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33354 Efficacy of apremilast in patients with mild to moderate psoriasis assessed by the physician global assessment and body surface area composite tool: Post hoc analysis from ADVANCE

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Efficacy and safety of once-daily roflumilast cream 0.3% in patients with knee/elbow involvement: Pooled results from phase 3 trials (DERMIS-1 and DERMIS-2)

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Roflumilast cream 0.3% is a selective and potent phosphodiesterase-4 inhibitor under investigation as a once-daily treatment for psoriasis. Psoriatic plaques on the knees/elbows can be challenging to treat due to thicker stratum corneum, which impedes topical absorption. We present pooled efficacy results from a post hoc analysis of the subgroup of patients with knee and/or elbow involvement from two identical phase 3 randomized controlled trials of roflumilast (DERMIS-1: NCT04211363 and DERMIS-2: NCT04211389). Patients (≥2 years) with psoriasis involving 2-20% of body surface area were randomized to roflumilast (n = 576) or vehicle (n = 305) for 8 weeks. Three-quarters (76.3%) of patients had knee/elbow involvement at baseline (roflumilast: n = 446 [77.4%]; vehicle: n = 226 [74.1%]). More roflumilast-treated than vehicle-treated patients achieved the primary efficacy endpoint of Investigator Global Assessment (IGA) Success (Clear or Almost Clear IGA status plus ≥2-grade improvement from baseline) at Week 8 (41.2% vs. 5.1%; $P < .0001$). Almost half (48.6%) of roflumilast-treated patients with knee/elbow involvement achieved IGA of Clear/Almost Clear at Week 8 versus 7.6% of vehicle-treated patients ($P < .0001$). At all post-baseline timepoints, more roflumilast-treated patients with knee/elbow involvement and baseline Worst Itch-Numeric Rating Scale ≥4 achieved a ≥4-point reduction ($P < .0001$). Overall incidence of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation were low with similar rates between roflumilast and vehicle. Local tolerability was highly favorable on patient and investigator assessments. Once-daily roflumilast cream 0.3% provided superior improvement across multiple efficacy endpoints in patients with psoriasis involving knees/elbows in two phase 3 trials.

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Efficacy of apremilast in patients with mild to moderate psoriasis assessed by the physician global assessment and body surface area composite tool: Post hoc analysis from ADVANCE

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Background: In ADVANCE (NCT03721172), apremilast 30 mg BID (APR) demonstrated significantly greater sPGA response vs. PBO at Week 16 (22% vs. 4%; $P < .0001$) in patients with mild-to-moderate psoriasis. The Physician Global Assessment and Body Surface Area Composite Tool (PGA × BSA) is a simple, sensitive measure of psoriasis severity for patients with BSA<10%. We performed a post hoc analysis of the efficacy results from ADVANCE using the PGA×BSA.

Methods: This current post hoc analysis included all randomized patients. Missing data were imputed by multiple imputation. PGAxBSA-50/75/90 was 50%, 75% and 90% improvement in PGAxBSA from baseline.

Results: Of 595 randomized patients (APR: 297; PBO: 298), baseline characteristics were similar for mean BSA (APR: 6.4; PBO: 6.3), sPGA score 2 (APR 31%; PBO: 31%), sPGA score 3 (APR: 69%; PBO: 70%), and mean PGA×BSA (APR: 17.6; PBO: 17.5). At Week 16, significantly more patients achieved PGAxBSA-50/75/90 response with APR vs. PBO: PGA×BSA-50, 67% vs. 26% ($P < .0001$), difference 41%, 95%CI (32.7,48.5) PGA×BSA-75, 46% vs. 13% ($P < .0001$), difference 33%, 95%CI (25.8,40.2) PGA×BSA-90, 27% vs. 3% ($P < .0001$), difference 24%, 95%CI (18.3,29.6) A significant improvement from baseline at Week 16 in PGA×BSA was observed with APR vs PBO: Mean % change (SE) in PGA×BSA, -51.8 (4.2) vs. 1.97 (4.3); difference (95%CI): -53.8 (-65.4, -42.2), $P < .0001$.

Conclusions: The PGA×BSA Composite Tool appeared to be a sensitive and a relevant measure for mild-to-moderate psoriasis that showed significantly greater treatment differences at 50%, 75%, and 90% response thresholds at Week 16 with APR compared with PBO in ADVANCE.

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Efficacy of 80 mg/week dose of adalimumab (Humira) in treatment of hidradenitis suppurativa

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Hidradenitis suppurativa (HS) is an inflammatory skin condition involving the apocrine gland-bearing regions, such as the axillae, groin, anogenital, and inframammary areas. Though its etiology is unknown, disease manifests when hair follicles become obstructed, leading to the release of inflammatory mediators, such as TNF-α and IL-17. Levels of TNF-α have been found to be elevated in lesions of HS, providing a basis for the use of biologics in treatment of severe HS. Adalimumab is a recombinant human IgG1 anti-TNF monoclonal antibody which acts via antagonism of TNF-α. Although adalimumab has been studied in phase 2 and 3 trials and has been approved as a treatment modality for HS at a 40 mg weekly dose, numerous patients still suffer on a day-to-day basis due to the severity of their disease and do not respond to this conventional dosing. We present a series of 6 such patients whose response to an 80 mg/week dose of adalimumab has been positive, with a decrease in severity and number of HS lesions, leading to improvement in the Hidradenitis Suppurativa Clinical Response (HiSCR) in the absence of serious adverse effects. Although this dosing regimen has not been well-documented in literature, it is important to consider the lasting benefits of treatment with a higher dose in individuals afflicted with treatment-resistant HS, including a decreased likelihood of comorbidities and complications and an improved quality of life.

Commercial Disclosure: None identified.

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Efficacy of oral sarecycline in Hispanics with facial inflammatory acne

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In 2019, 60.6 million in the U.S. were Hispanics, with acne affecting 32% of Hispanic women. Sarecycline is a narrow-spectrum, third-generation tetracycline-class antibiotic, FDA approved for the treatment of moderate-to-severe acne in patients aged 9 and older. With increasing focus on outcomes in skin of color, we report pooled post hoc analysis of efficacy and safety data on sarecycline in Hispanics from pivotal phase 3, multicenter, randomized, double-blind, placebo-controlled studies SC1401 and SC1402. Of 2002 subjects, 27% were Hispanic. Patients were randomized 1:1 to receive once daily oral sarecycline at 1.5 mg/kg/day or placebo. In Hispanics, facial inflammatory lesions decreased at week 3 by 26% (CI: -6.06 (-11.45, -0.66), $P = .0279$), at week 6 by 41% versus 30% (CI: -10.70 (-16.48, -4.93), $P = .0003$), at week 9 by 51% versus 38% (CI: -13.09 (-19.18, -6.99), $P < .0001$), and at week 12 by 55% versus 37% (CI: -17.29 (-24.39, -10.20), $P < .0001$) in patients on sarecycline vs placebo, respectively. IGA success at week 12 was achieved in 24% versus 15% of Hispanics on sarecycline vs placebo, respectively (CI: 10.13 (3.65, 16.62), $P = .0023$). Gastrointestinal TEAE rates were low, with 6.1% vs 4.3% (sarecycline vs placebo). Vestibular, phototoxic, vulvovaginal candidiasis, and mycotic infections were all ≤1.1%. Thus, the narrow-spectrum sarecycline demonstrated statistically significant greater percent reduction in facial inflammatory lesion counts as early as week 3 ($P = .0279$,) and IGA success at week 12 in 24% ($P = .0023$).

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