

SELECTED ABSTRACTS

Selected Abstracts from GDPA Pearls Conference 2026

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

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

Methods: Guinea pigs were inoculated with 1 strain of terbinafine-resistant *T. indotineae* that was applied to an abraded area of the dorsal

skin. Three days post-inoculation, this area was treated once daily with commercially available topical antifungals for 7 days (efinaconazole 10% [diluted to 1%], tavaborole 5% or ciclopirox 8% [reconstituted]). Clinical efficacy, measured by percent improvement from baseline in skin appearance score (range: 0 [no lesions] to 5 [redness, scaling, hair loss, scabbing]) relative to untreated, and mycological efficacy (defined as percent reduction of infected hairs relative to untreated) were assessed 3 days after treatment end.

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

Conclusion: In a previous in vitro analysis, antifungal activity of efinaconazole was more potent than tavaborole or ciclopirox against *T. indotineae* strains that were terbinafine-resistant. These results were confirmed in the present in vivo model of *T. indotineae* dermatophytosis, where 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

Efficacy and safety of brodalumab in participants with high BMI and moderate-to-severe plaque psoriasis: the patient journey

Presenters: Mark G. Lebwohl, MD;¹ Eingun James Song, MD, FAAD;² Tina Bhutani, MD, MAS, FAADC;³ Wilson Liao, MD;³ April W. Armstrong, MD, MPH⁴

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Introduction: Psoriasis and obesity frequently occur together since 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 irrespective 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). Here, we present efficacy and safety outcomes from 5 clinical trial participants with obesity to highlight their brodalumab treatment journey.

Methods: In AMAGINE-1, -2, and -3 (NCT01708590, NCT01708603, NCT01708629, respectively), 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. 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. We summarize descriptive data for select participants with baseline BMI ≥ 30 kg/m² 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 aged 47 to 69 years with BMI of 33.1 to 37.5 kg/m² 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 the 5 selected cases presented here, participants with obesity (BMI ≥30 kg/m²) achieved substantial reductions in PASI scores, and most AEs were unrelated to treatment. These clinical trial cases align with previously published post hoc analyses of BMI subgroups from pivotal phase 3 trials and reaffirm 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.

Funding: Ortho Dermatologics

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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Introduction: 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 in patients with baseline WSI-NRS ≥4), and ≥25% itch improvement per Dynamic Pruritus Score (DPS25).

Results: The phase 2, single-arm, open-label study enrolled 101 infants. Treatment-emergent adverse events were reported for 43.6% of infants, 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%), and 58.3% (95% CI: 48.3–67.7%) of infants achieved vIGA-AD success, vIGA-AD 0/1, and EASI75, respectively; 72.7% (95% CI: 61.9–81.4%) of infants achieved WSI-NRS success at last observation, and 46.6% (95% CI: 36.5–56.9%) of infants achieved DPS25 within 10 minutes of first application.

Conclusion: Roflumilast 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.

Funding: Sponsored by Arcutis Biotherapeutics, Inc.

Long-term efficacy and tolerability of clindamycin phosphate 1.2%/adapalene

0.15%/benzoyl peroxide 3.1% gel for acne in participants with Fitzpatrick skin phototypes IV–VI: pooled results from two 24-week studies

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Introduction: Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (CAB) gel is the only triple-combination topical treatment approved for acne. CAB has demonstrated efficacy and favorable tolerability in 12-week clinical trials and in 24-week studies. Since acne presentation and sequelae vary by skin type, long-term management strategies that account for differences in skin pigmentation are required. This post hoc analysis evaluated long-term efficacy and tolerability of acne treatment with CAB gel in participants with Fitzpatrick skin phototypes (FSP) IV to VI.

Methods: Two identical, postmarketing, 24-week, single-center, open-label studies of once-daily CAB gel were conducted in a total of 50 participants ≥12 years of age with moderate-to-severe acne (Investigator's Global Assessment [IGA] score: 3 or 4). Data were pooled and analyzed in participants with darker skin (FSP IV–VI). Endpoints included changes from baseline in IGA score and inflammatory/noninflammatory lesions at Week 24. Scarring (assessed using the Goodman Qualitative Scar Scale), skin appearance (dryness, postinflammatory hyperpigmentation [PIH], postinflammatory erythema [PIE]), tolerability (itching, burning, redness, swelling), and adverse events (AEs) were also assessed.

SELECTED ABSTRACTS

Results: Of 24 participants with FSP IV to VI, 22 completed the studies. Participants were a mean age of 26.6 years, and 86.4% were female. At Week 24, treatment success (≥ 2 -grade reduction from baseline in IGA score and clear/almost clear skin) was achieved by 73% of participants; inflammatory and noninflammatory lesions were reduced by 90% and 66% from baseline, respectively. Scarring, PIH, and PIE improved from baseline by 32%, 71%, and 87%, respectively. No participants reported tolerability issues at Week 24 and all had skin dryness scores of 0 (none). One participant experienced an AE (bronchitis), which was deemed unrelated to study product.

Conclusion: Six months of once-daily CAB gel use in participants with darker skin phototypes led to 73% treatment success and inflammatory lesion reductions of 90%. These improvements are higher than those reported at Week 12 in the pivotal trials and support the long-term use of CAB gel in patients with darker skin phototypes.

Funding: Ortho Dermatologics

Real-world brodalumab outcomes in relation to pivotal trials for moderate-to-severe plaque psoriasis

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Introduction: 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. Here, we examine effectiveness and safety of brodalumab in adult patients in the Canadian Real-World Evidence

(CARE) study alongside results from pivotal phase 3 trials.

Methods: CARE is a Canadian, 12-month, multicenter, prospective, observational phase 4 study (NCT05132231) in adult patients initiating brodalumab as part of routine clinical care. The findings reported here correspond to a prespecified interim analysis through Month 6. In the phase 3 AMAGINE-1, AMAGINE-2, and AMAGINE-3 trials (NCT01708590, NCT01708603, NCT01708629, respectively), participants were initially randomized to brodalumab (140 or 210 mg) or placebo via subcutaneous injection every 2 weeks, with an additional dose at Week 1, for a 12-week induction period. At Week 12, brodalumab-treated patients were rerandomized to placebo or the same brodalumab dose (AMAGINE-1) or various brodalumab regimens (AMAGINE-2 and -3) through Week 52. Brodalumab's performance at the approved 210 mg dose was evaluated using Psoriasis Area and Severity Index (PASI) scores and adverse event (AE) rates. Descriptive summaries of real-world effectiveness (3 and 6 months) and safety (up to 6 months) are presented alongside efficacy and safety results from the pivotal trials at 3 months. No formal statistical comparisons were conducted.

Results: In the CARE study, 351 patients (58% male, 74% Caucasian, mean age: 51 years, baseline mean PASI score: 14.1) completed the 6-month visit. At 3 months, ≥ 75 –/90–/100-percent improvement in PASI (PASI75/90/100) responses were achieved by 78.2% (265/339), 64.0% (217/339), and 43.4% (147/339) of patients, respectively, increasing at 6 months to 82.1% (276/336), 72.6% (244/336), and 52.1% (175/336). Overall, AEs were reported in 44.4% of patients, with serious AEs occurring in 2.0%. In the phase 3 trials with brodalumab 210 mg (n=1,458, 69–73% male, 90–91% Caucasian, mean age: 45–46 years, baseline mean PASI score: 19.4–20.4), PASI75/90/100 response rates at 3 months (Week 12) ranged from 83% to 86%, 69% to 70%, and 37% to 44%, respectively. A total of 56.8% to 59.0% of patients experienced AEs, while serious AEs were reported in 1.0% to 1.8%.

Conclusion: Real-world outcomes with brodalumab are consistent with the efficacy and safety profile established in pivotal phase 3 trials. These findings highlight the robustness and generalizability of brodalumab's clinical

profile across controlled trials and routine-care settings, supporting its use as an effective treatment option for moderate-to-severe plaque psoriasis.

Funding: Bausch Health, Canada Inc. and Ortho Dermatologics.

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

Presenters: Alexandra K. Golant,¹ Adam Friedman,² Angela Lamb,¹ Peter A. Young,³ Douglas DiRuggiero,⁴ Melodie Young,⁵ Sally Laden,⁶ Jennifer C. Jaworski,⁷ Krista Bohnert,⁷ Melissa S. Seal,⁷ Diane Hanna⁷

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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 using a variety of search terms, including, but not limited to: corticosteroids, topical corticosteroids, glucocorticoids, dose-response, threshold dose, cumulative dose, potency, duration, frequency, population-based, cohort, registry, claims database, observational study, and case-control study, as well as specific AEs (eg, type 2 diabetes, osteoporotic fracture, adrenal suppression). Reference lists of selected articles were also searched. A total of 9 papers for topical CS and 30 papers for oral CS were identified. Papers were screened, and those that reported risks of topical CS (n=7) and oral CS (n=28) use were summarized.

SELECTED ABSTRACTS

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. 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.

Conclusion: 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.

Funding: Sponsored by Arcutis Biotherapeutics, Inc. [NPPA](#)

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