32970 Efficacy and safety of a fixed-dose clindamycin 1.2%, benzoyl peroxide 3.1%, and adapalene 0.15% gel for moderate-to-severe acne: Randomized phase 2 and phase 3 studies of the first triple-combination drug

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efficacy and safety of apremilast 30 mg BID (APR) efficacy and safety vs placebo (PBO) for moderate to severe acne. Randomized phase 2 and phase 3 studies of the first triple-combination drug
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A 3-pronged approach to acne treatment—combining an antibiotic, antibacterial, and retinoid—may provide greater efficacy and tolerability than single/double treatments while potentially reducing antibiotic resistance and increasing patient compliance. Clindamycin 2%/BPO 3%/adapalene 0.15% (IDP-126) gel is the first triple-combination, fixed-dose topical acne product in development that addresses the major pathophysiological abnormalities in acne patients. A phase 2 (N = 741) and a phase 3 (N = 188; N = 180), double-blind, randomized, 12-week studies enrolled participants aged ≥9 years with moderate to severe acne. Participants were randomized to receive once-daily IDP-126 or vehicle; the phase 2 study included 3 additional additional groups containing only gels: BPO/adapalene; clindamycin phosphate/BPO; and clindamycin phosphate/adapalene (data not shown). Endpoints included participants achieving ≥2 grade reduction from baseline in Evaluator's Global Severity Score and clear/almost clear skin (treatment success) and least-squares mean percent change from baseline in inflammatory and noninflammatory lesion counts. Treatment-emergent adverse events (TEAEs) were also assessed. In all 3 studies at week 12, half of participants achieved treatment success with IDP-126 (phase 2: 52.5%; phase 3: 49.6%; 50% versus less than one-fourth with vehicle (81%; 24.9%; 20.5%; P < 0.01). IDP-126 resulted in >70% reductions in inflammatory and noninflammatory lesions at week 12, significantly greater than vehicle (range: inflammatory, 75.7%; noninflammatory, 71.0; 73.5%; 45.8%–49.0%; P < 0.001). Most TEAEs were of mild-moderate severity, and <4% of IDP-126-treated participants discontinued study/treatment due to AEs. The innovative fixed-dose, triple-combination IDP-126 gel was efficacious and well tolerated in three clinical studies of children, adolescents, and adults with moderate to severe acne.

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efficacy and safety of ruxolitinib cream for the treatment of vitiligo by patient demographics and baseline clinical characteristics: Pooled subgroup analysis from two randomized phase 3 studies
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Ruxolitinib (Janus kinase [JAK] 1/2 inhibitor) cream is in development for the treatment of vitiligo, a chronic autoimmune skin disease. Two phase 3 randomized studies (TRuE-V1 [NCT04052425]; TRuE-V2 [NCT04057573]) conducted in North America and Europe enrolled patients aged ≥12 years with nonsegmental vitiligo with depigmentation covering ≥10% total body surface area (BSA). Patients (mean age, 50 years) were randomized 2:1 to receive 1.5% ruxolitinib cream (n = 450) or vehicle (n = 224) for 24 weeks of double-blind treatment. At Week 24, ≥75% improvement from baseline in facial Vitiligo Area Scoring Index (F-VASI75; primary endpoint) was achieved by significantly more patients who applied ruxolitinib cream vs vehicle (70.7%/9.9%; P < 0.001). Efficacy by F-VASI75 response was identified in all demographic and clinical characteristic subgroups. Substantive F-VASI75 responses were seen for men (n = 270), 26.6%/10.8% and women (n = 322), 33.9%/9.2% and based on age group (12–17 years [n = 68], 52.0%/18.4%; 18–64 years [n = 484], 30.2%/11.0%; ≥65 years [n = 40], 33.3%/7.7%). F-VASI75 responses were also generally consistent based on Fitzpatrick skin phototype (I vs II [n = 193], 27.9%/9.4%; III–VI [n = 899], 32.0%/10.2%), facial BSA (<1.5% vs 484), 29.2%/11.3%; ≥1.5% [n = 108], 56.8%/3.1%), investigator-assessed disease stability (stable [n = 438], 29.9%/8.3%; progressive [n = 154], 32.7%/14.9%), and previous therapies (topical corticosteroids [n = 165], 32.2%/9.1%; topical calcineurin inhibitors [n = 198], 32.4%/6.5%; phototherapy [n = 191], 35.9%/7.8%). Treatment-related adverse events occurred in 14.7%/7.6% who applied ruxolitinib cream or vehicle, respectively, with generally similar rates among demographic subgroups for patients who applied ruxolitinib cream. In 12-week extension, ruxolitinib cream demonstrated similar efficacy and safety results in patients with vitiligo regardless of demographic or clinical characteristic subgroup.

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34007
efficacy and safety of baricitinib in adult patients with severe alopecia areata with or without an atomic background from 2 randomized, placebo-controlled, phase 3 trials
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Background: Atyo is associated with alopecia areata (AA) and may influence treatment response. Among 1200 patients enrolled in 2 independent phase 3 trials of baricitinib for severe AA, 37.8% had an atomic background, defined by medical history or ongoing atomic dermatitis, allergic rhinitis, allergic asthma, or allergic conjunctivitis at baseline. Descriptive treatment efficacy and safety in patients with or without an atomic background are reported.

Methods: BRAVE-AA1 (NCT03570749) and BRAVE-AA2 (NCT03899259) are ongoing double-blind, placebo-controlled randomized (1:1:1) trials (randomization [3:2:2] to receive once-daily baricitinib 4 mg, 2 mg, or placebo). Using pooled data, we evaluated safety and efficacy outcomes (Severity of Alopecia Tool [SALT] score ≤20 and Clinician-Reported Outcomes for Eyebrow Hair Loss and Eyelash Hair Loss scores of 0 or 1 with ≥2-point improvement, among those with baseline scores ≥2) at week 16.

Results: Mean baseline SALT score was 87.2 vs. 84.2 for patients with or without an atomic background, respectively. At Week 16, SALT ≤20 was achieved by 40.8%, 21.5%, and 2.1% of patients with an atomic background with baricitinib 4 mg, 2 mg, and placebo, respectively, vs. 30.2%, 18.6%, and 5.4% without an atomic background. Improvements in eyebrow/eyelash measures occurred in 37.6%/36.5%, 19.1%/15.5%, and 6.0%/6.4% of patients with an atomic background with baricitinib 4 mg, 2 mg, and placebo, respectively, vs. 30.4%/32.1%, 13.7%/9.5%, and 2.2%/2.8% without an atomic background. The baricitinib safety profile in both subgroups was similar to that in the overall population.

Conclusion: The safety profile and improvements in hair regrowth in baricitinib-treated patients with severe AA were independent of atomic background.

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