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34794 Long-term safety and disease control of ruxolitinib cream among Black or African American patients with atopic dermatitis: Pooled results from 2 phase 3 studies

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Long-term efficacy of dupilumab in adults with moderate-to-severe atopic dermatitis (AD): Results from an open-label extension (OLE) trial up to 4 years

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Background: AD is a chronic systemic inflammatory disease often requiring long-term management. Here, we present long-term efficacy of dupilumab up to 4 years in adult patients with moderate-to-severe AD.

Methods: The OLE (NCT01949311), with an initial duration of 3 years, enrolled adults with moderate-to-severe AD who participated in a dupilumab parent study. Protocol amendments extended the maximum treatment duration to 5 years. Following protocol amendments in 2017 and 2018, 114 and 272 patients re-entered the trial; 103 and 207 patients had a treatment interruption of >8 weeks between Weeks 148 and 164. Patients were treated with 300 mg dupilumab weekly. In 2019, patients transitioned to 300 mg every 2 weeks to align with approved dosage. Concomitant topical anti-inflammatory treatments were permitted. Data shown are for the overall study population (N = 2677).

Results: 2207/1065/557/362/352 patients completed up to 52/100/148/172/204 weeks of treatment. 240 patients had treatment duration >204 weeks. Most withdrawals (59.5%) were due to dupilumab approval; 8.4%/4.3% withdrew due to adverse events/lack of efficacy. At Week 204, 95%/91%/76% of patients achieved 50%/75%/90% reductions in Eczema Area and Severity Index from parent study baseline (PSBL). 78.7%/70.8% of patients achieved ≥3/≥4-point reduction in the Peak Pruritus Numerical Rating Scale score from PSBL at Week 204. Treatment-emergent adverse events were reported in 2273 (84.9%) patients, with 99 (3.7%) permanently discontinuing treatment.

Conclusions: Long-term dupilumab treatment showed sustained efficacy substantiated by improvement of AD signs and symptoms in patients with moderate-to-severe AD up to 204 weeks. Safety data were consistent with prior studies.

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Long-term safety and disease control of ruxolitinib cream among Black or African American patients with atopic dermatitis: Pooled results from 2 phase 3 studies

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Atopic dermatitis (AD) is an inflammatory skin disease with a prevalence in the United States of approximately 20%/5%−10% in Black or African American children/adults. In 2 phase 3 studies (TRuE-AD1/TRuE-AD2), 1249 patients (≥12 years old, Investigator's Global Assessment [IGA] score 2/3, 3%−20% affected body surface area [BSA]) were randomized (2:2:1) to twice-daily 0.75% ruxolitinib (Janus kinase [JAK] 1/JAK2 inhibitor) cream, 1.5% ruxolitinib cream, or vehicle for an 8-week, double-blind vehicle-controlled period, followed by a double-blind long-term safety period (LTS; as-needed treatment; assessments every 4 weeks) up to Week 52. Patients initially randomized to ruxolitinib remained on their regimen during the LTS; patients initially on vehicle were rerandomized to either ruxolitinib strength. During the LTS, patients treated areas with active AD only, stopped treatment 3 days after lesion clearance, and restarted treatment at recurrence. Among self-identifying Black or African American patients in the 0.75%/1.5% ruxolitinib groups for the full study in this pooled analysis (n = 91/n = 97), 53.8%/61.9% achieved clear/almost clear skin (IGA 0/1) at Week 8. From Week 12−52, 55.2%−73.3%/59.3%−78.7% of patients (range) achieved IGA 0/1. Mean affected BSA was 8.6%/8.3% at baseline, 3.8%/3.6% at Week 8, and 1.7%−3.3%/1.3%−2.5% (range of mean values) through Week 52. Over 52 weeks, treatment-emergent adverse events were reported in 59.3%/56.7% of patients; treatment-related adverse events were reported in 4.4%/6.2%. Incidence of application site reactions was low. In summary, the majority of Black or African American patients achieved clear/almost clear skin using ruxolitinib cream monotherapy, which was well tolerated.

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33006

Long-term improvement of patient-reported outcomes in adult patients with atopic dermatitis treated with baricitinib in the US and Canada

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Objective: To evaluate long-term patient-reported outcome (PRO) improvements in patients with atopic dermatitis (AD) treated with baricitinib, a Janus kinase (JAK) 1/JAK2 inhibitor.

Methods: Data were derived from 2 phase 3 studies: double-blind placebo-controlled BREEZE-AD5 (NCT03435081) and long-term open-label extension BREEZE-AD6 (NCT03559270) through 52 weeks of treatment. Low-potency topical corticosteroids were permitted after Week 16 in BREEZE-AD5 and throughout BREEZE-AD6. PROs [Dermatology Life Quality Index (DLQI), Patient-Oriented Eczema Measure (POEM), and Hospital Anxiety Depression Scale (HADS-anxiety and HADS-depression)] were assessed to Week 52 using descriptive statistics with missing data imputed by last observation carried forward.

Results: In 146 patients receiving baricitinib 2 mg, the quality of life measure DLQI (mean ± standard deviation at baseline 15.0 ± 7.6) showed a mean change from baseline of −7.0 ± 8.2 at Weeks 48-52. Patient-reported improvements in skin symptoms as measured by POEM were −7.3 ± 8.8 at Weeks 48-52 from mean baseline value of 21.7 ± 5.4. By Weeks 48-52, 68.9% and 57.6% of patients had achieved a clinically meaningful ≥4-point improvement in DLQI and POEM, respectively. HADS-anxiety and HADS-depression scores were 7.0 ± 4.4 and 5.2 ± 4.3 at baseline, respectively, with patients reporting a change from baseline of −1.9 ± 3.7 and −1.8 ± 3.3 at Weeks 48-52.

Conclusion: Patients with moderate to severe AD treated with baricitinib 2 mg experienced clinically meaningful PRO improvements in skin symptoms, quality of life, and anxiety and depression over 52 weeks.

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Long-term safety and efficacy of roflumilast cream 0.3% in patients with chronic plaque psoriasis: Interim results from a 24-week, phase 3 open-label study

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Roflumilast cream is a selective, highly potent phosphodiesterase-4 inhibitor under investigation as a nonsteroidal, once-daily treatment for psoriasis. A phase 3, 24-week, open-label extension (DERMIS-OLE; NCT04286607) is being conducted in patients (aged ≥2 years) with psoriasis who successfully completed a prior roflumilast cream study (Cohort-1) and patients (aged ≥2-17 years) naïve to roflumilast/vehicle (Cohort-2). We present interim results from Cohort-1, comprising 264 patients from two 8-week phase 3 studies. As of December 2020, 84.1% of Cohort-1 completed the study, 3.8% were ongoing, and 12.1% discontinued. One (0.4%) patient discontinued due to an adverse event (AE). Overall, 69 (26.1%) patients experienced a treatment-emergent AE; most were mild or moderate. One AE was considered likely treatment-related and 3 were possibly related; none were serious. Investigator tolerability assessments demonstrated ≥96.3% of patients had "no evidence of irritation" at each visit. At Week 24 of the OLE, key efficacy results were: 50.0% of patients had Investigator Global Assessment (IGA) status of Clear/Almost Clear, >75% of patients with intertriginous-IGA of at least Mild (≥2) at Baseline achieved intertriginous-IGA Success, 43.8% of patients had 75% reduction on the Psoriasis Area and Severity Index, and 62.4% of patients achieved 4-point improvement on the Worst Itch-Numeric Rating Scale from a baseline of ≥4. With cumulative treatment up to 32 weeks (including parent study), safety and tolerability were consistent with the previous phase 2, 52-week study. In this long-term safety study, roflumilast cream demonstrated excellent tolerability with no unexpected AEs and effectively maintained Clear/Almost Clear skin.

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