy Fitzgerald3, Marta Delgado5, Mercedes E. Gonzalez6, Stephen C. Piscitelli2

1Northwestern University Feinberg School of Medicine, Chicago, IL, USA; 2Dermavant Sciences, Inc., Morrisville, NC, USA; 3McGovern School of Medicine and Children’s Memorial Hermann Hospital, UTHouston McGovern, Houston, TX, USA; 5UTHealth McGovern Medical School, Houston, TX, USA; 6RM Medical Research, Inc., Miami Lakes, FL, USA; 7Pediatric Skin Research, LLC Miami, FL, USA

**Introduction:** Tapinarof cream 1% once daily (QD) demonstrated significant efficacy versus vehicle and was well tolerated in adults and adolescents with moderate to severe AD in a previously reported phase 2b trial. The pharmacokinetic (PK) profile of tapinarof across psoriasis and AD trials in adults is characterized by minimal-to-no systemic absorption and decreasing plasma concentrations over the course of treatment.

**Objective:** Here, we report PK, tolerability, and safety of tapinarof cream 1% QD in adolescents and children down to age 2 years with extensive AD.

**Methods:** Adolescents and children with a Validated Investigator Global Assessment score for Atopic Dermatitis™ (vIGA-AD™) score ≥3 and body surface area (BSA) involvement ≥25% (ages 12–17 years) or ≥35% (ages 2–11 years) were enrolled into three age cohorts (2–6,
7–11, and 12–17 years) and were treated with tapinarof cream 1% QD for 4 weeks. Primary endpoints included PK parameters, investigator-assessed Local Tolerability Scale (LTS) scores by visit (overall and for sensitive areas), and treatment-emergent adverse events (TEAEs).

**Results:** Overall, 36 patients (12 per cohort) were enrolled. Patients’ mean age was 8.9 years and 66.7% were male. At baseline, 77.8% (28/36) of patients had a vGQA-AD™ score of 3 (moderate), mean BSA affected of 42.8% (range 26–90%), and mean Ezema Area and Severity Index (EASI) score of 23.8. Minimal-to-no tapinarof systemic exposure was observed; mean maximum plasma concentration (C_{\text{max}}) was 2.4 ng/mL and the median time to C_{\text{max}} was approximately 3 hours, for all patients. Approximately 25% of post-treatment plasma samples below the quantifiable limit of the highly sensitive assay (<50 pg [10-12]/mL). There was no correlation between tapinarof exposure (C_{\text{max}} on Day 1) and baseline %BSA affected. Mean overall investigator-assessed LTS score was 0.1 (no irritation) at Weeks 1 and 4; most patients had no irritation (LTS=0), including on sensitive and intertriginous skin. TEAEs were reported by 8 patients (22%) and were all mild or moderate; one patient discontinued due to two unrelated TEAEs. One case of mild folliculitis and no contact dermatitis occurred. Most patients (87.5%) chose to enroll in the 48-week long-term extension trial.

**Conclusions:** Tapinarof cream 1% QD demonstrated minimal-to-no systemic exposure in children with extensive AD, even when measured with a highly sensitive assay. There was a low incidence of TEAEs in patients with up to 90% BSA affected. Tapinarof cream was well tolerated, including on sensitive and intertriginous skin areas.

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**References:**

study evaluated the association between patient-reported disease burden and treatment switching from nonbiologic to biologic therapy in patients with plaque psoriasis enrolled in the CorEvitas Psoriasis Registry.

**Methods:** This cross-sectional study included biologic-naïve patients aged ≥18 years who had used nonbiologic systemic therapy 28–365 days prior to their Registry enrollment between April 2015 and August 2022. A switch to biologic therapy was defined as the introduction of biologic treatment up to 45 days post-enrollment, in addition to or in place of the initial nonbiologic systemic therapy. Measures of patient-reported disease burden collected at enrollment were: the Dermatology Life Quality Index (DLQI); Work Productivity and Activity Impairment Index (WPAI); itch, skin pain, fatigue, and Patient Global Assessment (PGA), measured on visual analog scales (VAS); and the EuroQoL 5-Dimension, 3-Level (EQ-5D-3L) questionnaire. The association between each patient-reported disease burden measure and switching to biologic therapy was evaluated using multivariable logistic regression models, adjusting for age, sex, race, ethnicity, work status, body mass index, psoriasis duration, psoriatic arthritis status, disease severity, number of prior nonbiologic therapies used, and history of difficult-to-treat areas. A secondary analysis stratified each model by patients with PASI scores ≤2 or >2.

**Results:** Of 848 patients included in the analysis, 323 (38.1%) switched to biologic treatment at enrollment. Significantly higher odds of switching were observed for patients reporting greater vs lesser burden on the DLQI (adjusted odds ratio [aOR] = 1.55; 95% CI, 1.08–2.23); VAS measures of itch (aOR = 2.14; 95% CI, 1.49–3.08), skin pain (aOR = 2.18; 95% CI, 1.45–3.29), fatigue (aOR = 1.66; 95% CI, 1.15–2.40), or PGA (aOR = 3.09; 95% CI, 1.94–4.91); or WPAI activities impairment (aOR = 2.51; 95% CI, 1.72–3.65). Numerically higher odds of switching were observed for greater vs lesser burden measured by EQ-5D-3L. In the secondary analysis, 52 of 330 patients with PASI scores ≤2 (15.8%) switched to biologic treatment. Among patients with PASI scores ≤2, those with greater vs lesser burden for VAS itch, skin pain, or PGA, or with impairment of their usual activities as measured by EQ-5D-3L had significantly higher odds of switching to biologic treatments.

**Conclusion:** Data collected from real-world patients with plaque psoriasis suggest that, in addition to disease severity, patient-reported disease burden, such as itch and skin pain, may be an important driver of switching from a nonbiologic to biologic therapy, even among patients with a low degree of skin involvement.

**35. The 31-Gene Expression Profile Outperforms Ajcc and Cp-Gep in Stratifying Risk of Recurrence in Patients with Stage I Cutaneous Melanoma**

Sebastian Podlipnik, MD1,4, Valentina Petkov, MD, MPH1, Jung Byun, PhD, MPH2, Christine Bailey, MPH3, Robert Cook, PhD3, Kelli Ahmed, PhD3, Brian Martin, PhD3, Susana Puig, MD1,4,5

1Department of Dermatology, Hospital Clinic of Barcelona, Barcelona, Spain, 2Surveillance Research Program, National Cancer Institute, Bethesda, Maryland, USA, 3Castle Biosciences, Inc, Friendswood, Texas, USA, 4Department of Dermatology, University of Barcelona, Barcelona, Spain, 5Centro de Investigación Biomédica en Red de Enfermedades Raras, CIBERER, Instituto de Salud Carlos III, Barcelona, Spain

**Background:** American Joint Committee on Cancer (AJCC) staging stratifies patients with cutaneous melanoma (CM) according to risk of dying based on pathological tumor characteristics and the presence of locoregional/distant metastasis at diagnosis. Stage I CM is considered low risk for recurrence and melanoma-specific death; however, due to the large number of patients diagnosed as stage I, they account for the largest number of melanoma deaths. Thus, additional methods that better identify which patients are truly low risk versus who may benefit from increased clinical surveillance are needed. The 31-gene expression profile (31-GEP) test is validated to stratify patients into low (Class 1A), intermediate (Class 1B/2A), or high (Class 2B) risk of recurrence, metastasis, and death.

**Methods:** We analyzed survival data for patients with stage I CM who were 31-GEP tested and enrolled in previous prospective and retrospective studies (combined cohort, n=1261), and stage I patient data provided by Surveillance, Epidemiology, and End Results (SEER) registries (diagnosis=2013-2018) that were linked to data for patients clinically tested with the 31-GEP (SEER cohort, n=5651 after exclusions). AJCC and CP-GEP, another GEP-based prognostic test, data were from previously published reports.

**Results:** Patients with low-risk 31-GEP results had significantly higher 5-year recurrence-free survival (RFS) rates than those with intermediate- or high-risk 31-GEP results (97.3% vs. 88.6% vs. 77.3%, p<0.001)—better stratification than seen in AJCC stage IA versus stage IB patients (93.3% for IA vs. 87.6% for IB, p-value not reported) or another GEP-based test, CP-GEP (low-risk: 92.9% vs. high-risk: 86.0%, p=0.184). The 31-GEP stratified 5-year melanoma-specific survival (MSS) in both the combined cohort and the SEER cohort (class 1A=99.7% and 98.0% vs. class 1B/2A=97.6% and 97.5% vs. class 2B=88.8% and 92.3%, p<0.001) better than AJCC (IA=98.5% vs. IB=96.1%, p-value not reported). CP-GEP did not report MSS.

**Conclusions:** In stage I CM patients, the 31-GEP provided more prognostic stratification of 5-year RFS and MSS than AJCC staging alone, while the CP-GEP test did not provide more stratification. Incorporating the 31-GEP into clinical practice can help guide risk-aligned care in a low-risk population by identifying high-risk patients who may be missed using AJCC staging alone.

**36. Aesthetic Outcomes of Combining a Series of In-Office Chemical Peels with an At-Home Topical Pigmentation Control Regimen to Treat Facial Hyperpigmentation**

Katie Schneider, BS1, Lisa T. Goberdhan, MSHS1, Arielle Bautista, BS1, Tsing Cheng, PhD1, Rahul C. Mehta, PhD1, Elizabeth T. Makino, BS CCRA MBA1

1Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA
Purpose: Combination treatments have shown greater effectiveness than individual therapies in managing hyperpigmentation, and can be tailored to patients' specific needs. We conducted a series of 6 case studies to assess the cosmetic changes of a combination of 3 different in-office chemical peels with an at-home skincare regimen including a novel collection of pigmentation control products, in subjects with mild to severe facial hyperpigmentation.

Procedure: The chemical peels I, V, and R, are superficial depth peels with different exfoliation strengths (I < V < R), based on their individual blend of active ingredients. Participants received 3 in-office chemical peels every 3, 4, or 5 weeks, with increasing recovery time depending on the peel strength. In between peel treatments, participants followed an at-home multimodal hyperpigmentation (HP) skincare regimen that consisted of HP pads (up to twice daily), an HP serum (twice daily), and an HP spot treatment (once daily). Outcomes included the modified Melasma Area and Severity Index (mMASI) score, changes from baseline in investigator-graded facial skin parameters (eg, Global Improvement in Overall Hyperpigmentation, dark spot intensity, dark spot contrast), instrumentation data, and participant self-assessments of facial skin appearance and treatment attributes. Tolerability was assessed by investigators and participants at all study visits.

Results: Six female participants (n=2/group) aged 30-63 years, with Fitzpatrick Skin Types II to VI, who self-identified their ethnicity as Asian, Caucasian, African American, and Hispanic, were included in the study. All participants in the 3 groups displayed improved mMASI scores after the combined treatments. Additionally, investigators observed a reduction in overall hyperpigmentation scores in participants receiving 3 V peels and 12 weeks of the at-home skincare regimen and in 1 participant receiving 3 R peels plus 15 weeks of HP skincare regimen. Dark spot intensity and dark spot contrast improved after 3 V or R chemical peels and use of the at-home skincare regimen. Other aesthetic benefits reported by clinical investigators after the combined treatments were a decrease in fine and coarse lines and an improvement in facial radiance and skin tone evenness. The 3 combination treatments were highly rated by participants in self-perceived efficacy and product satisfaction. Furthermore, the treatments were well tolerated. Mean scores for all tolerability parameters were ≤1 (mild or below mild) at all study visits.

Conclusions: Results suggest that combining peel treatments with this novel topical pigmentation control regimen may provide an effective and well-tolerated approach to treating hyperpigmentation and addressing other skin imperfections such as fine lines and/or dullness. Superficial peel treatments with higher strength can result in more effectiveness.

observed within/ after 4 weeks post- vaccination. Additional research is needed to assess the safety of live attenuated vaccines in patients on dupilumab and to investigate whether dupilumab impacts vaccine efficacy.

38. Efficacy and Safety of Roflumilast Cream 0.15% in Adults and Children Aged ≥6 with Mild to Moderate Atopic Dermatitis in Two Phase 3 Trials (INTEGUMENT-1 and INTEGUMENT-2)

Eric Simpson,¹ Lawrence Eichenfield,² Melinda Gooderham,³ Mercedes E. Gonzalez,⁴ Adelaide Hebert,⁵ Kim Papp,⁶ Vimal Prapajati,⁷ David Krupa,⁸ Patrick Burnett,⁸ David Berk,⁸ Robert Higham⁸
¹Oregon Health & Science University, Portland, OR, USA; ²University of California, San Diego and Rady Children’s Hospital, San Diego, CA, USA; ³SkinCentre for Dermatology, Probody Medical Research and Queen’s University, Peterborough, ON, Canada; ⁴Pediatric Skin Research, LLC Miami, FL, USA; ⁵UT Health McGovern Medical School, Houston, TX, USA; ⁶Probody Medical Research and Alliance Clinical Research, Waterloo, ON, Canada; ⁷Dermatology Research Institute, Skin Health & Wellness Centre, University of Calgary, and Probody Medical Research, Calgary, AB, Canada; ⁸Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA.

Introduction: Roflumilast is a selective, highly potent phosphodiesterase 4 inhibitor under investigation as a non-steroidal, once-daily cream for treatment of atopic dermatitis (AD). (INTEGUMENT-AD.) INTEGUMENT-1 (n=654; NCT04773587) and INTEGUMENT-2 (n=683; NCT04773600) were identical phase 3 randomized controlled trials conducted in 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.

Methods: Patients were randomized 2:1 to apply once-daily roflumilast cream 0.15% or vehicle for 4 weeks. The primary efficacy endpoint was vIGA-AD Success (defined as score of 0 [clear] or 1 [almost clear] with 2-grade improvement from baseline) at Week 4. Secondary endpoints included 75% improvement in EASI (EASI-75).

Results: At Week 4, significantly more roflumilast- treated than vehicle-treated patients achieved vIGA-AD Success (INTEGUMENT-1: 32.2% vs 15.2%; P<0.0001; INTEGUMENT-2: 28.9% vs 12.0%; P<0.0001) and EASI-75 (INTEGUMENT-1: 43.2% vs 22.0%; P<0.0001; INTEGUMENT-2: 42.0% vs 19.7%; P<0.0001). Incidence of Treatment Emergent Adverse Events (AEs) was low in both arms, with most assessed as mild to moderate in severity. No AE occurred in more than 3.5% of patients in either arm with low rates of application site pain in both the roflumilast- and vehicle-treated patients (INTEGUMENT-1: 2.1% vs 0.5%; INTEGUMENT-2: 0.9% vs 0.9%). Local tolerability was favorable with >90% of roflumilast-treated patients reporting no or mild sensation across arms in both trials at any timepoint.

Conclusion: Once-daily roflumilast cream 0.15% improved AD across multiple efficacy endpoints while demonstrating favorable safety and tolerability in two phase 3 trials.

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39. Integrated Safety Analysis of Abrocitinib in 3802 Patients With Moderate-To- Severe Atopic Dermatitis With Over 5000 Patient-Years of Exposure

Eric L. Simpson¹, Jonathan I. Silverberg², Audrey Nosbaum³, Kevin Winthrop⁴, Emma Guttmann-Yassky⁵, Alexander Egeberg⁶, Haiyun Fan⁶, Justine Alderfer⁶, Susan Johnson⁷, Saleem Farooqui⁸
¹Oregon Health & Science University, Portland, OR, USA; ²The George Washington University School of Medicine and Health Sciences, Washington, DC, USA; ³Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, Pierre Bénite, France; ⁴Icahn School of Medicine, Mount Sinai Medical Center, New York, NY, USA; ⁵Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark; ⁶Pfizer Inc., Collegeville, PA, USA; ⁷Pfizer Inc., Raleigh-Durham, NC, USA; ⁸Pfizer R & D UK Ltd., Sandwich, Kent, UK

Introduction: Abrocitinib is efficacious and well tolerated in patients with moderate-to-severe atopic dermatitis (AD). Here, we describe the updated long-term integrated safety profile of abrocitinib in the JADE clinical program.

Methods: The analysis included 3802 patients (exposure: 5213.9 patient-years [PY]) from 7 parent phase 2/3 trials and one long-term extension trial (data cutoff September 25, 2021). Incidence rates (IRs; number of unique patients with events/100 PY) of serious adverse events (SAEs) and treatment-emergent AEs of special interest were assessed.

Results: Of the total 3802 patients in the pooled safety population, 3004 received the same abrocitinib dose throughout exposure; duration of exposure was ≥96 weeks in 26.3% of patients who received abrocitinib 200 mg (n=1981) and 41.3% of patients who received abrocitinib 100 mg (n=1023). Median age was 30.0 years. Incidence was higher in older (≥65 years, n=146) versus younger (18 to <65 years, n=2368) patients for SAEs (17.6 [95% CI: 1.7-25.5] vs 6.7 [5.8-7.8]), herpes zoster (HZ, 8.1 [4.3-13.8] vs 3.8 [3.1-4.6]), malignancy (excluding nonmelanoma skin cancer, 2.4 [0.6-6.0] vs 0.1 [0.0-0.4]), major adverse cardiac events (1.2 [0.1-4.2] vs 0.3 [0.1-0.6]), thrombocytopenia (confirmed platelet count <75x10³/ mm³, 1.8 [0.4-5.1] vs 0.3 [0.1-0.6]), and lymphopenia (3.5 [1.3-7.6] vs 0.1 [0.0-0.3]). The most frequent serious infections with abrocitinib 200 mg and 100 mg were HZ (0.5% and 0.2%), herpes simplex (0.1% with either dose), and pneumonia (0.2% with either dose).

Conclusion: Abrocitinib has an acceptable long-term safety profile with >5000 PY of exposure in appropriate patients with moderate-to-severe AD.

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40. The 40-gene expression profile (40-GEP) test allows for an improved prognostication of the likelihood of metastasis in patients with T1 cutaneous squamous cell carcinoma (SCC) with high-risk factors
Ally-Khan Somani, MD, PhD; Javier Cañueto MD, PhD; Vincent Smith, DNP, ANP-C; Andrew Berg, NP-C; Alison L. Fitzgerald, PhD; Jennifer J. Siegel, PhD; Anesh Prasai, PhD; Shernif F, Ibrahim, MD, PhD; Sarah T. Arron, MD, PhD

1 Department of Dermatology, Indiana University School of Medicine, Indianapolis, Indiana, USA; 2 Department of Dermatology, Universidad del Salvador, Manila, Spain; 3 Pinnacle Dermatology, Little Rock, Arkansas, USA; 4 Dermatology Specialists of Kansas City, Kansas City, MO, USA; 5 Research and Development, Castle Biosciences, Inc., Friendswood, Texas, USA; 6 Rochester Dermatologic Surgery, Victor, NY, USA; 7 Peninsula Dermatology, Burlingame, California, USA

Introduction: The majority of cutaneous squamous cell carcinomas (cSCC) with at least one high-risk factor are staged as T1 tumors by the Brigham and Women’s Hospital (BWH) or American Joint Committee on Cancer 8th edition (AJCC8) systems. However, approximately 30% of BWH T1 cSCCs will go on to metastasize, potentially due to risk factors including immunosuppression, rapidly growing tumors, location, poorly defined borders, etc and molecular mechanisms are not captured in clinical-pathologic staging. The clinically available 40-gene expression profile (40-GEP) test was independently validated to accurately classify risk for regional and/or distant metastasis in patients with primary cSCC with one or more high-risk factors into three classes (Class 1-low risk; Class 2A-high; Class 2B-high risk) and provides independent prognostic value when combined with current staging systems. This study aimed to demonstrate the effectiveness of the 40-GEP in identifying BWH or AJCC T1 tumors that developed metastasis.

Study: Within a cohort of cSCC cases with at least one high-risk factor (n=954), 446 cases were BWH stage T1, and 501 cases were AJCC8 stage T1. Kaplan-Meier survival analysis and Cox regression analysis were used to determine metastasis-free survival (MFS) of T1 tumors according to 40-GEP risk class.

Results: A statistically significant difference in 3-year MFS rates was observed for the T1 cohorts when comparing 40-GEP risk groups (Class 1 AJCC8/BWH: 95.5%/96.9%; Class 2A: 84.8%/88.7%; Class 2B: 64.7%/66.7%; log-likelihood tests p<0.0001) Additionally, the 40-GEP test sensitivity for identifying metastatic cases was 70% (32/46) in the AJCC8 group and 67% (20/30) in the BWH group, while the negative predictive value of the 40-GEP was >90% in each cohort.

Conclusions: These findings demonstrate the ability of the 40-GEP to identify biologically high-risk tumors in patients deemed low risk by traditional staging methods, i.e., staged as T1 by either BWH or AJCC8 staging. Within the T1 population, the 40-GEP test identified high-risk patients with metastasis rates similar to the historical BWH T3 and AJCC8 T4 groups. Incorporating 40-GEP test results in clinical assessments with traditional clinical-pathologic risk factors can improve the stratification of high-risk cSCC T1 patients and contribute to risk-appropriate surveillance and treatment decisions.

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

Linda Stein Gold, MD; Leon H Kircik, MD; Emil A Tanghetti, MD; Hilary Baldwin, MD; Zoe D Draelos, MD; Michael Gold, MD; Edward Lain, MD, MBA; David M Paiser, MD; Neil Sadick, MD; Radhakrishnan Pillai, PhD; Varsha Bhatt, PhD

1 Henry Ford Hospital, Detroit, MI; 2 Icahn School of Medicine at Mount Sinai, New York, NY; 3 Indiana University Medical Center, Indianapolis, IN; 4 Physicians Skin Care, PLLC, DermResearch, PLLC, and Skin Sciences, PLLC, Louisville, KY; 5 Center for Dermatology and Laser Surgery, Sacramento, CA; 6 The Acne Treatment and Research Center, Brooklyn, NY; 7 Robert Wood Johnson University Hospital, New Brunswick, NJ; 8 Dermatology Consulting Services, PLLC, High Point, NC; 9 Tennessee Clinical Research Center, Nashville, TN; 10 Austin Institute for Clinical Research, Austin, TX; 11 Eastern Virginia Medical School, Norfolk, VA; 12 Virginia Clinical Research, Inc., Norfolk, VA; 13 Department of Dermatology, Weill Cornell Medical College, New York, NY; 14 Sadick Dermatology, New York, NY; 15 Bausch Health US, LLC; Petaluma, CA

Background: A three-pronged approach to acne treatment—combining an antibiotic, antibacterial agent, and retinoid in a single formulation—has been investigated as a means to provide greater efficacy than single/double treatments while potentially reducing antibiotic resistance. Clindamycin phosphate 1.2%/BPO 3.1%/adapalene 0.15% (IDP-126) gel is the first triple-combination, fixed-dose topical acne product in development that addresses the major pathophysiological abnormalities in acne patients. The efficacy, safety, and tolerability of IDP-126 gel was evaluated in phase 2 and 3 studies of patients with moderate-to-severe acne.

Methods: A phase 2 (N=741; NCT03170388) and two phase 3 (N=183; N=180; NCT04214639; NCT04214652) double-blind, randomized, 12-week studies enrolled participants aged ≥9 years with moderate-to-severe acne. Participants were randomized to receive once-daily IDP-126 gel or vehicle; the phase 2 study included three additional randomization arms containing dyad gels: BPO/adapalene; clindamycin phosphate/BPO; and clindamycin phosphate/adapalene (data not shown). Endpoints included participants achieving ≥2-grade reduction from baseline in Evaluator’s Global Severity Score and clear/almost clear skin (treatment success) and least-squares mean percent change from baseline in inflammatory and noninflammatory lesion counts. Treatment-emergent adverse events (TEAEs) were also assessed.

Results: In all three studies at week 12, half of participants achieved treatment success with IDP-126 (phase 2: 52.5%; phase 3: 49.6%, 50.5%) versus less than one-fourth with vehicle (8.1%; 24.9%, 20.5%; P<0.01, all). IDP-126 resulted in over 70% reductions in inflammatory and noninflammatory lesions at week 12, significantly greater
42. 24 Month Drug Persistence of Guselkumab in Biologic-Naïve Plaque Psoriasis Patients

Bruce Strober,1 Timothy Fitzgerald,2 Rachel Teneralli,3 Judson Janak,4 Maya Marchese,4 Katelyn Rowland,2 Olivia Choi,2 Daphne Chan,2 Elizabeth Lesser,4 Michael Cameron,3 Mark Lebwohl5

1Yale University School of Medicine, New Haven, CT; 2Central Connecticut Dermatology, Cromwell, CT; 3Janssen Scientific Affairs, Horsham, PA; 4Janssen Global Services, LLC, Horsham, PA; 5CorEvitas, LLC, Waltham, MA; 6icahn School of Medicine at Mount Sinai, New York, NY

Introduction: While psoriasis clinical trial results showed guselkumab (GUS) maintains high levels of clinical efficacy and improvement in patient-reported outcomes through five years, there remains limited long-term comparisons between GUS and other biologic therapies in real-world patients. This study compared treatment persistence over a 24-month follow-up period of biologic (bio)-naïve patients initiating GUS compared to three biologic therapies: ixekizumab (IXE), secukinumab (SEC), and adalimumab (ADA).

Methods: This was a retrospective cohort study of bio-naïve patients with plaque psoriasis from the CorEvitas Psoriasis Registry initiating either GUS or a comparator biologic therapy between 7/13/2017 and 1/10/2022. Patient characteristics were collected at biologic treatment initiation. To estimate the average treatment effect on the treated, standardized mortality ratio weighting (SMR-W) was used to adjust for potential confounding between patients initiating GUS and each comparator separately. Risk of discontinuation: GUS vs. SEC (HR: 0.5 [95% CI: 0.4, 0.8]) and GUS vs. ADA (HR: 0.3 [95% CI: 0.2, 0.5]). GUS initiators had numerically longer 24-month SMR-W average treatment persistence compared to IXE: GUS vs. IXE (6 weeks [95% CI: -0.4, 12]); and lower relative rates of discontinuation: GUS vs. IXE (HR: 0.7 [95% CI: 0.5, 1.1]).

Conclusion: This study is one of the first US real-world studies to compare persistence of GUS to three commonly used biologic treatments among patients with bio-naïve plaque psoriasis. Our findings demonstrated that GUS had longer treatment duration and lower discontinuation rates vs. SEC and ADA in a bio-naïve patient population. Moreover, in a large psoriasis registry, GUS had a trend of longer treatment persistence among all four biologics up to two years of follow-up.

43. Bimekizumab maintenance of response and safety in patients with moderate to severe plaque psoriasis: Results from the open-label extension period (Weeks 48–144) of the BE RADIANT phase 3b trial

Bruce Strober,1,2 Luis Puig,3 Andrew Blauvelt,4 Diamant Thaci,1 Boni Elewski,6 Maggie Wang,7 Veerle Vanvooren,8 Delphine Deherder,9 Fabienne Staelens,9 Susanne Wiegratz,10 Carle Paul11  

1Yale University, New Haven, CT, USA; 2Central Connecticut Dermatology Research, Cromwell, CT, USA; 3Hospital de la Santa Creu i Sant Pau, Universitat Autonoma de Barcelona, Barcelona, Spain; 4Oregon Medical Research Center, Portland, OR, USA; 5Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; 6University Hospitals of Cleveland, Case Western Reserve University, Cleveland, OH, USA; 7UCB Pharma, Morrisville, NC, USA; 8UCB Pharma, Brussels, Belgium; 9UCB Pharma, Braine-l’Alleud, Belgium; 10Toulouse University and CHU, Toulouse, France

Introduction: Clinical improvements through Week (Wk)96, with no unexpected safety findings, have previously been reported with bimekizumab (BKZ), in the BE RADIANT phase 3b trial.1,2

Objective 1: To evaluate the efficacy of BKZ, as measured by complete or near complete skin clearance using the Psoriasis Area and Severity Index (PASI), in patients with moderate to severe plaque psoriasis over 144 weeks.

Objective 2: To assess long-term safety of BKZ treatment.

Methods: Patients with moderate to severe plaque psoriasis received BKZ (320mg every 4 wks [Q4W] through Wk16, then Q4W or Q8W) or secukinumab (SEC; 300mg weekly to Wk4, then Q4W) through Wk48, then BKZ (Q4W or Q8W; all received Q8W from Wk64/next scheduled visit). Wks48–144 (open-label extension [OLE]) overlapped with the COVID-19 pandemic. Wk48–144 efficacy data are reported for patients treated with BKZ or SEC to Wk48 who entered the OLE, receiving BKZ Q4W or Q8W. Patients discontinuing due to lack of efficacy/
treatment-related adverse events (AEs) were considered non-responders; multiple imputation was used for other missing data (modified non-responder imputation [mNRI]). Wk48-144 safety data (incidence/100 patient-years [PY]) are grouped for patients receiving ≥1 BKZ dose in this period.

**Results:** 336/373 BKZ-randomized and 318/370 SEC-randomized patients entered the OLE. Among these, 74.9% BKZ vs 52.8% SEC (WK48) and 68.8% BKZ/BKZ vs 69.1% SEC/BKZ (WK144) achieved PASI100; 94.3% vs 83.9% (WK48) and 89.8% vs 87.0% (WK144) achieved PASI≤2. Wk48-144 serious AE rate with BKZ was low (5.4/100PY). Four deaths (two from coronavirus infection [unvaccinated patients]) occurred; none treatment-related. The most common AEs were: nasopharyngitis (8.4/100PY); oral candidiasis (7.1/100PY); coronavirus infection (5.1/100PY). Most (98.3%) oral candidiasis events were mild/moderate; three led to discontinuation.

**Conclusions:** Clinical improvements with BKZ were maintained through Wk144; outcomes improved for SEC-treated patients after switching to BKZ (Wk48-144). AEs were consistent with BKZ’s safety profile.1,3

**Funding:** UCB Pharma.

**References:**
1. Strober B et al. Presented at AAD 2022, poster 34321;

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**44. Improvement in patient-reported outcomes with deucravacitinib in moderate to severe psoriasis: results from the POETYK PSO-1 and POETYK PSO-2 randomized phase 3 clinical trials**

Bruce Strober,1 April W. Armstrong,2 Joe Zhuo,3 Brandon Becker,4 Yichen Zhong,3 Jennifer L. Beaumont,3 Tan P. Pham,4 Andrew Napoli,3 Subhashis Banerjee,3 Kim A. Papp2

1Yale School of Medicine, Yale University, New Haven, CT, and Central Connecticut Dermatology Research, Cromwell, CT, USA; 2Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; 3Bristol Myers Squibb, Princeton, NJ, USA; 4Clinical Outcomes Solutions, Chicago, IL, USA; 5Prophy Medical Research Inc., Waterloo, ON, Canada

**Introduction:** This study described the longitudinal trends in improvements in patient-reported outcomes (PROs), as assessed by the Psoriasis Symptoms and Signs Diary (PSSD) and the Dermatology Life Quality Index (DLQI), in patients with moderate to severe plaque PsO in the POETYK PSO-1 and PSO-2 phase 3 clinical trials with deucravacitinib (DEUC).

**Methods:** Adults aged ≥18 years with moderate to severe plaque PsO were randomized 2:1 to DEUC 6 mg once daily, placebo (PBO), or apremilast 30 mg twice daily. At Week 16, patients receiving PBO switched to DEUC 6 mg once daily. Switches in the DEUC and apremilast arms occurred at Week 24 depending on the study design.
PSSD and DLQI assessments were evaluated weekly, with higher scores indicating more severe impact. Data presented herein are from pooled and study-specific analyses of POETYK PSO-1 and PSO-2. Mixed-effects models were fit to longitudinal data with adjustment for randomized treatment, time, interaction between treatment and time, treatment assignment, and baseline PRO score; results for Weeks 0–24 are reported as least squares means; due to treatment reassignment at Week 24, descriptive means are reported for Weeks 24–52.

**Results:** In this post hoc analysis, significantly greater improvements in the PSSD total score (TS) ($P<0.01$) and DLQI ($P<0.01$) were observed in patients treated with DEUC compared with apremilast starting as early as Week 4 (improvement maintained through Week 24). Placebo patients who switched to DEUC at Week 16 had rapid improvements in PSSD-TS in both studies; in PSO-1, response in the PBO group (17 weeks post-switch to DEUC) at Week 33 was comparable to patients who had received DEUC from trial inclusion (improvement maintained through Week 52). Apremilast patients who had not achieved Psoriasis Area and Severity Index (PASI) 50 responses and were switched to DEUC at Week 24 showed rapid improvements in PSSD-TS scores. In PSO-2, apremilast PASI 75 non-responders switching to DEUC at Week 24 had rapid improvements in PSSD-TS. Similar trends for DLQI were observed for patients who switched treatments in both studies.

**Conclusion:** In these patients, DEUC provided rapid and durable improvement in PSSD and DLQI, and greater improvements in these PROs than apremilast. Patients who did not achieve PASI 50 or PASI 75 responses with apremilast achieved rapid and durable improvements in these PROs when switched to DEUC.

**45. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase 2 Inhibitor, in Moderate to Severe Plaque Psoriasis: 2-Year Efficacy by Prior Biologic Treatment in the Phase 3 POETYK PSO Program**

Richard B. Warren,1 April W. Armstrong,2 Shinichii Imafuku,3 Carle Paul,4 Leon Kirck,5 Subhashis Banerjee,6 Elizabeth Colston,7 Thomas Scharnnitz,8 Tao Wang,9 Bruce Strober6

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

**Introduction:** Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate- to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In the POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials, deucravacitinib was superior to placebo and apremilast in patients with moderate to severe plaque psoriasis. This study evaluated long-term clinical outcomes by prior biologic treatment status in patients with ≥2 years of continuous deucravacitinib exposure.

**Methods:** Patients in POETYK PSO-1 were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. At Week 52, patients could enter the POETYK long-term extension (LTE; NCT04036435) trial and receive deucravacitinib for up to 2 years. Efficacy outcomes included ≥75% and ≥90% reductions from baseline in Psoriasis Area and Severity Index (PASI 75 and PASI 90) and static Physician’s Global Assessment score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline (sPGA 0/1), which were assessed in biologic treatment-naive, anti-tumor necrosis factor (TNF)-experienced, and anti-interleukin (IL)-17/anti-IL-23-experienced patients. Efficacy is reported using modified nonresponder imputation methodology.

**Results:** A total of 265 patients received continuous deucravacitinib treatment from Day 1 in POETYK PSO-1 until Week 112 in the POETYK LTE, including 157 biologic treatment-naive, 36 anti-TNF-experienced, and 72 anti-IL-17/anti-IL-23-experienced patients. There were high clinical responses at Week 112 in each prior biologic treatment subgroup (biologic treatment-naive: PASI 75 83.3%, PASI 90 54.3%, sPGA 0/1 67.1%; anti-TNF-experienced: PASI 75 80.1%, PASI 90 55.9%, sPGA 0/1 67.1%; anti-IL-17/anti-IL-23-experienced: PASI 75 79.9%, PASI 90 53.3%, sPGA 0/1 62.6%).

**Conclusion:** Continuous deucravacitinib treatment is associated with durable efficacy responses over 2 years regardless of prior biologic treatment.

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