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Activity of topical antifungals against the terbinafine-resistant dermatophyte *Trichophyton indotineae*: in vivo analysis

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Background: The terbinafine-resistant dermatophyte *Trichophyton indotineae* (*T. indotineae*) is typically associated with superficial skin infections and has recently been detected in cases of toenail infection (onychomycosis). Efinaconazole has demonstrated greater in vitro activity against clinically isolated *T. indotineae* strains than ciclopirox and tavaborole in a previous analysis of antifungals, with a mean minimum inhibitory concentration of 0.014 µg/mL compared with 0.406 µg/mL and 4.75 µg/mL, respectively. The present follow-up study explored in vivo activity of these topical antifungals in a guinea pig model of *T. indotineae* dermatophytosis. The objective was to explore the in vivo clinical and mycological efficacy of 3 commercially available topical antifungals (ciclopirox 8%, efinaconazole 10%, tavaborole 5%) in a guinea pig model of *T. indotineae* dermatophytosis.

Methods: Guinea pigs were inoculated with 1 strain of terbinafine-resistant *T. indotineae* (applied to an abraded area of the dorsal skin). Starting at 3 days after inoculation, the inoculated area was treated once daily with commercially available topical antifungals for 7 days (efinaconazole 10% was diluted to 1%, and tavaborole 5% and ciclopirox 8% were reconstituted). Clinical efficacy, as measured by percent improvement from baseline in skin appearance score (0 [no lesions] to 5 [redness, scaling, hair loss, scabbing]) relative to untreated, and mycological efficacy (percent reduction of infected hairs relative to untreated) were assessed 3 days after treatment ended.

Results: In vivo clinical efficacy (as measured by skin appearance) of efinaconazole 1% was 51.8%, significantly greater than untreated controls ($P<0.01$) and numerically greater than tavaborole 5% (33.3%) and ciclopirox 8% (17.5%). Mycological efficacy was similar across antifungals (97–100%); however, skin sampling instead of hair root invasion may have been a better assessment in this model.

Conclusion: In a previous in vitro analysis, antifungal activity of efinaconazole was more potent than ciclopirox or tavaborole against terbinafine-resistant *T. indotineae* strains. These results were confirmed in the present in vivo model of *T. indotineae* dermatophytosis, in which efinaconazole demonstrated 1.6- and about 3-fold higher clinical efficacy than tavaborole and ciclopirox, respectively. These findings suggest efinaconazole may be effective in treating onychomycosis resulting from terbinafine-resistant *T. indotineae*.

Funding: Ortho Dermatologics

An eczema itch spray with colloidal oatmeal and a bacteriophage-encoded endolysin (Ecz-Rx): a novel treatment for itch associated with atopic dermatitis

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Background: The itch associated with atopic dermatitis (AD) remains a significant unmet need, driving interest in nonprescription, nonsteroidal therapies. A novel eczema itch spray containing colloidal oatmeal (CO) and a bacteriophage-encoded endolysin targeting *Staphylococcus aureus* (*S. aureus*) (eczrx) was evaluated for its antipruritic effects.

CO is well established as a skin protectant with moisturizing, anti-inflammatory, and antipruritic properties. Bacteriophage-derived endolysins are highly specific enzymes that rapidly lyse target bacteria with a low risk of resistance development. Combining these technologies may offer a novel approach to itch management by addressing both barrier dysfunction and microbial dysbiosis.

Methods: This comparator-controlled, randomized, double-blind pilot study enrolled 29 adults (18–65 years) with mild-to-moderate AD of at least 1 year's duration. Participants were randomized to receive either vehicle with CO or CO plus endolysin (CO+E). Products were applied twice daily for 14 days to affected areas. All participants used standardized cleanser and moisturizer throughout the study.

Clinical assessments were conducted across 8 on-site visits and included Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), Dermatology Life Quality Index (DLQI), and adverse event monitoring. Primary endpoints included itch severity using the Peak Pruritus Numerical Rating Scale (PP-NRS), erythema, and sleep impact.

Results: At Day 14, participants receiving CO+E demonstrated a 30% reduction in PP-NRS itch scores from baseline compared with a 4% reduction in the CO group. Improvements were evident by Day 3 and were sustained throughout the study period. Positive trends in sleep disturbance and erythema were observed, with almost 80% and 83%, respectively.

Conclusion: This pilot study suggests that a topical spray combining CO with a bacteriophage-derived endolysin may provide greater and earlier itch relief than CO alone in patients with mild-to-moderate AD. The findings are consistent with emerging evidence linking microbial dysbiosis, particularly *S. aureus* colonization, to itch pathogenesis. Limitations include the small sample size, short treatment duration, and lack of microbiome or biomarker assessments. As the study was not powered for statistical comparisons, results should be considered preliminary and hypothesis-generating. Larger, longer-term studies incorporating microbiome analyses are warranted to confirm efficacy and further explore mechanisms of action.

Brodalumab in high BMI participants with moderate-to-severe plaque psoriasis: the patient journey

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Introduction: High body mass index (BMI) is a risk factor for psoriasis, and individuals with psoriasis have a higher likelihood of obesity. High BMI has also been associated with reduced efficacy of biologic therapies in psoriasis, and some biologics incorporate weight-based dosing. Brodalumab, the only interleukin-17 (IL-17) receptor A blocker approved for moderate-to-severe plaque psoriasis, blocks downstream signaling of multiple IL-17 isoforms and is indicated as 210 mg doses regardless of body weight. Efficacy and safety of brodalumab were demonstrated in 3 pivotal, phase 3, multicenter, randomized trials in participants with moderate-to-severe plaque psoriasis (AMAGINE-1, AMAGINE-2, and AMAGINE-3). Efficacy and safety outcomes from 5 clinical trial participants with obesity are presented to illustrate their brodalumab treatment journey.

Methods: In AMAGINE-1, -2, and -3 (NCT01708590, NCT01708603, NCT01708629), participants were initially randomized to brodalumab (140 or 210 mg) or placebo subcutaneous injection every 2 weeks, with an additional dose at Week 1, for a 12-week induction period; AMAGINE-2 and -3 also included a randomized active comparator arm with the IL-12/23 inhibitor ustekinumab. At Week 12, brodalumab-treated participants were rerandomized to placebo or the same brodalumab dose (AMAGINE-1) or various brodalumab regimens (AMAGINE-2 and -3) through Week 52. Descriptive data are summarized for select participants with baseline BMI of ≥30 kg/m^2 who provided consent for photography and had available data after 12 weeks of brodalumab 210 mg treatment. Outcomes included absolute Psoriasis Area and Severity Index (PASI) scores and treatment-emergent adverse events (AEs).

Results: Prior to treatment with brodalumab 210 mg, selected participants (N=5) were 47 to 69 years with BMI of 33.1 to 37.5 kg/m^2 and absolute PASI scores of 13.6 to 34.1; 2 participants received prior biologic therapy. Two of 5 participants received brodalumab 210 mg for the duration of the trial, while 3 participants were rerandomized to brodalumab 210 mg at the Week 12 visit, either from brodalumab 140 mg (n=1) or placebo (n=2). After brodalumab 210 mg treatment, absolute PASI scores decreased to 0 to 21.4 after 12 weeks, reflecting reductions from baseline of 14% to 100%. Continued improvement or maintenance of absolute PASI scores to 0 to 3.5 was observed at the end of treatment (≤52 weeks), corresponding to reductions from baseline of 74% to 100%. Most AEs were deemed not related to treatment.

Conclusion: Across all 5 cases presented here, participants with obesity (BMI ≥30 kg/m^2) achieved substantial reductions in PASI scores, and most AEs were unrelated to treatment. These clinical trial cases are consistent with post hoc analyses of BMI subgroups from pivotal phase 3 trials and reinforce that brodalumab is an important, well-tolerated therapeutic option for achieving high levels of disease control in patients with obesity and moderate-to-severe plaque psoriasis.

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Concomitant use of SSRI/SNRIs and NSAIDs with remibrutinib in the phase 3 REMIX1/-2 studies

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Background: Remibrutinib is an oral Bruton tyrosine kinase (BTK) inhibitor approved for adult patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1-antihistamine (H1-AH) treatment. As BTK is expressed in platelets, the hemostatic safety profile for remibrutinib warrants detailed evaluation. Notably, no increase in mucocutaneous bleeding events with concomitant acetylsalicylic acid or clopidogrel have been reported. Here, we present results from REMIX-1/-2 (NCT05030311 and NCT05032157, respectively), evaluating mucocutaneous bleeding events in patients who received remibrutinib concomitantly with medications that affect platelet function: selective serotonin reuptake inhibitors (SSRIs)/serotonin and norepinephrine reuptake inhibitors (SNRIs) or nonsteroidal anti-inflammatory drugs (NSAIDs).

Methods: REMIX-1/-2 were 2 identical, double-blind, randomized, placebo-controlled phase 3 clinical trials assessing remibrutinib in adult patients with CSU inadequately controlled by H1-AHs. Patients were randomized 2:1 to receive remibrutinib 25 mg twice daily (BID) or placebo for 24 weeks, followed by open-label remibrutinib 25 mg BID for an additional 28 weeks. Mucocutaneous bleeding events were analyzed among patients who received remibrutinib with concomitant SSRIs/SNRIs or NSAIDs at Week 24 and Week 52 in the pooled REMIX-1/-2 study population.

Results: At Week 24, in the remibrutinib group, ≥1 mucocutaneous bleeding event occurred in 9.1% (55/606) of all patients, 8.5% (5/59) of patients with concomitant SSRI/SNRI use, and 7.1% (8/113) of patients with concomitant NSAID use. In the placebo group, ≥1 mucocutaneous bleeding event occurred in 2.0% (6/306) of all patients, 4.5% (1/22) of patients with SSRI/SNRI use, and 1.9% (1/53) of patients with NSAID use. Among the

5 patients with concomitant remibrutinib and SSRI/SNRI use who had ≥1 mucocutaneous bleeding event, 16 events occurred: these were mild (12/16 [75.0%]) or moderate (4/16 [25.0%]) and most commonly presented as ecchymosis or petechiae (2 patients each), and moderate events were managed with remibrutinib treatment interruption in 2 patients. Among the 8 patients with concomitant remibrutinib and NSAID use who had ≥1 mucocutaneous bleeding event, 9 events occurred: these were mild (8/9 [88.9%]) or moderate (1/9 [11.1%]), most commonly presented as petechiae (3 patients), and were managed without remibrutinib treatment interruption. With longer exposure through Week 52, no meaningful change in the incidence or severity of mucocutaneous bleeding events was observed among patients who received remibrutinib with concomitant SSRIs/SNRIs or NSAIDs.

Conclusion: In REMIX-1/-2, the incidence and severity of mucocutaneous bleeding events among patients receiving remibrutinib concomitantly with SSRIs/SNRIs or NSAIDs were consistent with the safety profile observed in all patients. These findings support the favorable safety profile of remibrutinib in patients with CSU.

Dupilumab in prurigo nodularis: 3-months follow-up insights into GLOBOSPIN, a global observational study

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Background: Prurigo nodularis (PN) is a chronic inflammatory disease that profoundly impacts quality of life. GLOBOSPIN is the first global real-world observational study aiming to characterize the use patterns and effectiveness of dupilumab in patients with PN during the first 3-month observation period.

Methods: The GLOBOSPIN 18-month, multinational, observational study (NCT05991323) enrolled 108 patients aged ≥18 years with PN who were prescribed dupilumab based on physician decision made independently of study participation, according to country-specific Prescribing Information. Assessments were performed at baseline and every 3 months. Effectiveness of dupilumab was evaluated using the Investigator Global Assessment of Chronic Prurigo Stage and Activity (IGA-CPG; 0 [clear]–4 [severe]).

Results: The proportion of patients achieving IGA-CPG Activity score of 0/1 was 4.1% at baseline, increasing to 32.9% at 3 months. The proportion of patients with an IGA-CPG Activity score of 3 (67.6%) or 4 (27.0%) at baseline, decreased to 32.9% and 4.3% at 3 months, respectively. The proportion of patients achieving IGA-CPG Stage score of 0/1 was 4.1% at baseline, increasing to 35.7% at 3 months. The proportion of patients with an IGA-CPG Stage score of 3 (58.1%) or 4 (17.6%) at baseline, decreased to 24.3% and 0% at 3 months, respectively.

Conclusion: The results of this study provide broader real-world insights on the effectiveness of dupilumab treatment in reducing itch and lesion count in patients with PN, as early as 3 months after treatment initiation.

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Dupilumab monotherapy improves xerosis and dyspigmentation in patients with skin of color and moderate-to-severe atopic dermatitis

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Introduction: Dyspigmentation and xerosis are clinical manifestations in patients with skin of color (SoC) and atopic dermatitis (AD) that have not been well studied. We report the effect of dupilumab on dyspigmentation and xerosis in patients with SoC and AD.

Methods: DISCOVER (NCT05590585) was a phase 4, open-label, single arm, 24-week dupilumab study in patients ≥12 years old, with Fitzpatrick skin types (FSTs) IV/V/VI, and moderate-to-severe AD. Self-reported White/Caucasian patients were ineligible. Patients received dupilumab monotherapy every 2 weeks for 24 weeks (≥30−<60 kg: 200 mg; ≥60 kg: 300 mg). Results are for subgroups of patients who reported being "very/extremely bothered" by skin hyperpigmentation, as assessed by dyspigmentation in AD questionnaire (D-AD; 0 [no pigmentation]–10 [worst pigmentation]) and/or by how dry skin felt, as assessed by xerosis in AD questionnaire (X-AD; 0 [not dry at all]–10 [extremely dry]).

Results: Of the 120 DISCOVER participants, 81.7%/10.8%/7.5% were Black/Asian/Other and 42.5%/48.3%/9.2% had FST IV/V/VI. In this subgroup analysis, at baseline, 43 patients reported being "very/extremely bothered" by hyperpigmentation, and 63 patients by how dry skin felt. From baseline to Week 24, the proportion of patients reporting being "very/extremely bothered" decreased for hyperpigmentation (48.8%/51.2% to 25.9%/11.1%) and for how dry skin felt (36.5%/63.5% to 11.6%/11.6%). By subgroup, mean±standard deviation improvement for D-AD and X-AD were 2.3±2.8 and 3.6±2.8, respectively. Safety was consistent with the known dupilumab safety profile.

Conclusion: Dupilumab monotherapy reduced patient-reported hyperpigmentation and xerosis in patients with SoC and AD who were very or extremely bothered by hyperpigmentation and/or how dry skin felt before treatment.

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Efficacy and safety of topical acne treatments in participants with skin of color

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Background: Acne treatment in patients with skin of color involves unique considerations. This review summarizes efficacy and safety of topical treatments containing a retinoid, clindamycin phosphate (clinda), or benzoyl peroxide (BPO) alone or in combination in Black/African American (Black), Fitzpatrick IV to VI, or Hispanic participants with acne.

Methods: This narrative review evaluated clinical trial data reported in Black, Fitzpatrick IV to VI, or Hispanic participants with acne. Assessments comprised treatment success (≥2-grade reduction in acne severity and/or clear/almost clear skin), lesion reductions, and treatment-emergent adverse events (TEAEs).

Results: Efficacy and safety were reported for clinda 1.2%/adapalene 0.15%/BPO 3.1% (CAB) gel, clinda 1.2%/BPO 3.75% gel, clinda 1.2%/BPO 2.5% gel, adapalene 0.1%/BPO 2.5% gel, adapalene 0.3%/BPO 2.5% gel, clinda 1.2%/tretinoin 0.025% gel, tretinoin 0.05% lotion,

and tazarotene 0.045% lotion. Participant numbers varied across analyses (active treatment: Black, n=17–165; Fitzpatrick IV–VI, n=17–378; Hispanic, n=64–371). At Week 12, treatment success rates in Black, Fitzpatrick IV to VI, and Hispanic participants ranged from 18% to 32%, 27% to 28%, and 20% to 56%, respectively. Reductions in inflammatory lesions in Black, Fitzpatrick IV to VI, and Hispanic participants ranged from 58% to 69%, 46% to 65%, and 60% to 77%, respectively. Noninflammatory lesions were reduced by 49% to 58% in Black, 44% to 61% in Fitzpatrick IV to VI, and 51% to 76% in Hispanic participants. Triple-combination CAB gel demonstrated the greatest efficacy in Black and Hispanic participants. Overall, TEAEs were generally mild to moderate in severity.

Conclusion: Acne topicals containing a retinoid, clinda, or BPO alone or in combination demonstrated efficacy and favorable safety profiles in participants with skin of color. Fixed-dose, triple-combination CAB gel generally demonstrated the greatest treatment success rates and lesion reductions in Black, Fitzpatrick IV to VI, and Hispanic participants.

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Efficacy of apremilast in patients with moderate psoriasis, including high-impact site involvement: a pooled analysis of six trials

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Introduction: Plaque psoriasis can significantly impact quality of life, even with limited skin involvement, in particular if high-impact sites (HIS) are involved. We evaluated the efficacy of apremilast in patients with plaque psoriasis with limited skin involvement (baseline affected body surface area [BSA] 3–10%), including some with HIS involvement in scalp, nails, and/or genitals.

Methods: Patients were pooled from 5 placebo-controlled trials (randomized to apremilast or placebo until Week 16 followed by open-label apremilast through at least Week 32: ADVANCE [NCT03721172)], DISCREET [NCT03777436], EMBRACE [NCT03774875], STYLE [NCT03123471], and UNVEIL [NCT02425826]) and 1 single-arm apremilast trial (open-label apremilast through Week 32: PROMINENT [NCT03930186]). Assessments at Weeks 16 and 32 included achievement of BSA ≤1%, BSA ≤3%, 75% reduction from baseline BSA (BSA-75), Psoriasis Area and Severity Index (PASI) score <3, Static Physician's Global Assessment (sPGA) score 0/1, Dermatology Life Quality Index (DLQI) score 0/1, Scalp PGA (ScPGA) score 0/1 (in patients with ScPGA score ≥2 at baseline), percent change from baseline in Nail Psoriasis Severity Index (NAPSI; in patients with NAPSI score >1 at baseline), and sPGA-Genitalia (sPGA-G) score 0/1 (in patients with NAPSI score ≥2 at baseline); nonresponder imputation for missing data.

Results: This pooled analysis included 1,152 patients (HIS involvement: scalp, 62.5%; nails, 32.6%; genitals, 22.4%); 671 patients received apremilast and 481 placebo. Baseline characteristics were generally similar between treatment arms (mean BSA: apremilast, 6.3%; placebo, 6.2%). At Week 16, apremilast significantly improved skin clearance and quality of life vs placebo ($P<0.0001$ for BSA ≤1%, BSA ≤3%, BSA-75, PASI <3, sPGA 0/1, and DLQI 0/1). At Week 32, improvements were generally maintained with apremilast across all outcomes assessed. Apremilast also yielded significant improvements by HIS at Week 16 ($P<0.01$ vs placebo for ScPGA 0/1, NAPSI, sPGA-G 0/1, and DLQI 0/1); improvements were also generally maintained at Week 32.

Conclusion: Pooled data from 6 apremilast trials demonstrate that apremilast improves skin clearance and quality of life in patients with psoriasis with limited skin involvement (BSA 3–10%), including in those with HIS involvement (scalp, nail, and/or genitals).

Growth improvement in children 6 to 11 years old with severe atopic dermatitis treated with dupilumab irrespective of TCS use

Presenters: Alan D. Irvine,[1] Amy S. Paller,[2,3] Elaine C. Siegfried,[4,5] Michael J. Cork,[6,7] Lisa A. Beck,[8] Jiangnan Lyu,[9] Annie Zhang,[10] Stephane Levy,[9] Sonya L. Cyr,[9]

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Background: The impact of topical corticosteroids (TCS) on stature in children with atopic dermatitis (AD) is incompletely understood. Here, we assess the impact of TCS use on growth in children 6 to 11 years old treated with dupilumab vs placebo.

Methods: Children 6 to 11 years old with severe AD were enrolled in the Phase 3, 16-week, placebo-controlled LIBERTY AD PEDS trial (NCT03345914). The proportion of patients below the 30th height percentiles at baseline with a ≥5-percentile change from baseline in height at Week 16 of dupilumab treatment vs placebo (n=114) was previously reported. TCS use was standardized in this trial. Cumulative TCS use, and TCS- and inhaled corticosteroid (ICS)–free days were recorded over the 16-week treatment period. Multiple logistic regression models were conducted, and the response variable was defined as achieving a ≥5-percentile increase in height from baseline to Week 16 in a subset of patients below the 30th baseline height percentile. Covariates were cumulative TCS dose and medication-free days from baseline (TCS alone and TCS+ICS).

Results: While TCS use was standardized in the trial, patients treated with dupilumab (n=181) used TCS less frequently than those

receiving placebo (n=123; 219.11g [standard deviation: 305.40] vs 292.48 g [287.36]), and they had more TCS-free days (21.42 [24.95] vs 12.17 [20.37]) and more TCS+ICS-free days (17.60 [24.72] vs 9.10 [16.17]). In the unadjusted model (n=114 [n=45: placebo+TCS; n=69: dupilumab+TCS]), the odds ratio (OR) for dupilumab vs placebo was 3.74 (*P*=0.01), indicating that patients receiving dupilumab were 3.7 times more likely to achieve a ≥5-percentile height increase vs those receiving placebo. The cumulative dose covariate-adjusted model demonstrated a significant impact of dupilumab treatment with an OR of 4.21 (*P*=0.01). In both the medication-free days covariate-adjusted models, a significant impact of dupilumab treatment was observed with an OR of 4.11 (*P*=0.01; TCS medication-free days) and 3.63 (*P*=0.02; number of TCS+ICS-free days).

Conclusion: TCS use and medication-free days appear to be independent of the effect of 16-weeks dupilumab treatment on increased growth in children 6 to 11 years vs placebo. These results suggest that the TCS use reduction in dupilumab-treated patients may not be contributing to increased growth observed or that any potential negative effects of TCS use on growth could be counteracted by dupilumab.

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Lyu J, Levy S, Cyr SL: Regeneron Pharmaceuticals Inc.—employees and shareholders.

Head and neck atopic dermatitis: therapeutic response after switching to upadacitinib in moderate-to-severe atopic dermatitis patients who had inadequate response to dupilumab

Presenters: Diego Ruiz Dasilva,[1,2] Mona Shahriari,[3,4] Masatoshi Abe,[5] Tiago Torres,[6,7] Simone Ribero,[8] Henry Yu,[9] Lauren Miller,[10] Kathy Altman,[11] Michael Lane,[11] Alvaro A. Moreira,[11] Ayman Grada,[11] Christopher G. Bunick[12]

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Introduction: Head and neck (HN) atopic dermatitis (AD) remains a therapeutic gap in patients with moderate-to-severe AD. Here, we evaluated the efficacy of switching to upadacitinib (UPA) after inadequate HN response on dupilumab (DUPI).

Methods: In the Heads Up (HU) study, patients were randomized to DUPI 300 mg or UPA 30 mg (UPA30) before entering the open-

label extension (OLE) at Week 24, where all patients received UPA30. In the Level Up (LU) study, patients were randomized to DUPI 300 mg or UPA 15 mg (UPA15) with dose escalation to UPA30 based on clinical response. In the OLE at Week 16, patients with inadequate disease response either remained on UPA (staying on or escalating to UPA30) or switched from DUPI to UPA15 with dose escalation to UPA30 based on clinical response at Week 20. Achievement of HN Eczema Area and Severity Index ≥75/90/100% (EASI75/90/100) was assessed at Week 4 and Week 16 postswitch in DUPI-treated patients who didn't achieve HN EASI75 (inadequate responders).

Results: Mean baseline HN EASI scores were similar between HU (2.7; n=50) and LU (2.8; n=165) in DUPI HN inadequate responders. Mean HN EASI scores at switch point were similar between DUPI inadequate responders in HU (Week 24: 1.4; n=50) and LU (Week 16: 1.8; n=102). Most patients in HU who switched from DUPI to UPA at Week 24 achieved HN EASI75 (Week 28: 81.3%; Week 40: 80.9%) and HN EASI90 (Week 28: 64.6%; Week 40: 63.8%), with many achieving HN EASI100 (Week 28: 35.4%; Week 40: 46.8%). Median HN EASI improved from baseline by 95% 1 month after switching. Patients in LU who switched from DUPI to UPA at Week 16 achieved HN EASI75 (Week 20: 58.9%; Week 32: 68.8%), HN EASI90 (Week 20: 36.2%; Week 32: 48.1%), and HN EASI100 (Week 20: 20.9%; Week 32: 33.8%). Median HN EASI improved from baseline by 78.3% and 87.9% at Months 1 and 4 after switching, respectively. Most patients reported clinically meaningful improvement in overall itch after switching to UPA.

Conclusion: In moderate-to-severe AD, switching to UPA improved HN lesions in patients who had inadequate response to DUPI, with many achieving improvement in as early as 1 month.

Identifying systemic-ready phenotype(s) to estimate systemic treatment needs with predictive analytics and EHR data among US topical-initiating patients with psoriasis

Presenters: Linda Stein Gold,[1] Michael Cameron,[2] Rita De Cassia Castro,[3] Cynthia Deignan,[3] Kuan-Yu Chen,[3] Kate Orroth,[3] Kathy V. Tran,[3] April Armstrong[4]

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Background: Despite availability of effective systemic therapies, undertreatment of psoriasis remains prevalent. In 2020, the International Psoriasis Council recommended initiating systemic therapy in patients with psoriasis with affected body surface area (BSA) >10%, high-impact site involvement, or topical failure (Strober 2025); adoption of these guidelines in clinical practice is not known. We aimed to identify systemic-ready patient phenotypes and estimate unmet treatment needs with a data-driven approach using real-world data.

Methods: This retrospective cohort study includes adults (≥18 years) with plaque psoriasis from the United States (US) electronic health record (EHR)–based OM1 PremiOM™ psoriasis database, ≥1 topical therapy (indexing event), baseline BSA measure, and no prior systemic use. Cluster analysis was implemented to distinguish among clusters of known systemic-initiators, patients receiving topical therapy suspected of being systemic-ready, or patients who were topical-sufficient. We hypothesize similarities between the first 2 groups.

Results: Among 18,865 systemic-naïve patients with psoriasis, key potential predictors (*t*-/Chi-squared test *P* value <0.05) of initiating systemic therapies include age, insurance, high-impact site involvement, psoriatic arthritis (PsA), baseline BSA, and topical treatment history. Compared with noninitiators (n=11,297), systemic-initiators (n=7,568) were more likely aged <65 years (79.2% vs 64.1%) and to have commercial insurance (41.7% vs 34.2%), high-impact site involvement (40.3% vs 33.5%), PsA (13.3% vs 3%), higher baseline BSA (mean [standard deviation]: 13.1 [16.1] vs 7.3 [11.3]), and more topical therapy use (37.1% vs 25.7% with ≥4 unique topical therapies ever). Cluster and predictive modeling results are forthcoming.

Conclusion: This data-driven study using novel predictive analytics and real-world data may help accelerate identification of systemic-ready patients and initiation of systemic treatment among patients with psoriasis experiencing undertreatment.

Impact of facial hair regrowth on patient-reported outcomes (PROs) in patients with severe alopecia areata: interim results from a phase 3 trial

Presenters: Matthew Brunner,[1] Arash Mostaghimi,[2] Carolyn Goh,[3] Melissa Piliang,[4] Ahmed M. Soliman,[5] Kent Hanson,[5] Kaili Ding,[5] Sharanya Ford,[5] Andreas Lazar,[5] Brett King,[6] JangMi Johnson[7]

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Introduction: Alopecia areata (AA) is a chronic autoimmune disease resulting in nonscarring hair loss. Loss of facial hair—beard, eyebrows (EB), and eyelashes (EL)—may have a substantial impact on health-related quality of life (HRQoL). We evaluated the relationship between facial hair regrowth and HRQoL in patients with AA using the phase 3 UP-AA clinical trial data.

Methods: UP-AA (NCT06012240) is an ongoing, multicenter, phase 3, randomized, placebo-controlled, double-blind study evaluating once-daily oral upadacitinib (UPA) in adults and adolescents with severe AA, randomized to UPA 15 mg, UPA 30 mg, or placebo for 24 weeks (wk24). For beard hair loss (BHL), beard hair regrowth was evaluated using I-ALFO clinician reported-outcome (ClinRO) where 0=no hair growth; 1=mostly areas with hair loss, some areas of hair growth; 2=mostly normal hair growth, some areas of hair loss; and 3=normal hair growth. Male patients with available I-ALFA scores and completed patient-reported outcome (PRO) data, and baseline BHL scores of 0/1 were included in the analysis. EB/EL regrowth were each evaluated using 4-point ClinRO scales where 0=no hair loss; 1=minimal hair loss; 2=significant hair loss; and 3=no noticeable hair. Patients who had available EB/EL scores and PRO data, and baseline EB/EL scores ≥2 were included. HRQoL at wk24 was assessed using 2 PROs: Skindex-16 for AA and the Alopecia Areata Symptom Impact Scale (AASIS). For EB/EL regrowth, differences in PRO scores were compared between ClinRO-defined responders (0/1 score) and nonresponders (2/3 score) using ANCOVA. I-ALFA-defined responders were those with a 2/3 score.

Results: A total of 1,381 patients were enrolled with a mean (standard deviation) age of 35.9 (13.3) years and baseline Severity of Alopecia Tool (SALT) score of 84.0 (18.9). A total of 41.4% of patients were male, 51.3% had very severe AA (SALT score ≥95), and 43.3% had a disease duration ≥3 years. Overall, 29.5%, 41.3%, and 42.1% patients achieved BHL, EB, and EL response, respectively. At wk24, BHL responders experienced significantly greater improvement in Skindex-16 AA emotions ($P<0.05$) and functioning ($P<0.001$) scores than nonresponders. At wk24, EB/EL ClinRO responders experienced significantly ($P\leq0.001$ for all comparisons) greater improvements from baseline in Skindex-16 AA emotions and functioning domains compared with nonresponders. Similarly, at wk24, BHL and EB/EL responders experienced significantly greater improvement in AASIS interference ($P<0.001$) and symptom severity ($P<0.001$) scores than nonresponders.

Conclusion: Patients with severe AA who achieved a clinically meaningful response in facial hair regrowth experienced significant multidimensional HRQoL benefits, including improvements in symptom severity, emotional wellbeing, and daily functioning. These results highlight the clinical relevance of beard, EB, and EL regrowth as criteria for treatment success in severe AA and further demonstrate that regrowth beyond the scalp contributed to meaningful HRQoL improvements in patients with AA.

INTEGUMENT-INFANT: once-daily roflumilast cream 0.05% in infants aged 3 to <24 months with atopic dermatitis

Presenters: Lawrence F. Eichenfield,[1] Mercedes E. Gonzalez,[2] Adelaide A. Hebert,[3] Vimal H. Prajapati,[4] David Krupa,[5] Saori Kato,[5] Scott Snyder,[5] Diane Hanna,[5] Melissa S. Seal,[5] David R. Berk;[5] on behalf of the INTEGUMENT-INFANT investigators

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Background: Efficacy and safety of roflumilast cream, a highly potent phosphodiesterase 4 inhibitor formulated without potentially irritating ingredients, for mild-to-moderate atopic dermatitis (AD) in patients aged ≥2 years were demonstrated in phase 3 clinical trials. The phase 2, single-arm, open-label INTEGUMENT-INFANT (NCT06998056) study evaluated roflumilast cream 0.05% in infants aged 3 to <24 months with AD.

Methods: Caregivers of infants aged 3 to <24 months with AD (Validated Investigator Global Assessment for AD [vIGA-AD] mild/moderate [2/3]; ≥3% body surface area affected) applied roflumilast cream 0.05% once daily for 4 weeks. Primary endpoints were safety and application-site tolerability. Exploratory efficacy endpoints included vIGA-AD success (clear/almost clear [0/1] with ≥2-point improvement), vIGA-AD 0/1, ≥75% improvement in Eczema Area and Severity Index (EASI75), Worst Scratch/Itch-Numeric Rating Scale (WSI-NRS) success (≥4-point improvement), and ≥25% itch improvement per Dynamic Pruritus Score (DPS-25).

Results: In total, 101 infants were enrolled. Treatment-emergent adverse events were reported for 46.6%, all mild or moderate. Clinicians reported no evidence of irritation for ≥97.9% of infants at Week 2 or 4. At Week 4, 34.4% (95% confidence interval [CI]: 25.6–44.3%), 49.0% (95% CI: 39.2–58.8%), 58.3% (95% CI: 48.3–67.7%), and 60.6% (95% CI: 48.9–71.1%) achieved vIGA-AD success, vIGA-AD 0/1, EASI75, and WSI-NRS success, respectively; 46.6% (36.5–56.9%) achieved DPS-25 within 10 minutes of first application.

Conclusion: Roflumilast cream 0.05% was well tolerated and reduced AD signs and symptoms in infants with AD. These results support safe and efficacious use of roflumilast cream in patients as young as 3 months, a population with substantial disease burden and limited evidence-based treatment options.

Lebrikizumab dosed every 8 weeks as maintenance provides long-lasting response in patients with moderate-to-severe atopic dermatitis

Presenters: Jonathan Silverberg,[1] Vivian Laquer,[2] Peter Lio,[3] Kim Papp,[4] Alan Irvine,[5] Andrew Blauvelt,[6] Hany Elmaraghy,[7] Louise DeLuca-Carter,[7] Heidi Crane,[7] Gaia Gallo,[7] Evangeline Pierce,[7] Yuxin Ding,[7] Amy S. Paller[8]

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Introduction: Lebrikizumab every 4 weeks (LEBQ4W) in ADjoin maintained responses up to 3 years in Week 16 responders with atopic dermatitis (AD). During Weeks 16 to 52 in ADvocate1/2, many patients showed durable efficacy in the lebrikizumab withdrawal (placebo) arm, hinting at less frequent dosing. We report results from a 32-week extension to ADjoin assessing efficacy and safety of LEBQ8W.

Methods: ADjoin is a 100-week long-term extension study assessing lebrikizumab 250 mg every 2 weeks (LEBQ2W) and every 4 weeks (LEBQ4W) in patients who completed qualifying parent studies. Qualifying patients from ADvocate1, ADvocate2, ADore, and ADopt-VA who completed ADjoin Week 100 were rerandomized to open-label LEBQ8W or LEBQ4W for a 32-week extension. Primary outcomes were percentages of patients achieving Investigator's Global Assessment score of 0 or 1 (IGA 0/1) and ≥75% improvement in Eczema Area and Severity Index (EASI75) at Week 32. Key secondary outcomes included percentage of patients achieving EASI90 and change from baseline in the Patient-Oriented Eczema Measure (POEM). Safety data were collected throughout the extension. A combined nonresponder imputation and multiple imputation method were used to address intercurrent events and missing data. The study was not powered to detect if LEBQ4W dosing is comparable to LEBQ8W dosing.

Results: A total of 103 patients (LEBQ8W, n=51; LEBQ4W, n=52) enrolled in the 32-week extension (mean 60 days without lebrikizumab from ADjoin Week 100 to start of extension). Mean values for parent study baseline characteristics in LEBQ8W and LEBQ4W, respectively, were: AD disease duration, 17.1 and 17.7 years; EASI, 31.0 and 26.6; body surface area, 48.3% and 39.3%; and POEM, 20.9 and 19.8. Upon entering the extension,

64.7% and 73.1% of LEBQ8W and LEBQ4W patients, respectively, had achieved EASI90, and mean (standard deviation [SD]) POEM scores were 8.7 (7.6) and 6.0 (5.4), respectively. At Week 32 of the extension, percentages of patients (95% confidence interval) who achieved IGA 0/1 were 62.0% (48.3, 75.8) and 73.0% (60.9, 85.1) in LEBQ8W and LEBQ4W, respectively; 79.1% (67.6, 90.5) and 86.2% (76.8, 95.7) of patients achieved EASI75 and 68.7% (55.8, 81.6) and 78.2% (66.8, 89.5) achieved EASI90; POEM mean (SD) absolute scores (as observed) were 9.2 (7.3) in LEBQ8W and 5.4 (5.2) in LEBQ4W. All adverse events (AEs) were mild or moderate in severity. No serious AEs or AEs leading to discontinuation were reported; there was no evidence of increased risk of antidrug antibodies with less frequent dosing.

Conclusion: Lebrikizumab dosed every 8 or 4 weeks provided long-lasting responses in patients with moderate-to-severe AD, indicating durable and potential disease-modifying effects.

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Lebrikizumab in real-world North American practice: preliminary Week 24 outcomes from the ADjoy prospective observational study in moderate to severe atopic dermatitis

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Background: ADjoy is the first North American prospective observational real-world study evaluating lebrikizumab in clinical practice. We report the preliminary results at Week 24.

Methods: ADjoy is an ongoing 104-week, observational, prospective, multicenter, phase 4 study evaluating lebrikizumab initiated as part of routine care in adolescents and adults with moderate-to-severe atopic dermatitis (AD) in the United States (US) and Canada. This interim analysis included data from 249 subjects with a March 2026 data cutoff. Primary endpoint was Investigator's Global Assessment (IGA) score 0/1 with a ≥2-point improvement at Week 24. Secondary outcomes included Eczema Area and Severity Index (EASI), pruritus Numeric Rating Scale (NRS), sleep-loss scale (SLS), and Patient Global Impression of Severity–AD (PGI-S-AD). Data were summarized descriptively without missing-data imputation.

Results: Among baseline participants, median age was 37.0 years and 53.4% were female at birth; 157 (63.1%) were White, 39 (15.7%) Black, and 28 (11.2%) Asian; 224 (90%) were from the US and 25 (10%) from Canada; 65.5% had moderate and 17.7% severe IGA severity; median EASI was 10.58, and median pruritus NRS was 7.0; 51.6% reported moderate or worse sleep loss (SLS ≥2), and 65% reported at least moderate PGI-S-AD (score ≥4). Prior AD treatments included biologics (62.3%) and other systemic medications (37.7%). For this interim analysis, 79 participants completed a Week 24 visit. A total of 22.0% (95% confidence interval [CI]: 16.0–28.9%) achieved IGA 0/1 with ≥2-point improvement (clear/almost clear skin) at Week 2 and 49.3% (95% CI: 37.2–61.4%) at Week 24. The participant proportion with severe disease (IGA 4) decreased from 17.7% (n=44) to 3.8% (n=7) at Week 4, 1.8% at Week 16 (n=2) and 0.0% at Week 24. Mean (standard deviation [SD]) change from baseline in EASI total absolute score at Week 24 was −10.40 (11.17) (95% CI: −12.95 to −7.85; n=76) with 68.4% achieving ≥75% improvement in EASI (EASI75), 46.1% EASI90, and 18.4% EASI100 at Week 24. Week 24 mean (SD) pruritus NRS was 3.8 (2.81), with a mean (SD) change from baseline of −2.5 (3.16). At Week 24, 52.5% achieved a ≥4-point improvement in pruritus NRS, 52.9% achieved ≥2-point improvement in sleep interference, and most participants rated their disease as no symptoms to mild on PGI-S-AD, with a mean (SD) score of 2.7 (1.13) (n=78).

Conclusion: In this real-world study, half of lebrikizumab-treated patients experienced improved skin clearance, pruritus relief, improved sleep, and reduced disease severity at Week 24. These findings are consistent with lebrikizumab evidence from randomized trials. Continued follow-up will elucidate long-term outcomes through 104 weeks.

Acknowledgments and funding sources: Eli Lilly and Company. Presented at the RAD 2026.

Long-term laboratory trends in patients with moderate-to-severe atopic dermatitis treated with upadacitinib: 140-week results from Measure Up 1 and 2

Presenters: David G Cotter,[1] Mona Shahriari,[2] Diego Ruiz Dasilva,[3,4] Erik Domingues,[5,6] Shanthi Narla,[7] Mark G. Kirchhof,[8] Rachel Goldberg,[9] Meerat Oza,[9] Deanne Dilley,[9] Ayman Grada,[9] Alan D. Irvine[10,11]

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Introduction: Upadacitinib (UPA) is a Janus kinase 1 (JAK1) selective inhibitor approved for moderate-to-severe atopic dermatitis (AD).

Methods: Laboratory trends were analyzed for ≤140 weeks in patients aged ≥12 years with moderate-to-severe AD treated with UPA in the phase 3 Measure Up 1 (NCT03569293) and 2 (NCT03607422) trials. Patients received once daily UPA 15 mg (UPA15, n=603), UPA 30 mg (UPA30, n=610), or placebo (PBO, n=601); PBO patients were rerandomized to UPA15 or UPA30 at wk 16.

Results: Mean baseline laboratory values were within normal limits across all groups: high-density lipoprotein cholesterol (HDL-C), 1.4 mmol/L; low-density lipoprotein cholesterol (LDL-C), 2.5 to 2.6 mmol/L; total

cholesterol, 4.4 to 4.6 mmol/L; triglycerides, 1.3 to 1.4 mmol/L; aspartate transaminase (AST), 21.9 to 23.0 U/L; and alanine transaminase (ALT), 20.8–23.0 U/L. Any changes of laboratory values occurred early, were generally transient, and stabilized thereafter: HDL-C, 1.6 to 1.7 mmol/L; LDL-C, 3.0 to 3.2 mmol/L; total cholesterol, 5.2 to 5.4 mmol/L; triglycerides, 1.3 to 1.4 mmol/L; AST, 24.3 to 28.7 U/L; and ALT, 24.7 to 28.9 U/L. Treatment discontinuations due to laboratory abnormalities were uncommon: 0.7% at week 52 and remained low (<2%) at week 140. Weight increase was infrequent, occurring at wk 16 in 1.8% with UPA15 and 1.9% with UPA30 vs 0.6% with PBO. By week 140, the exposure-adjusted event rate for weight increase remained low (1.27 [UPA15] and 1.79 [UPA30] per 100 patient-years).

Conclusion: These findings support the long-term safety profile of UPA for moderate-to-severe AD.

Mortality and adverse outcomes in patients with pyoderma gangrenosum (PG) in the US

Presenters: Arash Mostaghimi,[1] Clinton Hall,[2] Rhonda L. Bohn,[2] Gretchen R. Chiu,[3] Ajit Londhe,[3] Carmen Ng,[3] Valentina Dini[4]

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Background: Population-level data on mortality and other adverse outcomes in patients with pyoderma gangrenosum (PG) are limited. We explored these parameters among United States (US) adults with incident PG. The objectives were to (1) assess mortality associated with a diagnosis of PG using observational claims data from the US and (2) assess other outcomes of interest, including hospitalization and serious infections, among patients with PG.

Methods: This noninterventional cohort study utilized claims data from Optum's de-identified Clinformatics® Data Mart Database (January 2016–March 2024). Eligible patients had ≥365 days without a PG claim, followed by 3 unique PG claims within 365 days of follow-up (third claim: index date [ID]). Crude all-cause mortality was calculated among patients with continuous enrollment throughout 1- and 2-year periods post-ID, stratified by age group, sex, and presence of PG-related comorbidity. Selected adverse outcomes were also assessed.

Results: Overall, 1,663 patients were enrolled (≥65 years old, 65.7%; female, 65.4%; White, 69.2%; PG-related comorbidity, 65.8%). Of these, 161/1,158 (13.9%) and 206/850 (24.2%) of patients died within 1- and 2-years post-ID, respectively. Mortality was highest among older patients (deaths within 1-year post-ID: ≥65-year-olds, 18.5%; 51–64-year-olds, 6.5%; 18–50- year-olds, 1.3%). One-year post-ID mortality was slightly higher among male (14.7%) than female (13.5%) patients and among patients with PG-related comorbidities (15.1%) than no known PG-related comorbidities (11.4%). One-year post-ID, 51.7% of patients had any hospital stay for any cause and 25.2% of patients were hospitalized with a PG diagnosis code listed. Additionally, 44.6% were diagnosed with a serious infection, 8.9% had a major adverse cardiovascular event, 4.1% had peripheral neuropathy, and 2.8% had an amputation within 1-year post-ID.

Conclusion: Mortality burden was high among older patients with PG and those with PG-related comorbidities.

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Prevalence of comorbidities in patients with pyoderma gangrenosum (PG) in the US

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Introduction: Population-level data on PG-related comorbidities are limited. We assessed comorbidities in a US adult patient population with incident PG. The objectives were to (1) describe the natural history of PG among patients with incident PG using observational claims data from the US and (2) assess the prevalence of comorbidities among patients with incident PG.

Methods: This noninterventional cohort study utilized claims data from Optum's de-identified Clinformatics® Data Mart Database (January 2016–March 2024); eligible patients had ≥365 days without a PG claim, then 3 unique PG claims within 365 days of follow-up (third claim: index date [ID]). Prevalence of selected comorbidities and the 20 most diagnosed comorbidities 365 days pre- and post-ID were assessed. PG-related comorbidities were defined as having 1 diagnosis code for a pre-defined PG-associated comorbid condition within 365 days pre- and post-ID.

Results: Of 1,663 patients, mean (standard deviation [SD]) age was 67.1 (15.0) years; 65.4% were female; 69.2% were White; mean (SD) Charlson Comorbidity Index was 5.1 (3.2) and 65.8% had a PG-related comorbidity. Pre-ID, the most common pre-specified PG-related comorbidities were solid malignancy (19.3%), inflammatory bowel disease (16.5%), and inflammatory arthritis (15.6%); non-PG-related comorbidities included psychiatric disorders (61.1%) and endocrine disorders (56.9%). The most common non-PG-related comorbidities were essential hypertension (74.3%), hyperlipidemia (49.5%), and localized edema (39.7%). Atherosclerosis of the coronary artery without angina pectoris (26.5%), chronic pain (26.4%), and acute kidney injury (25.3%) were among the 20 most common comorbidities post-ID, but not pre-ID.

Conclusion: Comorbidity burden was high, with the most commonly diagnosed

prespecified PG-related comorbidity being solid malignancy, and non-PG-related comorbidity being essential hypertension. High prevalence of comorbidities among people with PG may impact clinical care, including treatment-based decisions.

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Remibrutinib demonstrated continuous efficacy and favorable safety in patients with chronic spontaneous urticaria in the randomized withdrawal period of the phase 3b REMIXED extension study

Presenters: Martin Metz,[1,2] Ana Maria Giménez-Arnau,[3] Michihiro Hide,[4] Mark Lebwohl,[5] Giselle Mosnaim,[6] Vipul Jain,[7] Koremasa Hayama,[8] Undine Lippert,[9] Michael Palumbo,[10] Bin Yang,[11] Kanokvalai Kulthanan,[12] Young-Min Ye,[13] Swapnil Dahale,[14] Sibylle Haemmerle,[15] Lukasz Jaskiewicz,[15] Karine Lheritier,[15] Clarice Field,[16] Luna Wei,[17] Sarbjit Saini[18]

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Background: Remibrutinib demonstrated efficacy and favorable safety profile in phase 3 studies (REMIX-1/REMIX-2/BISCUIT) for chronic spontaneous urticaria (CSU). We report primary efficacy and safety outcomes from the 24-week randomized withdrawal period of REMIXED.

Methods: REMIXED (NCT05513001) is a phase 3b, multicenter, double-blind, placebo-controlled, randomized withdrawal and open-label extension study. Patients with CSU with a weekly Urticaria Activity Score (UAS7) <16 were randomized 1:1 to remibrutinib 25 mg twice daily or placebo for 24 weeks; relapsed patients received open-label remibrutinib. The primary endpoint was time to first relapse; safety and tolerability were secondary endpoints.

Results: Patients with CSU (n=454) were randomized (227/arm); 21.4% had 6<UAS7<16 at baseline. Completion rates were 188 (82.8%) with remibrutinib and 105 (46.3%) with placebo; relapse-related discontinuations were 13.7% vs 48.0%. The primary endpoint was met: median time to first relapse was 4.5 weeks with placebo and not estimable with remibrutinib (72% risk reduction [hazard ratio: 0.28; 95% confidence interval: 0.21–0.38; 1-sided $P<0.001$]). Adverse events (AEs), serious AEs, and AEs leading to discontinuation occurred in 42.5% vs 37.6%, 2.2% vs none, and 0.4% vs 0.9% with remibrutinib vs placebo, respectively; no deaths reported. AE incidence differences may reflect variations in median exposure durations between remibrutinib vs placebo (24.0 vs 15.6 weeks). Bleeding events occurred in 8 (3.5%) vs 2 (0.9%) patients on remibrutinib vs placebo, all mild to moderate. No petechiae occurred with remibrutinib (1 case with placebo).

Conclusion: In REMIXED, relapse occurred earlier with placebo, with a 72% reduced relapse risk with remibrutinib.

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Risk of systemic adverse effects from topical and oral corticosteroids: time for a paradigm shift?

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Introduction: Corticosteroids (CS) are commonly prescribed by dermatology practitioners and clinicians in other specialties to manage inflammatory conditions. In 2023 alone, >15 million prescriptions for topical CS (any indication) were filled in the United States (US). Cutaneous adverse events (AEs) have traditionally been the primary acknowledged AE attributed to topical CS use, but growing evidence suggests that absorption may lead to a variety of systemic AEs. To better understand the data on CS and the risks associated with their use, a targeted literature search was performed.

Methods: PubMed was searched from 2010 to 2025 for English-language studies and meta-analyses using a variety of MeSH terms, including corticosteroids, topical, glucocorticoids, guidelines, and certain specific AEs; reference lists of selected articles were also searched.

Results: Topical CS: Cohort and case-control studies have shown that prolonged use of high-potency topical CS poses a modest, but clinically meaningful, systemic risk of type 2 diabetes, osteoporosis/osteoporotic fractures, and hypothalamic-pituitary-adrenal (HPA) axis suppression. Some doses of highly potent topical CS (eg, 49 g of high potency topical CS for 2 weeks) have been described as exceeding published thresholds for HPA axis suppression.

Oral CS: Short-term oral CS use (<30 days) is common, occurring in 21% of US adults across specialties and diseases. Findings from population-based studies and claims database analyses show that even short courses of oral CS (≤5 mg/day for ≤6 months) can contribute to hyperglycemia, elevated blood pressure, mood changes, sleep disturbance, sepsis, fracture, and venous thromboembolism.

Conclusion: Available data reveal that CS-related AEs may be more impactful than traditionally thought. This underscores the importance of a more discriminating approach to CS use, especially given the increasing availability of novel, effective alternatives. Judicious CS prescription should include individual patient risk assessment, routine safety monitoring, and use of the lowest effective dose for only the necessary duration. This review identifies an opportunity for a new era where non-CS therapies are used as replacements for topical CS to minimize patient risk without compromising treatment outcomes, especially in higher-risk patients and when the disease requires higher potencies, chronic use, and/or widespread topical application.

Spesolimab improves Generalized Pustular Psoriasis Physician's Global Assessment (GPPGA), affected body surface area (BSA), and quality of life (QoL) in generalized pustular psoriasis (GPP): EFFISAYIL 2 trial analyses

Presenters: Bruce E. Strober,[1] Joseph F. Merola,[2] Alice B. Gottlieb,[2] Arash Mostaghimi,[3]

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Background: Generalized pustular psoriasis (GPP) is an inflammatory, neutrophilic, potentially life-threatening skin disease characterized by episodic flares of widespread skin pustulation and chronic skin symptoms. EFFISAYIL 2 investigated the effects of subcutaneous (SC) spesolimab, an anti-interleukin-36 receptor monoclonal antibody, on GPP symptoms and patient quality of life (QoL).

Methods: The patients in this analysis received the United States Food and Drug Administration (FDA)–approved dose of 300 mg SC spesolimab every 4 weeks (q4w) after 600 mg SC loading dose (n=30). GPP Physician's Global Assessment (GPPGA) total score, average body surface area (BSA) involvement, Pain Visual Analog Scale (VAS), and Psoriasis Symptom Scale (PSS) scores were recorded at baseline and Weeks 4, 16, and 48. Dermatology Life Quality Index (DLQI) was measured at baseline and Weeks 4, 12, 36, and 48.

Results: In this analysis, average age was 40 years, 60% were female, and patients were either Asian (70%) or White (30%). The proportion of patients with GPPGA of 0 increased over time, from 10.0% at baseline, to 27.6% at Week 4, 48.1% at Week 16, and 52.2% at Week 48. Continuous treatment with spesolimab decreased average total BSA involvement over time (baseline: 13.3%; Week 4: 10.6%; Week 16: 9.4%; Week 48: 4.5%). BSA involvement also decreased over time when patients were stratified by time since their GPP diagnosis (≤5 years [n=13]: 14.7%, 15.0%, 11.7%, 5.0%; or >5 years [n=17]: 12.3%, 7.0%, 7.6%, 4.1%, respectively) and by use of systemic medication to treat GPP at baseline (yes [n=22]: 11.1%, 8.2%, 6.4%, 3.6%; or no [n=8]: 19.5%, 18.3%, 19.8%, 7.4%, respectively). Mean Pain VAS and PSS scores also decreased over time (Pain VAS: 29.1, 20.7, 12.6, 11.3; PSS: 5.34, 4.23, 3.19, 2.96, respectively). DLQI scores decreased from 11.14 at baseline to 8.62 at Week 4, 5.83 at Week 12, 5.35 at Week 36, and 4.57 at Week 48.

Conclusion: Continuous treatment with SC spesolimab improved GPPGA, BSA involvement, Pain VAS, PSS, and DLQI scores over 48 weeks. These findings suggest SC spesolimab can effectively control GPP and improve patient QoL.

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Sustained improvement in signs and symptoms of atopic dermatitis in adolescents and adults initiating dupilumab in real-world practice: 5-year completer interim analysis from the PROSE registry

Presenters: Hermenio C. Lima,[1] Luz Fonacier,[2,3] Benjamin Lockshin,[4,5] Tien Q. Nguyen,[6] Yonghao Ma,[7] Kwinten Bosman,[8] Andrew Korotzer[7]

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Background: This study aimed to provide effectiveness and safety data on adolescent and adult patients with atopic dermatitis (AD) who initiated dupilumab treatment per standard clinical practice and have completed 5 years of observation in the PROSE registry. PROSE (NCT03428646) is an ongoing, 5-year, prospective, observational study in the United States (US) and Canada, of adolescent and adult patients with AD who initiated dupilumab in the real world according to country-specific prescribing guidelines. Here, we present interim results for a subset of patients who completed 5 years of observation.

Methods: Patients received a dupilumab loading dose at baseline and were observed without restrictions on postbaseline AD treatment choices, including dosing changes or concomitant medications, and were encouraged to stay in the study if they discontinued dupilumab. Data are reported as observed.

Results: Of 857 patients enrolled in PROSE, 131 completed 5 years of observation, with mean (standard deviation [SD]) dupilumab treatment duration of 68.5 (4.4) months. Mean (SD) Eczema Area and Severity Index score improved rapidly from 17.2 (13.9) at baseline to 5.7 (9.1) at 3 months, until 1.6 (4.0) at 60 months. Similarly, Peak Pruritus Numeric Rating Scale score improved from 6.9 (2.2) at baseline to 3.3 (2.8) at 3 months and averaged approximately 2 at study completion. Similar temporal patterns of improvement were observed in the patient-assessed Dermatology Life Quality Index and Patient-Oriented Eczema Measure. A total of 271 adverse events were reported in 63 patients. Six patients reported serious adverse events; no deaths were reported.

Conclusion: In the PROSE registry, patients with moderate-to-severe AD who initiated dupilumab treatment showed improvements in AD signs, symptoms, and quality of life that were sustained for 5 years. Safety was consistent with the known dupilumab safety profile.

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Bosman K: Sanofi—employee and shareholder.

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The 487-gene expression profile test guides systemic therapy selection to improve outcomes for patients with atopic dermatitis: results from a prospective, multi-center trial

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Introduction: Atopic dermatitis (AD) is a heterogenous inflammatory skin disease. Systemic therapies, including biologics that target the Th2 inflammatory pathway (Th2-targeted therapies) and small molecules targeting multiple inflammatory pathways (Janus kinase inhibitors [JAKi]), have improved care for AD. However, current therapy selection is trial and error without consideration of each patient's underlying biology, resulting in inadequate disease control for about 45% of patients. A noninvasive molecular test characterizing the underlying disease biology that can guide therapy selection should improve the proportion of patients who achieve adequate disease control. The study objective was to develop and validate a noninvasive gene expression profile (GEP) test to guide AD systemic therapy selection.

Methods: A prospective observational study enrolled patients with AD or psoriasis. Samples were acquired via noninvasive skin scraping from affected lesions and analyzed by ribonucleic acid (RNA) sequencing. Therapy use, Eczema Area and Severity Index (EASI) outcomes, itch skin clearance (Validated Investigator Global Assessment for AD [vIGA-AD]), and flare frequency data were collected. A neural network ensemble algorithm (487-GEP test) was developed using 12 inflammatory and cutaneous biology pathways including 487 genes. A training set (n=192) was used to create 487-GEP, which identified patients with a Th2 Molecular Profile or a JAKi Responder Profile. The test was validated in an independent cohort of patients with AD ≥12 years receiving Th2-targeted therapies or JAKi (n=110).

Results: The 487-GEP test scored 30.4% of AD samples as JAKi Responder Profile. These patients achieved significantly higher rates of ≥90% improvement in EASI (EASI90; 45.5% vs 8.3%; P=0.021), achieved EASI90 3.8-times faster (P=0.049), were more likely to achieve complete skin clearance (vIGA-AD, 36.4% vs 0%; P=0.006) and "no itch" (PROMIS questionnaire, 45.5% vs 8.3%; P=0.021), and were more likely to be flare-free (54.5% vs 16.7%; P=0.041,) within 3 months when treated with low-dose JAKi versus Th2-targeted therapy. In contrast, patients with a Th2 Molecular Profile had similar responses to Th2-targeted therapies and JAKi.

Conclusion: In patients with AD, the 487-GEP test identifies a clinically meaningful group who are more likely to have high clinical benefit from JAKi than Th2-targeted therapies.

The i31-SLNB for cutaneous melanoma outperforms the clinicopathologic-only MIA nomogram at identifying patients at low risk of having a positive sentinel lymph node biopsy: a prospective, multicenter study

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Background: Sentinel lymph node biopsy (SLNB) for cutaneous melanoma (CM) provides essential prognostic information and is a component of American Joint Committee on Cancer (AJCC) staging. However, up to 88% of SLNBs are negative and 15% of patients experience surgery-associated morbidities. Improved tools are needed to predict SLN positivity, thereby avoiding unnecessary procedures, costs, and complications. The Melanoma Institute Australia (MIA) developed a nomogram based on clinicopathologic factors to predict a patient's likelihood of SLN positivity. The integrated 31-gene expression profile (GEP) for SLNB (i31-SLNB) combines the 31-GEP risk score with clinicopathologic factors to provide a precise risk of SLN positivity. It has been previously validated to improve SLN positivity prediction over AJCC staging. Using a prospective cohort, we compared the accuracy of the i31-SLNB to the MIA nomogram in predicting SLNB positivity.

Methods: This prospective, multicenter United States–based study included 430 patients with T1 to T4 tumors who underwent SLNB and had i31-SLNB results. The discriminative performance of the i31-SLNB and MIA nomogram was compared by calculating the area under the receiver operating characteristic curve (AUC) and using DeLong's test. Decision curve analysis was employed to compare the clinical net benefit of each test.

Results: In patients predicted to have <5% risk by i31-SLNB, the actual SLNB positivity rate was 2.6%. In contrast, those predicted to have <5% risk by MIA had an actual positivity rate of 5.8%. Overall, i31-SLNB performed significantly better than the MIA nomogram (i31-SLNB AUC: 0.74 vs MIA AUC: 0.61; P=0.001). Decision curve analysis demonstrated a superior clinical benefit of the i31-SLNB compared to the MIA nomogram across clinically relevant thresholds. Ninety-seven (23%) patients exhibited discordant i31-SLNB and MIA nomogram predictions (ie, 1 tool predicted <5% and the other predicted ≥5% risk). The actual SLNB positivity rate was 2.8% for patients with i31-SLNB predicted risk <5% and ≥5% MIA predicted risk vs 11.5% for patients with ≥5% risk by the i31-SLNB and <5% by MIA.

Conclusion: In this prospective, multicenter trial, the i31-SLNB accurately identified patients at high and low risk of SLN positivity, and more accurately predicted SLN positivity than the MIA nomogram. Utilizing i31-SLNB to aid SLNB decision-making can help low-risk patients safely avoid unnecessary SLNB and decrease the morbidity and cost associated with these procedures.

Thermal imaging for cryotherapy documentation in dermatology

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Background: Cryotherapy utilizes liquid nitrogen (LN_2) to treat common dermatologic conditions such as actinic keratoses (AKs), seborrheic keratoses, (SKs), and warts. To administer LN_2, providers typically use one hand to feel for lesions and the other hand to dispense LN_2 with a cryocanister. To document the treatment, providers rely on recall or scribes to chart the number, diagnosis, and locations of lesions. Human scribes are associated with rising costs and declining reimbursement, and newer artificial intelligence (AI)–audio scribe technologies cannot localize the exact locations of treated lesions. A provider commonly treats upwards of 50 lesions, making it exceedingly difficult to document all required elements for each lesion. Because LN_2 documentation is often imprecise, providers may unintentionally retreat the same lesions at subsequent visits, including lesions that may actually be skin cancers requiring surgical or anticancer therapy.

Methods: To address this workflow inefficiency and clinical practice gap, we sought out to develop a solution that will enable providers to perform and accurately document LN_2 treatments simultaneously.

Results: While visible imaging cannot capture LN_2 treatment sites, thermal imaging precisely captures cryotherapy sites. Cryotherapy-treated lesions appear as foci of cooler temperatures on thermal imaging and undergo temporal decay as they warm. We developed a Health Insurance Portability and Accountability Act (HIPAA)–compliant patent-pending solution that attaches an Android device with integrated visible and FLIR Lepton 3.5 thermal cameras to a cryocanister. After treating lesions with LN_2, the provider can easily tap the camera screen, capturing visible and thermal images of the area. Images are processed via an advanced machine learning (ML) pipeline for automated treatment site detection and anatomical mapping. The treatment summary displays each treatment site precisely mapped onto both patient-specific images and a 2D body diagram, accompanied by a list of anatomic locations treated. The provider can quick-select diagnoses, tag lesions to observe, and download a summary report that allows for electronic medical record integration.

Conclusion: Usage of AI-assisted thermal imaging in LN_2 documentation can lead to better patient outcomes through more accurate notation, decreased labor needs, decreased risk of treatment delays, and better long-term tracking of treated lesions. While our current standard of care of retreating the same lesions with LN_2 may be considered acceptable in some clinical scenarios, our technology will allow providers to avoid making uninformed treatment decisions and clearly know which lesions to consider for biopsy or topical anticancer therapy. Previously, thermal imaging has been used to assess other skin conditions like psoriasis, skin cancers, and burns. This represents a novel application of thermal imaging to enhance the effectiveness of cryotherapy treatments through precise documentation and anatomical mapping. Additionally, our current data shows statistically significant temperature differences between AKs and SKs when treated with LN_2. Future studies will explore the diagnostic uses of thermal imaging after LN_2 treatments. NPPA