CONTENTS

1. Real-world Use of Spesolimab in Generalized Pustular Psoriasis: Reports from Four Cases
2. Deucravacitinib in Plaque Psoriasis: 3-Year Safety and Efficacy Results From the Phase 3 POETYK PSO-1 and PSO-2 Trials
3. Effect of Secukinumab on Draining Tunnels in Patients with Moderate-to-Severe Hidradenitis Suppurativa
4. Long-Term Efficacy of Dupilumab in Adults with Moderate-to-Severe Atopic Dermatitis: Results from a 5-year Open-Label Extension Trial
5. Safety of Long-Term Dupilumab Treatment in Adults with Moderate-to-Severe Atopic Dermatitis: Results from a 5-Year Open-Label Extension Trial
6. Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Seborrheic Dermatitis in a Phase 3 Trial: Assessment of Pruritus
7. Safety and Tolerability of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Black participants With Acne
8. Patient and Healthcare Provider Perspectives on the Disease Burden of Seborrheic Dermatitis in the United States: Results from a National Survey
9. Challenges in Diagnosing and Managing Generalized Pustular Psoriasis: Learnings from 4 Cases in Clinical Practice
10. Sustained Efficacy and Safety of Bimekizumab in Patients with Active Psoriatic Arthritis and Prior Inadequate Response to Tumor Necrosis Factor Inhibitors: Results from the Phase 3 BE COMPLETE Study and its Open-label Extension Up to 1 Year
11. Comparison of Cutaneous Irritation With Repeated Application of Tazarotene 0.045% Lotion, Adapalene 0.3% Gel, and Trifarotene 0.005% Cream
12. A Phase 3 Study of Ruxolitinib Cream in Children Aged 2–<12 Years with Atopic Dermatitis (TRuE-AD3): 8-Week Analysis
13. Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Scalp and Body Psoriasis in the Phase 3 ARRECTOR Trial
14. Prevalence of Considerations Potentially Influencing JAK Inhibitor Use Among Patients With Moderate to Severe Atopic Dermatitis: a US Claims Database Analysis
15. Real-world Tralokinumab Use in Dupilumab-experienced Patients: A Retrospective Multi-center Case Series
16. Secukinumab in Moderate-to-Severe Hidradenitis Suppurativa: A Pooled Subgroup Analysis From the SUNSHINE and SUNRISE Phase 3 Trials
17. Dupilumab Is Efficacious in Patients With Prurigo Nodularis Regardless of History of Atopic Comorbidities: Pooled Results From Two Phase 3 Trials (LIBERTY-PN PRIME and PRIME2)
18. Rapid Improvements in Itch with Tapinarof Cream 1% Once Daily in Two Phase 3 Trials in Adults with Mild to Severe Plaque Psoriasis
19. Development of a patient-centered conceptual disease model for prurigo nodularis: a qualitative content analysis
20. Prophylaxis and Treatment of Dermatologic Adverse Events with Tumor Treating Fields Therapy in the Abdominopelvic Region: Practical Guidance from Clinical Experts
21. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase Inhibitor, in Moderate to Severe Plaque Psoriasis: Evaluation of Lipid Parameters in the Phase 3 POETYK PSO-1 and PSO-2 Trials
22. Dupilumab Improves Urticaria Signs and Symptoms and Quality of Life in Patients with Chronic Spontaneous Urticaria (CSU)
SDPA Presents Fall 2023 Digital Abstracts

CONTENTS

23. Risk Stratifying Skin Cancer Screening in SOTRs
24. Identifying Risk Factors for Metastatic Squamous Cell Carcinoma in Organ Transplant Recipients: A Single Institution Case Controlled Retrospective Study Protocol
25. Complete/near-complete Itch Response Observed in Adult and Adolescent Patients With Moderate-to-Severe Atopic Dermatitis Initiating Dupilumab Treatment in Real World Practice
26. Integrated Safety Analysis of Abrocitinib in 635 Adolescent Patients with Moderate-to-severe Atopic Dermatitis with Over 1000 Patient-years of Exposure
27. 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
28. Topical Clindamycin For Acne Vulgaris: Pharmacovigilance Safety Review and Retrospective Analysis of Gastrointestinal Events
29. Real-world Tralokinumab Use in Patients with Moderate-to-severe Atopic Dermatitis Resistant to Systemic Therapy: A Retrospective Case Series
30. A Case Series of Live Attenuated Vaccine Administration in Dupilumab-Treated Children with Atopic Dermatitis
31. Tapinarof Cream 1% Once Daily: Significant Efficacy in the Treatment of Moderate to Severe Atopic Dermatitis in Two Pivotal Phase 3 Trials in Adults and Children Down to 2 Years of Age
32. Rapid and Early Onset of Itch Relief with Tapinarof Cream 1% Once Daily in Two Pivotal Phase 3 Trials in Adults and Children Down to Two Years of Age with Moderate to Severe Atopic Dermatitis
33. 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)
34. Dupilumab Treatment in Patients With Hand and Foot Atopic Dermatitis: Results From a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial
36. A Study Evaluating the Safety and Effectiveness of Hyaluronic Acid Filler HA EYE for Correction of Infraorbital Hollows (IOH)
37. Study of Risk Factors for Metastatic Squamous Cell Carcinoma in Organ Transplant Recipients at an Academic Medical Center
38. The Sleep Disturbance Numerical Rating Scale (SD NRS): Content Validity, Psychometric Properties, and Meaningful within-patient Change in People with Prurigo Nodularis
39. Triple-Combination Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% for Moderate-to-Severe Acne: Efficacy and Safety Results from a Pooled Phase 3 Analysis
40. Effect of High-dose Subcutaneous Spesolimab on Skin Manifestations: Results from the Pivotal Effisayil 2 Trial of Flare Prevention in Generalized Pustular Psoriasis
41. Combination Halobetasol Propionate/Tazarotene Lotion for the Treatment of Psoriatic Plaques With Severe Elevation or Scaling
42. Clinically Significant Risk-stratification Prediction in Stage I Cutaneous Melanoma with the Integrated 31-gene Expression Profile (i31-GEP)
43. Bimekizumab 3-year Maintenance of Response in Week 16 Responders with Moderate to Severe Plaque Psoriasis: Results from Five Phase 3/3b Trials
44. Long-term Efficacy of Tralokinumab in Adolescents with Moderate-to-severe Atopic Dermatitis
1. Real-world Use of Spesolimab in Generalized Pustular Psoriasis: Reports from Four Cases

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Introduction: Generalized pustular psoriasis (GPP) is a rare, chronic, autoinflammatory skin disease characterized by widespread pustular eruptions. GPP is painful, distressing, and adversely affects patient quality of life (QoL). Spesolimab is a first-in-class anti-IL-36 receptor monoclonal antibody approved for the treatment of GPP flares.

Description of study: We describe 4 cases from our respective clinical practices, where individuals with GPP were treated successfully with spesolimab.

Results: Case 1 is a 72-year-old white female who presented with extensive plaque psoriasis. Two months later, she developed painful skin pustules, accompanied by systemic symptoms. A GPP diagnosis was made. GPP adversely affected her QoL; she was unable to work, and felt suicidal. GPP symptoms persisted despite various treatments including topical and systemic medications. Marked clinical improvement occurred following spesolimab treatment; pustules 100% improvement, pain 90% improvement, erythema 50% improvement. QoL also improved, and her mental health recovered.

Case 2 is a 44-year-old African-American female who had lived with GPP for 15 years. She experienced 1–2 GPP flares/year, occurring with increasing frequency and intensity. Multiple hospitalizations were required to manage her GPP flares. Previous treatments included high-dose corticosteroids, an anti-IL17 biologic, and an antimetabolite. Following spesolimab treatment, the patient experienced rapid (days) and sustained improvement in GPP symptoms, with a marked reduction in pustule number, erythema, and pain.

Case 3 is a 39-year-old white female, with a history of mild plaque psoriasis, who presented with a widespread, painful, pustular rash following corticosteroid treatment for an upper respiratory tract infection that occurred post-partum. Hand/fingertip pain prevented her from caring for her newborn baby. GPP was confirmed via skin biopsy. There was rapid improvement (days) in GPP symptoms following spesolimab treatment. QoL also improved; she was able to resume normal daily activities, including childcare.

Case 4 is a 54-year-old white female who had presented 11 years earlier with a diagnosis of chronic eczema. She experienced persistent rash on her hands/feet, with skin scaling and pustules on her legs and trunk. The presence of pustules, and lack of response to psoriasis treatments, led to a diagnosis of GPP (5 years after initial presentation). Chronic pain in her hands/feet made daily tasks problematic and affected mobility. Previous treatment included topical and systemic agents, including biologics. Spesolimab treatment resulted in marked clinical improvement in skin symptoms and pain over several weeks. Patient QoL significantly improved, and she was able to continue with her normal activities of daily life.

Conclusions: These cases highlight the physical and emotional burden, and QoL impact experienced by patients with GPP, and the need for long-term management in patients with chronic disease. Wider education on the severity of GPP is needed, as is a greater awareness of the availability of spesolimab as a safe and effective GPP-specific therapy.

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Data Availability Statement
Data sharing is not applicable, as no new data were created or analyzed in this report.

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

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**Introduction:** Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624217) and POETYK PSO-2 (NCT03611751) trials in moderate to severe plaque psoriasis. Upon completing the parent trials, patients could enroll in the ongoing POETYK long-term extension (LTE; NCT04036435) trial. Deucravacitinib-treated patients maintained long-term safety profiles and efficacy responses through 2 years with no new safety signals. Here, we report safety and efficacy of deucravacitinib for up to 3 years (Week 148).

**Methods:** PSO-1/PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib, or apremilast. At Week 52, patients in the LTE received open-label deucravacitinib. Safety was evaluated in patients who received ≥1 deucravacitinib dose. Exposure-adjusted incidence rate (EAIR) per 100 person-years (PY) is calculated as 100*(# of patients with an adverse event [AE])/total exposure time for all patients at risk (time to initial AE occurrence for patients with AE + total exposure time for patients without AE). Efficacy outcomes included PASI 75, PASI 90, and sPGA 0/1. Efficacy was reported using mNRI in patients who received continuous deucravacitinib from Day 1 in PSO-1/PSO-2.

**Results:** 1519 patients received ≥1 deucravacitinib dose; 513 received continuous deucravacitinib from Day 1 in PSO-1/PSO-2 and enrolled in the LTE. Cumulative exposure was 3294.3 PY. EAIRs/100 PY were similar, or decreased, from the 2- to 3-year cumulative period, respectively, for AEs (154.4, 144.8), serious AEs (6.1, 5.5), discontinuation due to AEs (2.8, 2.4), herpes zoster (0.7, 0.6), malignancies (0.9, 0.9), MACE (0.4, 0.3), VTE (0.1, 0.1), and deaths (0.4, 0.3). Clinical response rates were maintained at Week 148 by mNRI (PASI 75, 73.2% [95% CI, 68.7, 77.8]; PASI 90, 48.1% [43.2, 53.1]; sPGA 0/1, 54.1% [49.1, 59.1]).

**Conclusion:** Deucravacitinib demonstrated sustained clinical response with continuous treatment and a consistent safety profile through 3 years.

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Patients were randomized 1:1:1 to receive secukinumab 300 mg every 2 weeks (SEC Q2W) or 4 weeks (SEC Q4W) through Week 52. The change in number of draining tunnels seen at Week 16 in the secukinumab group was sustained up to Week 52 in the observed pooled data. The benefit did not have an increase from baseline in draining tunnels at Week 16 compared with placebo. The benefit seen at Week 16 in the secukinumab group was sustained through Week 52.

3. Effect of Secukinumab on Draining Tunnels in Patients with Moderate-to-Severe Hidradenitis Suppurativa

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Background: In patients with hidradenitis suppurativa (HS), draining tunnels are associated with more severe disease and poor response to therapy.

Objective: To report the effect of secukinumab on draining tunnels from baseline to Week 52 in patients with moderate-to-severe HS in the phase 3 SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials.

Methods: Patients were randomized 1:1:1 to receive secukinumab 300 mg every 2 (SEC Q2W) or 4 weeks (SEC Q4W) or placebo. At Week 16, patients randomized to SEC continued with the same dose regimen and patients randomized to placebo were switched to receive SEC Q2W or SEC Q4W through Week 52. The change in number of draining tunnels from baseline was assessed up to Week 52 in the observed pooled data.

Results: In total, 1084 patients from SUNSHINE and SUNRISE were included in this analysis (SEC Q2W, n = 361; SEC Q4W, n = 360; placebo, n = 363). At baseline, 66.2%, 60.6%, and 62.5% of patients in the SEC Q2W, SEC Q4W, and placebo treatment arms, respectively, presented with at least one draining tunnel. Among patients with at least one draining tunnel at baseline, a numerically greater proportion of patients receiving secukinumab did not have an increase from baseline in draining tunnels at Week 16 compared with placebo. The benefit seen at Week 16 in the secukinumab group was sustained through Week 52.
Conclusions: A greater proportion of patients treated with secukinumab had no increase in the number of draining tunnels at Week 16 versus placebo, with the effects sustained through Week 52.

Funding: This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland.

4. Long-Term Efficacy of Dupilumab in Adults with Moderate-to-Severe Atopic Dermatitis: Results from a 5-Year Open-Label Extension Trial

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Introduction: Topical therapies often cannot sufficiently control moderate-to-severe atopic dermatitis (AD). Systemic immunosuppressants are not recommended for the long-term treatment of moderate-to-severe AD due to safety concerns. Dupilumab, a fully human monoclonal antibody blocks the shared receptor component for interleukin (IL)-4 and IL-13, inhibiting the key drivers of type 2 inflammation. Data from the open-label extension (OLE) study, LIBERTY AD OLE (NCT01949311), previously demonstrated acceptable safety and sustained efficacy of dupilumab in adult patients for up to 204 weeks. Here we assess long-term efficacy and safety of dupilumab in adult patients with moderate-to-severe AD up to 5 years (the end of this OLE study).

Methods: Adults (≥18 years) with moderate-to-severe AD who had participated in any dupilumab parent study (phase 1 through phase 3) were enrolled into the long-term, multicenter OLE with a duration of up to 5 years. Initially, patients enrolled in the OLE were treated with 300 mg dupilumab weekly. In 2019, patients remaining in the study transitioned to dupilumab 300 mg every 2 weeks, in alignment with the approved dupilumab dose regimen. Concomitant treatments for AD were permitted, including topical corticosteroids and topical calcineurin inhibitors. Data are presented as observed for the overall study population (N=2,677).

Results: Of the 2,677 patients who enrolled, 2,207 completed treatment up to Week 52, 362 up to Week 172, and 334 up to Week 260. The most common reason for study withdrawals during the OLE study period was dupilumab approval and commercialization in the patient’s country of enrollment (708 [51.3%]). Fifty (1.9%) patients withdrew due to lack of efficacy. At the end of the study period, 88.9% of patients achieved a 75% reduction in Eczema Area and Severity Index (EASI) score from parent study baseline (PSBL) and 76.2% of patients achieved a 90% reduction in EASI score from PSBL. At Week 260, 66.5% of patients achieved a ≥4-point reduction in the Peak Pruritus Numerical Rating Scale score from PSBL. A total of 2,276 (85%) patients reported treatment-emergent adverse events (AEs), and 101 (3.8%) patients discontinued treatment permanently due to reported AEs. Dupilumab had an acceptable safety profile over 5 years of treatment.

Conclusions: In this long-term (5 year/260 week) open-label study, dupilumab demonstrated robust efficacy substantiated by sustained improvement of AD signs and symptoms (including skin lesions and pruritus) in adult patients with moderate-to-severe AD. The safety profile was acceptable and consistent with the known safety profile observed in previous dupilumab placebo-controlled studies.

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5. Safety of Long-Term Dupilumab Treatment in Adults with Moderate-to-Severe Atopic Dermatitis: Results from a 5-Year Open-Label Extension Trial

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Dupilumab, a fully human monoclonal antibody blocks interleukin (IL)-4 and IL-13, inhibiting the signaling of key drivers of type 2 inflammation. Data from the open-label extension (OLE) study, LIBERTY AD OLE (NCT01949311), demonstrated acceptable dupilumab safety in adult patients up to 204 weeks. Here we assess the long-term safety of dupilumab administered in adult patients with AD up to 5 years.

Methods: Adults with moderate-to-severe AD who had participated in any dupilumab parent study (phase 1 through phase 3) were enrolled into long-term, multicenter OLE trial of up to 5 years. During OLE, patients were treated with 300mg dupilumab weekly (qw). In 2019, patients transitioned to 300mg every 2 weeks to align with approved dosage. Concomitant treatments for AD were permitted, including topical corticosteroids (TCS) and topical calcineurin inhibitors. Because the OLE trial lacked a control arm, LIBERTY AD CHRONOS (NCT02260986) 52-week safety results for adults with moderate-to-severe AD receiving dupilumab 300mg qw+TCS were provided as a comparison. Data shown are for the overall study population (*N=*2,677).

Results: Of 2,677 patients, 2,207, 362, and 334 completed treatments up to Week 52, 172, and 260, respectively. The most common reason for study withdrawals during OLE was dupilumab approval and commercialization in patient’s country of enrollment (708 [51.3%]). Exposure-adjusted incidence rate (EAIR) of patients with ≥1 treatment-emergent adverse event (TEAE) was lower in this OLE vs 300mg qw+TCS arm of the 52-week CHRONOS trial (166.0 vs 322.4 number of patients/100 patient-years). Over this 5-year OLE, 10.6%, 10% and 1.2% of patients had ≥1 serious TEAE, severe TEAE, and serious TEAE related to the study drug, respectively, and 3.8% of patients experienced TEAE resulting in permanent drug discontinuation. Most common TEAEs observed were nasopharyngitis (28.9%) and conjunctivitis (20%), using a narrow customized MedDRA query (CMQ) containing conjunctivitis and related terms (conjunctivitis allergic/bacterial/viral, and atopic keratoconjunctivitis). Of the patients under narrow CMQ, 95% reported mild/moderate conjunctivitis TEAEs and 87.7% of conjunctivitis events were recovered/resolved.

Conclusions: Safety profile observed in this OLE trial up to 5 years was acceptable and consistent with the known safety profile of dupilumab observed in controlled studies. EAIRs of TEAEs overall did not increase over time and were lower than previously reported in 3- and 4-year interim analyses of this OLE trial and an earlier 52-week placebo-controlled trial.

References:

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

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7. Safety and Tolerability of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Black participants With Acne

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Background: As acne can cause inflammation-associated sequelae (eg, post-inflammatory hyperpigmentation) in individuals with melanin-rich skin, effective and rapid management must be balanced with minimization of skin irritation. Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (IDP-126) polymeric mesh gel is the first fixed-dose, triple-combination topical acne product in development. In clinical studies, over half of participants achieved treatment success with IDP-126 gel after 12 weeks. The objective of this pooled, post hoc analysis was to evaluate safety and tolerability of IDP-126 gel in Black participants.

Methods: In two identical phase 3, double-blind, randomized, 12-week studies (NCT04214639; NCT04214652), participants aged ≥9 years with moderate-to-severe acne were randomized (2:1) to receive once-daily IDP-126 or vehicle gel. Assessments included treatment-emergent adverse events (TEAEs) and cutaneous safety/tolerability (hyperpigmentation, hypopigmentation, erythema, scaling, itching, burning, and stinging; graded from 0 [none] to 3 [severe]). Post hoc analyses were based on participants’ self-identification of race as ‘Black or African American’ (hereafter referred to as Black).

Results: Of 363 randomized participants, 54 (14.9%) self-identified as Black. No serious TEAEs were reported and no TEAEs led to discontinuation. Treatment-related TEAEs were reported in 7 (17.5%) IDP-126-treated Black participants; the most common were application site pain (n=5 [12.5%]) and application site pruritus (n=2 [5.0%]). No vehicle-treated participants reported treatment-related TEAEs. TEAEs in Black participants were generally similar to the overall population.

Mean severity scores for all cutaneous safety/tolerability assessments following IDP-126 treatment were <0.55 at all study visits (1=mild). Rates of hyperpigmentation remained relatively unchanged throughout the study while erythema decreased by over 10% from baseline to week 12 with IDP-126 treatment. Rates of all other cutaneous safety/tolerability assessments were low (<9%) at both baseline and week 12.

Conclusions: Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (IDP-126) gel was safe and well tolerated in Black participants with moderate-to-severe acne over 12 weeks, with no discontinuations or serious TEAEs. Additionally, IDP-126 treatment led to improved erythema in Black participants and no substantial increases in hyperpigmentation. These post hoc analyses add valuable information to the limited literature describing treatment effects and tolerability of novel acne therapeutics in Black individuals.

Support: Ortho Dermatologics.

8. Patient and Healthcare Provider Perspectives on the Disease Burden of Seborrheic Dermatitis in the United States: Results from a National Survey

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ABSTRACTS

Generalized pustular psoriasis (GPP) is a rare autoinflammatory skin disease characterized by small, sterile pustules and is often accompanied by systemic symptoms. The physical and emotional burden of seborrheic dermatitis (SD) has not been well characterized.

Methods: The authors developed an online survey, conducted by the Harris Poll, on the burden, experiences, and preferences of patients with SD and healthcare providers (HCPs). Participants included 300 U.S. adults with HCPT-diagnosed SD and 601 dermatology HCPs who see ≥1 patient/week and ≥1 patient with SD/year.

Results: 84% of patients reported moderate-to-severe symptom severity, while HCPs estimated 60% of patients had this severity. Patients reported SD as a “lot” or “great deal” of negative impact on their emotional (49%) and physical (42%) well-being. Most patients felt it challenging to hide SD symptoms (81%) and reported negative impacts on day-to-day (46%) and social life (41%). Patients with SD reported significant mental health impact: 77% reported anxiety, 72% reported depression, and 73% felt isolated. Most patients (90%) stated SD negatively impacted self-esteem, with 82% feeling embarrassed about others’ comments on SD symptoms. Patients reported a negative work-life impact, specifically on the ability to do their job (73%); agreed that symptoms made them less confident at work (59%), they would be further along in their career if they didn’t have SD (61%), and SD made them choose a different career path (47%); and reported missed workdays because of SD (47%). Patients reported living with SD for an average 3.6 years, with 20% waiting ≥6 years, before seeking SD treatment.

Conclusion: These insights highlight an immense patient burden associated with SD and underscore the need for additional interventions.

Sponsored by Arcutis Biotherapeutics, Inc.

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

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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.

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Written informed consent was obtained from each participant for publication of the details of their medical case and any accompanying images.

Data sharing statement
Not applicable, as no new data were created or analyzed in this report.

10. Sustained Efficacy and Safety of Bimekizumab in Patients with Active Psoriatic Arthritis and Prior Inadequate Response to Tumor Necrosis Factor Inhibitors: Results from the Phase 3 BE COMPLETE Study and its Open-label Extension Up to 1 Year


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Introduction: We assess bimekizumab (BKZ) efficacy and safety to 52 weeks (wks) in psoriatic arthritis (PsA) patients (pts) with prior inadequate response to TNFi.

Procedure: BE COMPLETE included a 16-wk double-blind, placebo (PBO)-controlled period. Wk16 completers were eligible for BE VITAL OLE entry. Data here include pts randomized in BE COMPLETE only: 2:1 sc subcutaneous BKZ 160mg Q4W:PBO. At Wk16, PBO pts switched to BKZ (PBO/BKZ). Efficacy data are observed case or using non-responder/multiple imputation (binary/continuous). TEAEs reported to Wk52 for pts who received ≥1 BKZ dose, including PBO/BKZ switchers.

Results: 347/400 (86.8%) completed Wk52. Efficacy responses with BKZ were sustained Wk16–Wk52. At Wk52, 51.7% BKZ and 40.6% PBO/BKZ pts achieved ACR50. In pts with BL psoriasis (≥3% body surface area), 65.9% BKZ and 60.2% PBO/BKZ pts achieved PASI100 (complete skin clearance) at Wk52. At Wk52, 47.2% BKZ and 33.1% PBO/BKZ pts achieved minimal disease activity. To Wk52, 243/388 (62.6%) BKZ-treated pts had ≥1 TEAE (126.0/100PY); 23 (5.9%) pts reported a serious TEAE (7.0/100 PY). 2 (0.7%) pts receiving BKZ (0.8/100 PY) reported malignancies (excluding non-melanoma skin cancers). 25 (6.4%) pts receiving BKZ (7.7/100 PY) reported Candida infections; all reported as mild or moderate by investigators; none systemic. Two cases of oral candidiasis led to study discontinuation. There was one death (sudden death; history of cardiac events), two adjudicated major adverse cardiac events and no definite/probable adjudicated inflammatory bowel disease.

Conclusion: In pts with PsA and TNFi-IR, BKZ demonstrated sustained efficacy Wk16–Wk52. Safety profile consistent with previous reports.

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11. Comparison of Cutaneous Irritation With Repeated Application of Tazarotene 0.045% Lotion, Adapalene 0.3% Gel, and Trifarotene 0.005% Cream

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Introduction: Topical retinoids are recommended for acne treatment but associated cutaneous irritation may limit their use and patient adherence. Tolerability can be influenced by the retinoid itself, its concentration, vehicle used for its delivery, and skin hydration. Third- and fourth-generation topical retinoids have been developed using lower concentrations, enhanced vehicles, and/or novel retinoids to be efficacious while providing a more patient-friendly tolerability profile. Low-dose tazarotene 0.045% lotion was developed using polymeric emulsion technology to provide uniform and rapid distribution of tazarotene and hydrating ingredients (sorbitol, light mineral oil, diethyl sebacate, water) on the skin in a highly spreadable formulation. Here, we compare the tolerability of tazarotene 0.045% lotion with adapalene 0.3% gel and trifarotene 0.005% cream.

Methods: Healthy adults with Fitzpatrick skin types I-II were enrolled in two identical, double-blind, 12-day modified cumulative irritation patch studies (N=20 each). In each study, two active patches and one control patch (no product) were placed on participants’ upper back. Active patches included 0.1 cc of tazarotene lotion and either adapalene 0.3% gel (Study 1) or trifarotene 0.005% cream (Study 2). Patches were replaced every 2-3 days, totaling 5 applications. At each patch removal, Dermal Effects (0=no evidence of irritation, 7=strong reaction spreading beyond application site) and Other Effects (0=no other effects, 6=small petechial erosions and/or scabs) were assessed.

Results: In Study 1, tazarotene lotion and adapalene gel were both mildly irritating, with mean Dermal Effects scores <1 at all study visits. Overall, there was less irritation with tazarotene than adapalene (highest mean score: 0.50 vs 0.80, respectively), though differences were not significant at any assessment. Other Effects mean scores were negligible with both drugs at all study visits. In Study 2, Dermal Effects mean scores were significantly greater for trifarotene cream than tazarotene lotion 2 days after the first patch application (0.80 vs 0.05; P<0.05) and at each subsequent visit (P<0.001); mean scores ranged from 1.70-2.20 for trifarotene versus 0.10-0.70 for tazarotene. Other Effects mean scores were significantly greater with trifarotene than tazarotene after the second patch application and continuing through the final assessment (P<0.01, all). In both studies, no irritation was observed from the control patch at any time.

Conclusions: Tazarotene 0.045% lotion was found to be significantly less irritating than trifarotene 0.005% cream and numerically less irritating than adapalene 0.3% gel, one of the best-tolerated topical retinoids. The favorable tolerability profile of tazarotene 0.045% lotion may be due to the lower dose compared to other tazarotene formulations and the proprietary polymeric emulsion lotion vehicle that provides rapid and uniform delivery of tazarotene and hydrating ingredients.

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Ruxolitinib cream was well tolerated in patients ≥2 years old (y/o) with atopic dermatitis (AD) in a pediatric pilot pharmacokinetics (PK)/safety study (NCT03257644); efficacy was consistent with results in adolescents/adults (TRuE-AD1/TRuE-AD2 [NCT03745638/NCT03745651]). This phase 3 double-blind pediatric study (TRuE-AD3 [NCT04921969]) evaluated efficacy, safety, and PK of ruxolitinib cream in patients 2–<12 y/o with mild to moderate AD ≥3 months (Investigator’s Global Assessment [IGA] 2/3; 3%–20% affected body surface area [BSA]; [for 6–<12 y/o] mean itch Numerical Rating Scale [NRS] ≥4). Patients were randomized 2:2:1 to twice-daily 0.75%/1.5% ruxolitinib cream or vehicle for 8 weeks; rescue therapy was not permitted. Overall, 330 patients were enrolled (vehicle, n=65; 0.75%/1.5% ruxolitinib cream, n=134/n=131). Median (range) age was 6 (2–11) years. Mean (SD) affected BSA, 10.5% (5.40%); Eczema Area and Severity Index (EASI), 8.6 (5.40); 76.4% of patients had IGA 3. A clinical effect was observed in patients applying 0.75%/1.5% ruxolitinib cream vs vehicle at Week 2, increasing through Week 8 for IGA treatment success (IGA 0/1 with ≥2-grade improvement from baseline; 36.6%/56.5% vs 10.8%; P<0.0001 for both) and ≥75% improvement in EASI (51.5%/67.2% vs 15.4%; P<0.0001 for both). In patients 6–<12 y/o, ≥4-point improvement in itch NRS (NRS4) at Week 8 was achieved by 37.5%/43.4% vs 29.7%; median time to NRS4 was 11.0/13.0 days vs 23.0 days (hazard ratio, 1.74/1.77; P<0.05 for both). Treatment-related adverse events (AEs) through Week 8 were reported in 5.3% of patients applying ruxolitinib cream (combined) vs 3.1% applying vehicle; 2.7% and 0% reported application site pain, respectively. No AEs suggestive of systemic Janus kinase inhibition or serious AEs were reported. Mean (SD) steady-state plasma concentrations of ruxolitinib at Week 8 for 0.75%/1.5% ruxolitinib cream were 15.8 (30.4)/28.4 (59.2) nM, well below that associated with myelosuppression (281 nM). In patients 2–<12 y/o with mild to moderate AD, ruxolitinib cream achieved significant efficacy at Week 8 vs vehicle. Patients 6–<12 y/o had improved itch at Week 8 and reduced time to NRS4 vs vehicle. Ruxolitinib cream was well tolerated. These results were similar to results in adolescents/adults.

13. Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Scalp and Body Psoriasis in the Phase 3 ARRECTOR Trial

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Introduction: Roflumilast is a selective, nonsteroidal, highly potent phosphodiesterase 4 inhibitor under investigation as a once-daily foam for treatment of scalp and body psoriasis.

Methods: This phase 3 randomized controlled trial (NCT05028582) was conducted in patients ≥12 years old with scalp and body psoriasis, minimum Scalp Investigator Global Assessment (S-IGA) score of Moderate (3 on a 5-point scale), and minimum Body-IGA (B-IGA) of Mild (2). Overall body surface area affected by psoriasis was ≤25% (including ≤20% for non-scalp areas, not including palm/soles). Patients were randomized 2:1 to apply once-daily roflumilast foam 0.3% (n=281) or vehicle (n=151) for 8 weeks. The co-primary efficacy endpoints were S-IGA and B-IGA Success (S-IGA/B-IGA of Clear [0] or Almost Clear [1] plus ≥2-grade improvement from baseline) at Week 8.

Results: Significantly more roflumilast-treated than vehicle-treated patients achieved S-IGA Success (66.4% vs 27.8%; P<0.001) and B-IGA Success (45.5% vs. 20.1%; P<0.0001) with 40.0% and 27.8% of roflumilast-treated patients achieving S-IGA and B-IGA of Clear, respectively (P<0.0001; nominal for B-IGA) at Week 8. All secondary endpoints achieved statistical significance. Notably, improvement in itch was observed as early as 24 hours following first application (P=0.0164) as measured by change from baseline in Scalp Itch-Numeric Rating Score. Safety and local tolerability were favorable with ≥95% of patients reporting no or mild sensation. Rates of discontinuation due to adverse events were low and similar among roflumilast-treated (1.8%) and vehicle-treated (1.3%) patients.

Conclusion: Roflumilast foam 0.3% improved scalp and body psoriasis across multiple efficacy endpoints while demonstrating favorable safety and tolerability. Sponsored by Arcutis Biotherapeutics, Inc.
14. Prevalence of Considerations Potentially Influencing JAK Inhibitor Use Among Patients With Moderate to Severe Atopic Dermatitis: a US Claims Database Analysis

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Introduction: Oral Janus kinase (JAK) inhibitors have recently been approved for treatment of atopic dermatitis (AD). However, certain disease comorbidities, patient age, and drug interactions may affect patient selection for these therapies.

Methods: This was a retrospective study (January 2015–September 2020) using OptumInsight Clininformatics® Data Mart Database of adults with moderate-to-severe AD, defined by treatments received (including phototherapy, systemic immunomodulatory medication, or dupilumab). The index date was the date of first claim for treatments of interest. Patients must have 12 months of continuous enrollment pre-index. A targeted review of the literature and prescribing information identified the following considerations associated with JAK inhibitor use: black-box warnings (BBW), including risk of major cardiovascular events (MACE); thrombosis, infections, and malignancies; relative contraindications (conditions for which JAK inhibitor labels advise to “avoid”, “discontinue”, or that is “not recommended”); precautions (other identified conditions); or drug-drug interactions. In accordance with Pharmacovigilance Risk Assessment Committee (PRAC) recommendations, age ≥ 65 years was also considered to be a risk factor for complications with JAK inhibitor use. Number and proportions of patients meeting the aforementioned criteria during the 12-month pre-index period were assessed.

Results: 143,925 adult patients with moderate-to-severe AD were identified. Mean age (standard deviation) was 55.0 (19.8) years, 59.4% were female, 61.8% were white. The proportion of adults with conditions meeting any of the above consideration criteria was 63.2%. Of all adult patients, the most common considerations for use were BBW (46.2%) and precautions (42.4%). For those that involved consideration related to BBW, most patients (40.6%) had increased risk of MACE (patients with ≥ 1 high risk factor or ≥ 2 low/moderate risk factors), diabetes (15.8%) and/or smoking history (11.3%). For precautions, hyperlipidemia and/or hypolipidemia (38.1%) was the largest contributor. The proportion of patients with JAK-inhibitor related considerations due to age ≥ 65 years was 38.7%.

Conclusions: Over half of adults with moderate-to-severe AD had conditions that potentially influence the selection of JAK inhibitor treatment. To further confirm results, additional studies are needed with longer look-back periods and data sources where medical conditions can be confirmed by physicians.

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15. Real-world Tralokinumab Use in Dupilumab-experienced Patients: A Retrospective Multi-center Case Series
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Introduction: There is a need for treatment options that offer atopic dermatitis (AD) patients long-term disease control along with a favorable safety profile. Head-to-head studies of the two available FDA-approved biologics dupilumab and tralokinumab for adults with moderate-to-severe AD have not been performed, and real-world evidence of tralokinumab use in patients that were previously treated with dupilumab is limited.

Objective: To further characterize the tralokinumab efficacy and safety profile by evaluating clinical findings in patients previously treated with dupilumab in routine clinical practice who later switched to tralokinumab.

Method: Nine adult patients with moderate-to-severe AD previously treated with dupilumab, and subsequently switched to tralokinumab, were included. Data collected during routine clinical practice related to tralokinumab treatment included duration of treatment, dose, IGA, BSA, PROs, and AEs.

Results: Median (range) baseline IGA and IGA at time of tralokinumab administration were 4 (3-4) and 3 (2-4), respectively. Median baseline BSA and BSA at time of tralokinumab administration were 20% (4-30%) and 10% (1-30%), respectively. Disease duration ranged from 1-2 years to over 20 years. Duration of dupilumab treatment was 2-8 months (n=6). Reasons for discontinuing dupilumab treatment included AEs (n=5) and inadequately controlled AD on dupilumab (n=3). All 9 dupilumab-experienced patients were administered on-label tralokinumab (every 2 weeks, n=1; every 4 weeks, n=1) and had been on tralokinumab for 2-8 months. At the time of data collection, median (range) IGA and BSA for these patients were 0 (0-3) and 0% (0-10%), respectively. All patients experienced improvements in PROs; 67% (6/9) reported improvements in itch with NRS scores of 0/1, 44% (4/9) reported general clearance...
of AD signs and symptoms, and 44% (4/9) reported overall satisfaction of being on tralokinumab. AEs of conjunctivitis (n=3) and joint pain (n=1) completely resolved in patients upon switching from dupilumab to tralokinumab. No AEs were reported except in 1 patient with possible mild seborrheic dermatitis/head-neck dermatitis eruption that was treated with topicals, and 1 patient with herpes labialis, which was unclear if related to tralokinumab treatment.

**Conclusion:** This case series suggests tralokinumab is a potentially effective therapy in moderate-to-severe AD patients who have failed dupilumab due to lack of efficacy or AEs.

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

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**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 ≥2 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% improvement in AN counts from baseline vs placebo across all subgroups, and greater improvements in AN counts from baseline were achieved with secukinumab vs placebo across all subgroups, and were sustained through week 16.

**Conclusion:** 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.

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

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

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

**Materials and Method:** In the randomized, double-blind, placebo-controlled, 24-week studies, LIBERTY-PN PRIME (NCT04183335) and PRIME2 (NCT04202679), adults with PN inadequately controlled by topical prescription therapies, were randomized 1:1 to dupilumab 300 mg every 2 weeks or matched placebo. Atopic patients were defined as patients with a physician-documented history, or current diagnosis, of at least one of the following atopic comorbidities: AD, allergic rhinitis/rhinoconjunctivitis, asthma, or food allergy. Efficacy was assessed from baseline to Week 24 through the Worst Itch Numerical Rating Scale (WI-NRS; 0–10), and the
Prurigo nodularis (PN) or chronic prurigo

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

Conclusion: Dupilumab treatment improves itch and skin lesions in PN patients with and without a history of atopic comorbidities, indicating that underlying type 2 inflammation is present in patients with PN regardless of their history of atopic comorbidities.

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

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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. Here, we 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) on an 11-point scale (0=no itch; 10=worst imaginable itch) at Week 12. Mean change in itch (PP-NRS score) from baseline at Week 12; the Dermatology Life Quality Index (DLQI) itch item, a 4-point scale rating impact of itch on HRQoL (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=no itch; 10=worst imaginable), were also assessed.

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 across 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 from the first clinical assessment (Week 2) and were significantly greater at Week 12 across all measures with tapinarof versus vehicle. A higher proportion of tapinarof-treated patients versus vehicle achieved a PP-NRS score of 0 or 1 (itch-free state) at Week 12: 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), in PSOARING 1 and 2, respectively. Mean itch scores improved significantly more with tapinarof compared with vehicle at Week 12: 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), in PSOARING 1 and 2, respectively

Conclusions: Tapinarof cream 1% QD was superior to vehicle in improving pruritus 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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19. Development of a Patient-centered Conceptual Disease Model for Prurigo Nodularis: A Qualitative Content Analysis

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Introduction: Prurigo nodularis (PN) or chronic prurigo is characterized by chronic pruritus and multiple localized or generalized lesions. The intense itching people with PN experience often causes excoriation, leading to secondary 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 model.
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.

20. Prophylaxis and Treatment of Dermatologic Adverse Events with Tumor Treating Fields Therapy in the Abdominopelvic Region: Practical Guidance from Clinical Experts

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Introduction: Tumor Treating Fields (TTFields) therapy is a noninvasive, locoregionally delivered cancer treatment currently FDA-approved for glioblastoma and pleural mesothelioma. It consists of alternating electric fields delivered to the tumor site via skin-placed arrays. TTFields disrupt cancer cell viability through multiple mechanisms of action, including anti-mitotic effects, anti-migratory effects, preventing DNA repair mechanisms, and enhancing the immune system response. TTFields therapy demonstrated a tolerable safety profile in clinical and real-world settings. Mild-to-moderate dermatologic events beneath skin-placed arrays are the most common adverse events (AEs) associated with treatment. Ongoing studies are evaluating the effectiveness of TTFields therapy for ovarian cancer, pancreatic cancer, hepatocellular carcinoma, and gastric adenocarcinoma. Here we provide practical guidance for the prophylaxis and treatment of TTFields therapy-related dermatologic AEs in the abdominopelvic region.

Methods: Expert guidance presented is based on authors’ clinical expertise and previously published literature for the management of TTFields therapy-related dermatologic AEs (Lacouture 2020; Anadkat 2023).

Results: Commonly occurring TTFields therapy-related dermatologic AEs include contact dermatitis, pruritus, hyperhidrosis, and skin erosions/pressure necrosis. Risk factors for developing dermatologic AEs are classified as medical- (prior/concomitant treatments and pre-existing conditions), product- (chemical irritants and mechanical pressure), patient- (skin condition and lifestyle), and environment- (climate, humidity, and clothing) related. To reduce risk of dermatologic AEs, patients should be provided with instructions for optimal skin care such as shaving with electric razors, efficient skin cleaning, and removing natural oils/moisture prior to array placement. Patients should be counseled on proper procedures to carefully replace and reposition (~2 cm) arrays every 3–4 days. Low-potency topical corticosteroids (or cream calcineurin inhibitors) are recommended as early and/ or routine prophylactic treatment. Silicone-based barriers may also help reduce risk. Close monitoring of skin between changes will help promptly identify AEs to prevent exacerbation of easily manageable AEs. Treatment for dermatological AEs includes intermittent mid/high potency corticosteroids (contact dermatitis), antihistamines or anesthetics (pruritus), aluminum zirconium formulations or topical glycopyrrolate (hyperhidrosis), and prescribed antibiotics (infections secondary to skin erosions). Different vehicles of application may impact the electrical impedance of TTFields therapy; therefore, petroleum-based products should be avoided whilst wearing arrays.

Conclusion: Utilizing practices to identify, prevent, and manage TTFields therapy-related dermatologic AEs is essential to maximizing TTFields usage time, a factor associated with improved clinical outcomes. Dermatologists should be aware of this treatment
modality due to the frequency of dermatologic AEs – a multidisciplinary approach for patients on TTFIELDS therapy will ameliorate patient outcomes.

21. Deucravacitinib, an Oral, Selective, Allosteric Tyrosine Kinase Inhibitor, in Moderate to Severe Plaque Psoriasis: Evaluation of Lipid Parameters in the Phase 3 POETYK PSO-1 and PSO-2 Trials

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Introduction: Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (e.g., IL-23, Type 1 interferons) involved in psoriasis pathogenesis. Deucravacitinib, an oral, selective, allosteric TYK2 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. Deucravacitinib was significantly more efficacious than placebo or apremilast and was well tolerated in the phase 3 POETYK PSO-1 and PSO-2 trials. We evaluated changes in lipid parameters in these trials. Methods: PO-1 (NCT03624127) and PSO-2 (NCT03617751) were 52-week, double-blind trials conducted globally. Patients with moderate to severe plaque psoriasis (PASI ≥ 12, sPGA ≥3, BSA involvement ≥10%) were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. This analysis evaluated serum lipids in patients taking placebo, deucravacitinib, or apremilast during Weeks 0-16 and those taking deucravacitinib continuously during Weeks 0-52 in PSO-1 and PSO-2. Mean changes in total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides are reported, as are shifts from baseline in CTCAE v5 severity grade of hypercholesterolemia and hypertriglyceridemia.

Results: 666 and 1020 patients were randomized in PSO-1 and PSO-2, respectively. Mean baseline levels of total cholesterol, HDL cholesterol, and LDL cholesterol were comparable between treatment groups. Mean changes from baseline to Week 16 were small and none was clinically meaningful. Worsening of hypercholesterolemia grade from baseline was observed with similar frequencies among patients receiving placebo, deucravacitinib, and apremilast (10.6%, 11.7%, and 8.4%, respectively); nearly all shifts were 1 grade, and there was no grade ≥ 3 event. Baseline triglyceride levels were near the upper limit of normal (150 mg/dL) across treatment groups. A 10.3 mg/dL increase in mean triglycerides from baseline to Week 16 was observed with deucravacitinib, but worsening in hypertriglyceridemia >1 grade from baseline was rare (1.2%) and comparable to placebo (1.4%). Most deucravacitinib-treated patients maintained the same or shifted to a lower grade of hypertriglyceridemia from baseline to Week 16. Among patients treated with deucravacitinib continuously for 52 weeks, mean changes in total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides were small. Shifts in >1 grade from baseline for hypercholesterolemia and hypertriglyceridemia were uncommon (0.2% and 1.9%, respectively). No patient discontinued deucravacitinib due to a lipid-related adverse event.

Conclusion: There were no meaningful changes in cholesterol, HDL cholesterol, and LDL cholesterol levels with deucravacitinib treatment. Minimal increases in mean triglyceride levels from baseline to Weeks 16 and 52 were accompanied by very few worsening shifts >1 grade.

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ML, SB, and RMK: Employees and shareholders: Bristol Myers Squibb
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22. Dupilumab Improves Urticaria Signs and Symptoms and Quality of Life in Patients with Chronic Spontaneous Urticaria (CSU)

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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) is 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-Q2oL; range 0–100 [higher scores indicate greater QoL impairment]).

Results: Mean UAS7 and CU-Q2oL 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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23. Risk Stratifying Skin Cancer Screening in SOTRs
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Improvements in solid organ transplants and the prolonged expected lifespan of solid organ transplant recipients have important implications in cancer screening recommendations. Prolonged use of immunosuppressants in solid organ transplant recipients raises the risk of these patients developing malignancy, with skin malignancy being the most common. Traditionally, all these patients are referred for yearly skin checks with a dermatologist without consideration of their relative risk of developing a skin cancer. The Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC) is an attempt to stratify solid organ transplant recipients into groups based on their risk of developing a non-melanoma skin cancer. It incorporates patients’ skin tone, history of skin cancer, age at transplant, sex, and site of transplant to determine a patient’s 10-year risk of developing a non-melanoma skin cancer. Utilizing this model to guide skin cancer screening recommendations will better allocate resources to the highest risk patients while also avoiding unnecessary healthcare costs.

24. Identifying Risk Factors for Metastatic Squamous Cell Carcinoma in Organ Transplant Recipients: A Single Institution Case Controlled Retrospective Study Protocol
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Abstract
Skin cancer remains a prominent global health concern, contributing significantly to cancer-related morbidity and mortality. Solid organ transplant recipients are known to be particularly susceptible to the development of skin cancer. This research protocol outlines a comprehensive retrospective study designed to investigate additional risk factors associated with the progression to metastatic cutaneous squamous cell carcinoma (cSCC) in this vulnerable population.
This protocol utilizes data sourced from the Organ Procurement Transplant Network (OPTN) database, specifically focusing on one institution’s Transplant Recipient Forms (TRF), spanning from January 1, 1991, to July 30, 2022. The study groups will comprise of individuals spanning a diverse range within the transplant population including recipients of heart, lung, kidney, and liver. Utilizing this extensive database, we will assemble three cohorts of transplant recipients: an experimental group diagnosed with metastatic cSCC, age-sex-organ matched group with cSCC without metastases, and an age-sex-organ matched group without cSCC. Retrospective examination of clinical electronic health records will note the presence or absence of variables that may be correlated with development of metastatic cSCC in this population. Key variables under scrutiny include the recipient’s age at the time of transplant, the duration of survival post-
transplant, prior history of skin malignancies, history of other malignancies, family medical history, etc.

The primary objective of the study is to identify if there is an increased probability of metastatic cSCC development in the presence of the variables mentioned utilizing an odds ratio, or where appropriate, hazard ratio. The execution of this study protocol holds the potential to enhance our understanding of the risk factors influencing the progression of cutaneous squamous cell carcinoma to its metastatic form in organ transplant recipients. Ultimately, our findings may aid in the identification of high-risk individuals and the development of targeted interventions to reduce the burden of this life-threatening complication in this vulnerable population.

25. Complete/near-complete Itch Response Observed in Adult and Adolescent Patients With Moderate-to-Severe Atopic Dermatitis Initiating Dupilumab Treatment in Real World Practice

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Introduction: Chronic itch (pruritus) is a defining characteristic of atopic dermatitis (AD) and is a significant contributor to poor quality of life in patients. A Pruritus/Peak Pruritus Numerical Rating Scale (NRS) score of 0/1 could be considered a complete or near-complete itch response. Here, we report Pruritus NRS and Overall Disease Severity (ODS) score of 0/1 over time in patients older than 12 years with moderate-to-severe AD initiating dupilumab treatment in real-world practice.

Methods: Patients aged ≥12 years with moderate-to-severe AD, initiating real-world dupilumab treatment for AD per approved prescribing information in the USA and Canada, were eligible for entry into PROSE (NCT03428646). Enrolled patients received their first dose of dupilumab at the baseline visit; there were no restrictions on post-baseline dupilumab dosing changes, or concomitant medication use; patients were encouraged to stay in the study if they discontinued dupilumab. Data presented are from an interim analysis (data cut taken as of Nov 2022); only ≥36 months of patient experience in PROSE at the time of interim analysis is reported. No formal hypothesis testing was performed; descriptive statistics are presented.

Results: Among 857 patients (mean (SD) age 40.1 (17.9) years and 42% male), mean (SD) duration of dupilumab treatment was 23.1 (13.7) months. At Month 36, 185 patients (21.6%) had discontinued from the study; the main reason was withdrawal of consent by the patient (76 patients, 8.9%). The proportion of patients with available observations reporting a Pruritus NRS score of 0/1 increased from baseline (2.7%) to Month 3 (28.1%) and continued to increase up to Month 36 (56.3%). Similarly, the proportion of patients with a clinician-reported ODS score of 0/1 also increased from baseline (2.2%) to Month 3 (39.8%) and up to Month 36 (65.1%). Safety was consistent with the known dupilumab safety profile.

Conclusions: In this interim analysis of PROSE, a majority of patients reported a complete/near complete pruritus response and overall disease severity response over a 36-month period.

Keywords: Real-world, registry, dupilumab, pruritus

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26. Integrated Safety Analysis of Abrocitinib in 635 Adolescent Patients with Moderate-to-severe Atopic Dermatitis with Over 1000 Patient-years of Exposure

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______________________________
Introduction: The US Food and Drug Administration recently expanded the indication of abrocitinib in adolescent patients (12 to <18 years of age) with moderate-to-severe atopic dermatitis (AD). Abrocitinib was efficacious and well tolerated in adolescent patients exposed for approximately 1 year of treatment. We describe the updated long-term integrated safety profile of abrocitinib in adolescent patients in the JADE clinical program.

Methods: A total of 635 adolescent patients (exposure: 1011.4 patient-years [PY]) were pooled for safety analysis from the phase 3 JADE clinical trials MONO-1 (NCT03349060), MONO-2 (NCT03375871), TEEN (NCT03796676), and REGIMEN (NCT03627767) and subsequently enrolled in the ongoing phase 3 extension trial JADE EXTEND (NCT03422822; data cutoff: September 25, 2021). Incidence rates (IRs; number of unique patients with events/100 PY) of severe adverse events (SAEs) and AEs of special interest were assessed.

Results: Of the total 635 adolescents, 490 received the same abrocitinib dose throughout exposure (730.6 PY); 289 received abrocitinib 200 mg (424.5 PY) and 201 received abrocitinib 100 mg (306.1 PY). Duration of exposure was ≥96 weeks in 38% and 37%, and ≥144 weeks in 8% and 4% of patients who received abrocitinib 200 mg or 100 mg, respectively. In the 200-mg and 100-mg arms, AEs occurred in 243 (84%) and 153 (76%) patients; 8% (IR [95% CI], 5.87 [3.76-8.74]) and 9% (5.87 [3.48-9.27]) experienced SAEs, and 10% (6.96 [4.69-9.93]) and 8% (5.13 [2.93-8.33]) discontinued the study due to AEs, respectively. IRs of AEs of special interest were 1.84 (95% CI, 0.79-3.62) and 1.28 (0.35-3.27) for serious infection, 2.11 (0.97-4.01) and 1.62 (0.53-3.77) for all herpes zoster (HZ) infections, and 0.69 (0.14-2.03) and 0.32 (0.01-1.77) for opportunistic HZ infections in the 200-mg and 100-mg arms, respectively. One patient (aged 16 years) in the 200-mg arm had a nonfatal venous thromboembolism event (pulmonary embolism; IR, 0.23 [95% CI, 0.01-1.28]); patient had a family history of pulmonary embolism. There were no events of nonmelanoma skin cancer or other malignancies, tuberculosis, or other opportunistic infections (excluding HZ), major adverse cardiovascular events, or deaths.

Conclusions: In this integrated safety analysis using the most recent data cut from the ongoing JADE EXTEND trial, abrocitinib had an acceptable long-term safety profile in adolescent patients with moderate-to-severe AD.

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Disclosures


28. Topical Clindamycin For Acne Vulgaris: Pharmacovigilance Safety Review and Retrospective Analysis of Gastrointestinal Events

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Background: Clindamycin, a lincosamide antibiotic, was the 125th most prescribed medicine in the US in 2020. Topical formulations that combine clindamycin with benzoyl peroxide or a retinoid are commonly used for acne vulgaris (AV) treatment. While oral and topical clindamycin carry warnings/contraindications regarding the development of gastrointestinal (GI) adverse events (AEs), the real-world incidence of these AEs with topical clindamycin is unknown. The objective is to provide an overview of safety data for topical clindamycin when used for AV treatment.

Methods: Safety data from published literature on PubMed (case reports, clinical trials data, retrospective data), previously unpublished worldwide pharmacovigilance data (from January 1, 1900-December 31, 2022), and two unpublished retrospective cohort studies of US electronic medical records (EMR; January 1, 2011 to January 31, 2019) were reviewed, with a focus on inflammatory bowel disease (IBD) and GI AEs following topical clindamycin monotherapy or combination treatment.

Results: There have been only 4 published case reports of topical clindamycin-associated GI AEs, which were all published between the years 1981-1997. In 8 published pivotal phase 3 clinical trials of topical clindamycin monotherapy or combination treatment for AV, GI-related AEs were reported in 1.4% of clindamycin-treated participants (38/2,672; safety populations). According to the pharmacovigilance data, the rate of GI-related adverse drug reactions with topical clindamycin-containing products was 0.000045% (64/1,048,533). In 1 published retrospective report, there were 0 reports of colitis from the 1,124 patients estimated to have received topical clindamycin prescriptions in the years 1977-1980. In the first retrospective EMR study, results indicate that physicians prescribe topical clindamycin for AV treatment equally to patients with a history of IBD (19.0%; 98/515) or without (20.7%; 14,495/70,151). The second retrospective EMR study showed that among patients with AV and an initial prescription for topical clindamycin (monotherapy or combination; n=18,012), there were 3 (0.02%) incident cases of pseudomembranous colitis within 30 days; none of these cases had a history of IBD.

Conclusions: A review of published case reports, clinical trials safety data, worldwide pharmacovigilance data, and retrospective US prescription data demonstrate that GI events—including colitis or pseudomembranous colitis—in patients exposed to topical clindamycin is extremely low, regardless of IBD history.

Support: Ortho Dermatologics.

29. Real-world Tralokinumab Use in Patients with Moderate-to-severe Atopic Dermatitis Resistant to Systemic Therapy: A Retrospective Case Series

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Introduction: The systemic biologics dupilumab and tralokinumab are approved for the treatment of adults with moderate-to-severe atopic dermatitis (AD) in multiple countries. Head-to-head studies of dupilumab and tralokinumab have not been performed, however, and real-world evidence of tralokinumab use in moderate-to-severe AD patients that were previously
30. A Case Series of Live Attenuated Vaccine Administration in Dupilumab-Treated Children with Atopic Dermatitis

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Introduction: Phase 3 dupilumab clinical trial protocols for Atopic Dermatitis (AD) prohibited administration of live attenuated vaccines within 4 weeks before the baseline visits and during treatment. However, 1 patient in the LIBERTY AD PRESCHOOL (NCT03346434, part B) study received live attenuated vaccine with ≤12 weeks gap between dupilumab administration and vaccination, and 8 patients in the open-label extension (OLE) LIBERTY AD PED-OLE study (NCT02612454) received a live attenuated vaccine, 4 patients were vaccinated with ≤12 weeks gap and 4 patients >12 weeks after discontinuing dupilumab. This study describes the clinical course of children with moderate-to-severe AD who were administered live attenuated vaccine during LIBERTY AD PRESCHOOL or LIBERTY AD PED-OLE study.

Study: Pediatric patients with moderate-to-severe AD who had previously participated in the phase 2, multicenter LIBERTY AD PRESCHOOL study (part A; 3/6mg/kg dupilumab single dose) or randomized, double-blind placebo-controlled phase 3 study LIBERTY AD PRESCHOOL (part B; 200mg dupilumab every 4 weeks [q4w] if baseline weight 5 to <15kg, or 300mg q4w if 15 to <30 kg) were subsequently enrolled into the LIBERTY AD PED-OLE study (200mg dupilumab q4w if baseline weight 5 to <15 kg, 300mg q4w if 15 to <30kg, or 200mg q2w if 30 to <60kg). This case series includes 9 patients (8 males) with severe AD at the parent study baseline (Investigator’s Global Assessment score=4) and Peak Pruiritus Numerical Rating Scale (range 0–10) scores of 5.2 (n=1), 8 (n=2), 9 (n=4), or 10 (n=2), who were administered a live attenuated vaccine, with or without pause, during dupilumab treatment in LIBERTY AD PRESCHOOL (part B; n=1) or LIBERTY AD PED-OLE study (n=8).

Results: All were first diagnosed with AD between 0–6 months of age. Age at enrollment varied from 8–56 months old. Dupilumab treatment duration up to the date of vaccination with live attenuated measles, mumps, rubella (MMR) and varicella vaccines (n=5) or MMR vaccine only (n=4) ranged from 85–840 days. No adverse events (AEs), including serious AEs, treatment-emergent infections and infestations, or serious infections were observed in the 4-week window post vaccination.

Conclusions: In this limited prospective case series of children with moderate-to-severe AD who also received live attenuated MMR vaccine, with or without live attenuated varicella vaccine, no serious adverse events were observed within 4 weeks, or after 4 weeks post-vaccination. Additional research is needed to assess the safety of live attenuated vaccines in patients on dupilumab treatment and to investigate whether dupilumab treatment impacts vaccine efficacy.

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31. Tapinarof Cream 1% Once Daily: Significant Efficacy in the Treatment of Moderate to Severe Atopic Dermatitis in Two Pivotal Phase 3 Trials in Adults and Children Down to 2 Years of Age

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**Introduction:** ADORING 1 and 2 were two identical phase 3, randomized, double-blind, vehicle-controlled trials of tapinarof cream 1% once daily (QD) in adults and children down to 2 years of age with moderate to severe AD. Here, we report the pivotal phase 3 efficacy and safety results for tapinarof cream.

**Methods:** In ADORING 1 and 2, patients with a Validated Investigator Global Assessment for Atopic Dermatitis™ (vIGA-AD™) score of ≥3, an Eczema Area and Severity Index (EASI) of ≥6, and body surface area (BSA) involvement of 5%–35% were randomized 2:1 to tapinarof cream or vehicle QD for 8 weeks. The primary efficacy endpoint was vIGA-AD™ response (score of clear [0] or almost clear [1] and ≥2-grade improvement from baseline) at Week 8. Secondary efficacy endpoints included ≥75% improvement in EASI score (EASI75), and ≥4-point reduction in Peak Pruritus-Numerical Rating Scale (PP-NRS; patients aged ≥12 years). Safety assessments included incidence of adverse events (AEs).

**Results:** 407 and 406 patients were randomized in ADORING 1 and 2, respectively. At baseline, 84.0–89.9% of patients had vIGA-AD™=3 (moderate), mean EASI=12.5–13.3, and mean BSA affected=16.7–16.9% across trials. At Week 8, the primary and secondary efficacy endpoints were met with statistical significance in the tapinarof groups versus vehicle: vIGA-AD™ response, 45.4% vs 13.9% and 46.4% vs 18.0% (both P<0.0001); EASI75 response, 55.8% vs 22.9% and 59.1% vs 21.2% (both P<0.0001); and ≥4-point reduction in PP-NRS, 55.8% vs 34.2% (P=0.0366) and 52.8% vs 24.1% (P=0.0015), in ADORING 1 and 2, respectively. Most AEs were mild or moderate, and trial discontinuation rates due to AEs were lower with tapinarof cream than vehicle. Most common AEs (≥5% in any group) were folliculitis, headache, and nasopharyngitis.

**Conclusion:** Tapinarof cream 1% QD demonstrated statistically significant efficacy compared with vehicle and was well tolerated in adults and children down to 2 years of age with moderate to severe AD.

**Funding Support:** Dermavant Sciences, Inc.

32. Rapid and Early Onset of Itch Relief with Tapinarof Cream 1% Once Daily in Two Pivotal Phase 3 Trials in Adults and Children Down to Two Years of Age with Moderate to Severe Atopic Dermatitis

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**Introduction:** Itch is the most bothersome symptom for patients with atopic dermatitis (AD). In ADORING 1 and 2, two identical phase 3, double-blind, vehicle-controlled trials, tapinarof cream 1% once daily (QD) demonstrated significant efficacy and was well tolerated in adults and children down to 2 years of age with moderate to severe AD. Here, we evaluate time to onset of itch relief with tapinarof cream.
Methods: In ADORING 1 and 2, patients with a Validated Investigator Global Assessment for Atopic Dermatitis™ score ≥3, and Eczema Area and Severity Index score ≥6 were randomized 2:1 to tapinarof or vehicle QD for 8 weeks. Itch relief was assessed by changes in Peak Pruritus Numerical Rating Scale (PP-NRS) score from baseline by visit, and changes in daily PP-NRS score (patient diaries) through Week 8. PP-NRS considers itch over the past 24 hours, assessed on an 11-point scale (0 indicates "no itch" and 10 is "worst imaginable itch").

Results: In ADORING 1 and 2, 407 and 406 patients were randomized. Baseline mean PP-NRS scores were 6.7 and 6.8, respectively. There were greater improvements in mean PP-NRS scores for tapinarof versus vehicle as early as Day 1, 24 hours after initial application, in ADORING 1 (–1.2 vs –0.9), and Day 2 in ADORING 2 (–1.6 vs –1.4). Daily itch improvements with tapinarof continued through the first 2 weeks (Day 14; –3.0 vs –2.0 and –2.9 vs –1.8), and through Week 8 of both trials. Statistically significant reductions in mean weekly PP-NRS scores occurred at Week 1 (earliest assessment) for tapinarof versus vehicle (–2.0 vs –1.2 [P<0.0001]) and (–2.0 vs –1.3 [P=0.0010]) in ADORING 1 and 2. Significantly greater reductions in mean weekly PP-NRS scores occurred with tapinarof versus vehicle for all visits through Week 8 (–4.1 vs –2.6 and –4.1 vs –2.4 [both P<0.0001]).

Conclusion: Tapinarof cream 1% QD demonstrated rapid, significant, and clinically meaningful pruritus relief versus vehicle from 24 hours after initial application, with improvements increasing through Week 8.

Funding Support: Dermavant Sciences, Inc.
Results: The 133 patients enrolled were randomized to dupilumab (n=67) or placebo (n=66). At Week 16, the primary and all secondary endpoints were met. Significantly more patients in the dupilumab vs placebo group achieved IGA 0/1 (40.3% vs 16.7%; P=0.003; primary endpoint) and ≥4-point improvement in the H/F Peak Pruritus Numerical Rating Scale (52.2% vs 13.6%; P<0.0001; a key secondary endpoint). Dupilumab-treated patients experienced significant improvement in percent change from baseline in the modified Total Lesion Sign Score for H/F lesions vs placebo (LS mean [SE] −69.4 [5.8] vs −31.0 [3.9]; P<0.0001) and Hand Eczema Severity Index (LS mean [SE] −74.8 [6.3] vs −39.9 [6.2]; P<0.0001). The most common TEAEs (≥10%) were nasopharyngitis (16% vs 11%) and dermatitis atopica (5% vs 18%).

Conclusions: Dupilumab significantly improved signs and symptoms in patients with H/F AD and had an acceptable safety profile.

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Dubost-Brama A: Sanofi – employees, may hold stock and/or stock options in the company

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Background/Introduction: Hyaluronic acid (HA) fillers have been widely used in soft-tissue augmentation for over 26 years, with HARES receiving the first approval (1996, Europe). HARES is a supportive (high G') gel with a low degree of water affinity (gel swelling) and modification (<1% BDDE) that has a well-established safety and efficacy profile in the literature, especially for infraorbital hollow (IOH) rejuvenation. While rare in practice, there has been recent attention on delayed-onset nodules and inflammatory reactions to HA fillers.

Objective: This safety review reports 23 years of global post-marketing surveillance data for delayed onset (≥14 days post-treatment) nodules, hypersensitivity reactions, and granulomas related to HARES.

Study Design: Global post-marketing surveillance reports for HARES were collected between 1999 and 2022 (23 years) and categorized into delayed adverse events of interest (DAEIs) based on strict inclusion and exclusion criteria: non-inflammatory nodules, inflammatory nodules, hypersensitivity reactions, and granulomas. Reporting frequencies are based on number of syringes sold.

Results: Approximately 2.8% (n=227) of reports collected contained 256 DAEIs, with a majority being hypersensitivity reactions (n=134, 0.0009%), followed by non-inflammatory nodules (n=66, 0.0005%), inflammatory nodules (n=46, 0.0003%), and granulomas (n=10, 0.0001%). DAEIs occurring after IOH rejuvenation comprised 30% of all DAEIs identified, with a majority of those being hypersensitivity reactions (n=51, 65%).

Conclusions: This 23-year global post-marketing safety review establishes a long-term safety profile for HARES, with low reporting frequencies of delayed-onset nodules and inflammatory events. Notably, these data support its continued use in clinical practice as a product of choice for IOH rejuvenation.

36. A Study Evaluating the Safety and Effectiveness of Hyaluronic Acid Filler HAEXT for Correction of Infraorbital Hollows (IOH)

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Introduction: Injection of hyaluronic acid (HA) filler is a
minimally invasive approach to addressing infraorbital hollows (IOH). This study evaluated effectiveness and safety of HA_{EYE}, an HA filler with a high gel strength (G'), to correct IOH.

**Methods:** Subjects ≥22 years with moderate-to-severe IOH were randomized 6:1 to HA_{EYE} or no treatment. Injections were performed using a needle or cannula, with a 4-week optional touch-up. Assessments included Galderma Intraorbital Hollows Scale (GIHS), aesthetic improvement, subject satisfaction, and adverse events (AEs). Primary endpoint was ≥1-point GIHS improvement, assessed by blinded evaluators at Month 3 (remote visits excluded from analysis).

**Results:** In total, 287 subjects were randomized to HA_{EYE} and 46 to no treatment. Injections were mainly supraperiosteal. The primary endpoint, Month-3 GIHS responder rate, showed a statistically significant difference between HA_{EYE}, 87.4%, and no treatment, 17.7%, P<0.001, with similar results after injections using needle (89.6%, N=113) or cannula (84.9%, N=97). Most subjects in the HA_{EYE}-group maintained GIHS improvement (≥63.5% vs. ≥11.1% for no-treatment, P<0.001), aesthetic improvement (≥80%) and subject satisfaction with appearance (≥76%) throughout Month 12, including looking less tired (≥79%) and feeling more attractive (≥71%). After initial HA_{EYE}-treatment, 12.7% of subjects had treatment-related AEs, the most common being implant site swelling, implant site pain, and headache. All treatment-related AEs were non-serious and mild or moderate.

**Conclusions:** Results demonstrated that HA_{EYE} was well-tolerated and highly effective for correction of IOH, with high rates of aesthetic improvement and subject satisfaction, maintained throughout 12 months.

37. Study of Risk Factors for Metastatic Squamous Cell Carcinoma in Organ Transplant Recipients at an Academic Medical Center

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**Background:** Malignancy is the third leading cause of death in solid organ transplant recipients. Currently, cutaneous squamous cell carcinoma is the most common neoplasm found in transplant patients and is associated with increased morbidity and mortality. Challenges remain in clinical practice to identify patients at higher risk of developing metastatic cutaneous squamous cell carcinoma.

**Objectives:** The primary outcome of this study is to investigate known risk factors for squamous cell carcinoma and determine predictive variables for metastasis in the context of immunosuppressed solid organ transplant recipients. The results of this study will enable clinicians to accurately identify transplant patients at an increased risk of metastatic cutaneous squamous cell carcinoma and decrease mortality in this population.

**Methods:** The Organ Procurement Transplant Network (OPTN) database contains pre-transplant and post-transplant data on every transplant event occurring in the United States. Eligible participants will be identified using the Standard Transplant Analysis and Research file, based on OPTN for the period January 1, 1991, to July 30, 2022. The number of patient cases reported from our institution to OPTN is 2546. Chart review of these 2546 cases yielded 16 patients with metastatic cutaneous squamous cell carcinoma.

**Results:** Of 2546 reported transplant cases at our institution, 16 (<1%) patients were found to have metastatic cutaneous squamous cell carcinoma. Most patients were male (14 (88%)) with an average age of 59 years at time of transplant and more than half (10 (62%)) did not report having a vocational history that involves sun exposure. On average, the time from transplant to metastatic event was about 7 years while time from metastatic event to death was 9.25 months. Of the patients in our study, almost half (43%) died because of their metastatic cutaneous squamous cell carcinoma. Finally, none of the 16 patients reported receiving the HPV vaccine.

**Conclusion:** To conclude, our study findings are largely consistent with the current literature on known risk factors of cutaneous squamous cell carcinoma (cSCC) in organ transplant recipients. In addition, analysis of our sample leads one to wonder if HPV vaccination may be a protective factor against cSCC development in this population. With most organ transplant recipients developing cSCC within 7 years of transplant, close and frequent monitoring of patients in a dermatology clinic is imperative in early diagnosis of treatment in cSCC and decreasing mortality. More studies are needed to examine screening protocols and other preventative measures in organ transplant recipients and cSCC.
baseline, Week 4 (W4), and W8. Out of 21 patients who experienced sleep disturbance, 20 understood the SD-NRS as intended. The SD-NRS demonstrated test-retest reliability based on intra-class correlation coefficients for itch-stable participants (baseline to W4 score change ≤1) of 0.87 for the Average Pruritus Verbal Rating Scale (AP-VRS) and 0.76 for the Peak Pruritus VRS (PP-VRS). At baseline, Spearman’s rank-order correlation coefficients were moderate-to-strong (0.3-0.9) between the SD-NRS and the PP-NRS, PP-VRS, AP-NRS, and AP-VRS. Known-groups validity was demonstrated by higher SD-NRS scores in participants with worse scores on the PP-VRS, AP-NRS, AP-VRS, and Dermatology Life Quality Index. Improvements in SD-NRS scores were greater in patients classified as “improved” vs “worsened/unchanged” on the anchor PRO. Triangulation of estimates from the qualitative and quantitative analyses found a 2- to 4-point decrease on the 11-point SD-NRS scale as a meaningful within-patient change. Our results confirm that the SD-NRS is a well-defined, reliable, and valid PRO measure that can be used in daily practice and clinical trials to capture sleep disturbance in PN.

39. Triple-Combination Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% for Moderate-to-Severe Acne: Efficacy and Safety Results from a Pooled Phase 3 Analysis

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Background: A three-pronged approach to acne treatment that combines an antibiotic, antimicrobial agent, and retinoid in a single formulation may be more efficacious than single/double treatments while potentially reducing antibiotic resistance. IDP-126 polymeric mesh gel (clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide [BPO] 3.1%)—the first fixed-dose triple-combination acne topical in development—demonstrated superior efficacy to vehicle and component dyads, with good safety/tolerability in a phase 2 and two phase 3 studies of moderate-to-severe acne. This post hoc analysis further examined efficacy and safety of IDP-126 in data pooled from these phase 3 studies.

Methods: In two identical phase 3 (N=183; N=180; NCT04214639; NCT04214652), double-blind, randomized, 12-week studies, participants aged ≥9 years with moderate-to-severe acne were randomized 2:1 to receive once-daily IDP-126 or vehicle gel. Endpoints included ≥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/noninflammatory lesion counts. Treatment-emergent adverse events (TEAEs) and cutaneous safety/tolerability were evaluated.

Results: A total of 363 participants were randomized; a majority were female (58.4%) and had moderate acne (91.2%). At week 12, 50.0% of participants achieved treatment success with IDP-126 versus 22.6% with vehicle gel (P<0.001). IDP-126 resulted in over 70% reductions in inflammatory and noninflammatory lesions at week 12, which were significantly greater than vehicle (inflammatory: 77.9% vs 57.9%, respectively; noninflammatory: 73.0% vs 48.2%; P<0.001, both). Most TEAEs were of mild-moderate severity, and <3% of IDP-126-treated participants discontinued study/treatment due to AEs. Transient increases from baseline in investigator-assessed scaling and erythema and participant-assessed itching, burning, and stinging were observed with IDP-126, but resolved back to or near baseline values by week 12.

Conclusions: The innovative fixed-dose triple-combination clindamycin phosphate 1.2%/adapalene 0.15%/BPO 3.1% gel was efficacious and well tolerated in children, adolescents, and adults with moderate-to-severe acne. Half of participants achieved clear or almost clear skin by 12 weeks, rates not previously seen in clinical studies of other topical acne products.

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40. Effect of High-dose Subcutaneous Spesolimab on Skin Manifestations: Results from the Pivotal Effisayil 2 Trial of Flare Prevention in Generalized Pustular Psoriasis

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Introduction & Objectives: Generalized pustular psoriasis (GPP) is a chronic, rare and potentially life-threatening skin disease, characterized by flares of sterile pustules. Spesolimab, an anti-interleukin-36 receptor monoclonal antibody, is an effective and
approved treatment for GPP flares in adults. Effisayil 2 (NCT04399837) was a pivotal, randomized controlled trial that evaluated the efficacy and safety of subcutaneous spesolimab in preventing GPP flares. Here, we report the effect of high-dose spesolimab versus placebo on GPP lesions.

Materials & Methods: Eligible patients with a history of GPP were randomized (1:1:1:1) to receive one of three subcutaneous spesolimab regimens or placebo for 48 weeks. High-dose spesolimab regimen was loading dose 600 mg, followed by maintenance dose 300 mg every 4 weeks. GPP Physician Global Assessment (GPPGA) subscores for erythema, pustules and scaling/crusting, and total score were compared between high-dose spesolimab and placebo groups at baseline and over the treatment period (scale: 0, clear to 4, severe).

Results: Proportion of patients with baseline score of 0 for each GPPGA subscore and total score was generally similar between treatment groups, except for erythema; (high-dose spesolimab [n=30] vs placebo [n=31]: erythema, 13.3% vs 22.6%; pustules, 66.7% vs 67.7%; scaling/crusting, 23.3% vs 22.6%; total score, 10.0% vs 12.9%). By Week 4, proportion of patients with scores of 0 increased with high-dose spesolimab versus placebo, (erythema, 33.3% vs 19.4%; pustules, 80.0% vs 41.9%; scaling/crusting, 30.0% vs 19.4%; total score, 26.7% vs 16.1%), and high-dose spesolimab group had fewer flares (10.0% vs 35.5%). This trend was maintained at Week 24 (erythema, 36.7% vs 22.6%; pustules, 63.3% vs 45.2%; scaling/crusting, 36.7% vs 19.4%; total score, 33.3% vs 19.4%) and Week 48 (erythema, 36.7% vs 22.6%; pustules, 66.7% vs 45.2%; scaling/crusting, 43.3% vs 25.8%; total score, 36.7% vs 22.6%). There were no new flares after Week 4 in high-dose spesolimab group; however, flares increased with placebo (45.2% at Week 24; 51.6% at Week 48).

Conclusion: Versus placebo, high-dose subcutaneous spesolimab resulted in greater proportion of patients maintaining GPPGA scores of 0, lower proportion having flares at Week 4, and no new flares after Week 4. This was sustained at Weeks 24 and 48.

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Psoriasis with extensive elevation and scaling may have poor response to therapy. Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is indicated for the topical treatment of plaque psoriasis in adults. This post hoc analysis of two phase 3 trials of HP/TAZ investigated the efficacy and safety of HP/TAZ in the treatment of plaques with severe elevation or scaling.

Methods: Participants were randomized 2:1 to receive HP/TAZ or vehicle once daily for 8 weeks and were evaluated at weeks 2, 4, 6, 8, and 12 (4 weeks after treatment cessation). Participants were grouped into 2 subgroups: severe elevation or severe scaling (participants with a baseline target plaque score of 4 [severe] on a 0 to 4 scale for elevation or scaling, respectively). Elevation and scaling subgroups were not exclusive. Outcomes included treatment success (improvement in investigator’s global assessment [IGA] score ≥2 from baseline and an IGA score of 0 or 1), elevation or scaling success (≥2-grade improvement from baseline in elevation or scaling, respectively), and safety. Results were compared with a prior analysis of participants with mild (grade 2) scaling or elevation.

Results: In the phase 3 trials, 54 target plaques (HP/TAZ, n=34; vehicle, n=20) had severe elevation, 57 (HP/TAZ, n=37; vehicle, n=20) had severe scaling, 44 had mild elevation (HP/TAZ, n=30; vehicle, n=14), and 58 had mild scaling (HP/TAZ, n=36; vehicle, n=22). Participants with severe elevation or scaling achieved higher rates of treatment success with HP/TAZ versus vehicle (severe elevation: weeks 4 through 12, severe scaling: weeks 6 through 12; P<0.05 for all). At week 8, HP/TAZ was associated with significantly greater rates of elevation success in severely elevated plaques (72.9% vs 21.7%; P=0.004) and scaling success in severely scaled plaques (71.9% vs 26.6%; P=0.018) relative to vehicle. Additionally, at week 8, the rate of elevation success in severely elevated plaques (72.9%) was greater than that previously observed in mildly elevated plaques (43.1%), and the rate of scaling success in severely scaled plaques (71.9%) was greater than that of mildly scaled plaques (32.0%). Rates of treatment-emergent adverse events (TEAEs) were similar across groups, with no serious TEAEs. There were no reports of skin irritation with HP/TAZ.

Conclusions: HP/TAZ is effective in treating psoriasis with severe elevation or scaling. Thus, HP/TAZ is a therapeutic option for hyperkeratotic plaques.

References
5. Stein Gold et al. Poster presented at: DERM2021 NP/PA Conference; August 5-8, 2021; Las Vegas, NV.

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National Comprehensive Cancer Network (NCCN) guidelines do not provide an actionable recurrence risk threshold for when clinicians should intensify treatment plans for individual patients with stage I CM but rather assumes this population is low risk. Improving risk stratification in stage I CM can guide more appropriate treatment plans for these patients. The integrated 31-gene expression profile test (i31-GEP) provides a precise risk of recurrence prediction (i31-GEP for ROR) to identify patients at high risk of recurrent CM.

**Design:** Patients with stage I CM from four independent centers were combined with patients from a previously published meta-analysis (n=315 stage I CM patients). A recurrence risk threshold was established using the median i31-GEP predicted 5-year recurrence-free survival (RFS) for patients with stage IA disease (96.7%). Patients with an i31-GEP predicted 5-year RFS ≥96.7% or <96.7% were considered low and high risk for recurrence, respectively. RFS was assessed using Kaplan–Meier analysis and the log-rank test.

**Results:** Patients categorized as low risk had higher 5-year RFS (100%; 0 events out of 104 patients) than those categorized as high risk (89.8%; 16 events out of 211 patients; p=0.002). The i31-GEP for ROR had 100% sensitivity and 100% negative predictive value.

**Conclusions:** No specific risk threshold provides clinicians guidance regarding when to alter treatment plans for patients with stage I CM. Although most of these patients will have good outcomes, it is critical to identify patients who will experience tumor recurrence to implement risk-aligned care. The i31-GEP for ROR provides a patient’s precise risk of recurrence, allowing physicians to provide personalized recommendations according to each patient’s unique risk of recurrence and metastasis, taking into account not only standard clinical and pathological features but also tumor biology with the i31-GEP.

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43. Bimekizumab 3-year Maintenance of Response in Week 16 Responders with Moderate to Severe Plaque Psoriasis: Results from Five Phase 3/3b Trials


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**Introduction:** As losses of response are observed with some psoriasis therapies over time, studying long-term efficacy of new treatments is important. Here, maintenance of response over 3 years in patients who achieved complete/near-complete skin clearance after 16 weeks of BKZ treatment is reported.

**Procedure:** Data were pooled from BE VIVID, BE READY, and BE SURE phase 3 trials, their ongoing open-label extension (OLE), BE BRIGHT, and the BE RADIANT phase 3b trial. Patients were randomized to BKZ 320mg Q4W to Week 16, then either BKZ Q4W or Q8W until OLE entry (Week 48/52/56). All patients entered the OLE and received BKZ Q4W or Q8W; patients were re-assigned to BKZ Q8W in the third year of treatment. Maintenance of ≥90% improvement from baseline in PASI (PAS190), PAS1100, and Investigator’s Global Assessment (IGA) 0/1 responses through Year 3 (OLE Week 96) are reported in all Week 16 PAS190, PAS1100, and IGA 0/1 responders, respectively. Data are also reported for the subsets of these patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE). Patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints.

**Results:** 1,362 patients were randomized to BKZ; among these, 995 (73.1%), 719 (52.8%), and 985 (72.3%) achieved PAS190, PAS1100, and IGA 0/1, respectively, at Week 16 and entered the OLE; subsets of 348, 267, and 345 patients received BKZ Q4W/Q8W/Q8W. Among Week 16 PAS190 responders, 96.0% maintained PAS190 at Year 1 (Week 48), 93.9% at Year 2 (OLE Week 48), and 92.4% at Year 3 (OLE Week 96). Among Week 16 PAS1100 responders, 88.7% maintained PAS1100 at Year 1, 83.4% at Year 2, and 78.0% at Year 3. Among Week 16 IGA 0/1 responders, 95.8% maintained IGA 0/1 at Year 1, 93.6% at Year 2, and 91.7% at Year 3. Similar high responses were observed in patients who received BKZ Q4W/Q8W/Q8W.

**Conclusion:** The majority of patients who achieved disease control after 16 weeks of BKZ treatment maintained their responses through 3 years, including those who received BKZ Q4W/Q8W/Q8W dosing.

**References:**
5. BE BRIGHT: clinicaltrials.gov/cct2/show/NCT03598790;

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AA: Served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Pharma.

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To evaluate the efficacy of long-term treatment with tralokinumab in adolescents with moderate-to-severe atopic dermatitis (AD), a Phase 3, randomized, controlled study (ECZTRA 6) showed that tralokinumab provided significant improvement in signs and symptoms of AD, with 44% of adolescents achieving EASI-90 at 56 weeks. The study included 127 adolescents aged 12-17 years with moderate-to-severe AD, treated with subcutaneous tralokinumab 300 mg Q2W, with optional topical corticosteroids.

**Introduction:**
Tralokinumab is a monoclonal antibody that specifically neutralizes IL-13. ECZTRA 6 (NCT03526861) was a Phase 3, randomized, placebo-controlled trial of tralokinumab that included adolescents aged 12-17 years with moderate-to-severe AD who were enrolled in ECZTEND at least 56 weeks prior to the data cutoff (April 30, 2022).

**Method:**
Pts were treated with subcutaneous tralokinumab 300 mg Q2W, with optional topical corticosteroids (TCS), in ECZTEND. Endpoints at Wk 56 included proportion of pts achieving at least 75% or 90% improvement in Eczema Area and Severity Index (EASI) relative to parent trial baseline (EASI-75 or EASI-90), EASI ≤7, Worst Weekly Pruritus NRS ≤4, and Children’s Dermatology Life Quality Index (CDLQI) ≤6.

**Results:**
127 adolescents treated with tralokinumab for up to 2 yrs, ≤52 wks in parent trial and ≤56 wks in ECZTEND, were included in the efficacy analysis. At Wk 56 in ECZTEND, EASI-75 was observed in 84.4% and EASI-90 in 69.7% (mNRI: 82.8% and 66.4%). Proportions of pts achieving EASI ≤7 (no to mild disease) were 82.6% (mNRI: 81.0%), Itch NRS ≤4 (no to mild itch) 64.2% (mNRI 62.9%), and CDLQI ≤6 (no to small effect) 81.6% (mNRI: 77.6%). The safety profile remained consistent with that of ECZTRA 6.

**Conclusions:**
Treatment with tralokinumab for up to 2 yrs provided long-term disease control in adolescents with moderate-to-severe AD.