Long-Term Safety and Disease Control With Ruxolitinib Cream Among Patients With Atopic Dermatitis Based on Previous Medication History: Pooled Results From Two Phase 3 Studies

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Treatments for atopic dermatitis (AD) include topical corticosteroids (TCS), topical calcineurin inhibitors (TCI), and systemic immunomodulatory agents. However, their clinical benefit may be inadequate because of duration-of-use limitations and/or adverse reactions. Ruxolitinib cream is a Janus kinase (JAK) 1/JAK2 inhibitor in development for the treatment of AD. In two phase 3 randomized studies of identical design (TRuE-AD1 [NCT03745638] and TRuE-AD2 [NCT03745651]), 1249 patients aged ≥12 years with AD for ≥2 years with an Investigator’s Global Assessment (IGA) score of 2 or 3 and 3%–20% affected body surface area (BSA) were randomized (2:2:1) to twice-daily 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, or vehicle cream for an 8-week, double-blinded, vehicle-controlled (VC) period, followed by a double-blinded long-term safety (LTS) period up to Week 52. Patients initially randomized to ruxolitinib cream remained on their regimen during the LTS period; patients initially on vehicle were re-randomized (1:1) to either ruxolitinib cream strength. During the VC period, patients were instructed to continue treating lesions regardless of lesion improvement. During the LTS period, patients were to treat skin areas with only active AD and stop treatment 3 days after clearance of lesions. Patients were to restart treatment with ruxolitinib cream at first sign of recurrence. The use of systemic AD therapies or other topical therapies for AD (except bland emollients) was not permitted during the studies. In the 8-week VC period, ruxolitinib cream (both strengths) demonstrated anti-inflammatory activity, with rapid and sustained antipruritic action vs vehicle, and was well tolerated. Here we report pooled analyses of the disease control and safety of ruxolitinib cream in patients with AD in the TRuE-AD studies who received 0.75%/1.5% ruxolitinib cream in both the VC and LTS periods (N=426/446) analyzed by previous medication history (TCS, TCI, TCS+TCI, systemic therapies, or phototherapy). Regardless of prior therapy, an IGA score of 0/1 (no AD lesions or only minimal AD lesions) was achieved from Weeks 12 through 52 by a substantial proportion of patients who applied 0.75% ruxolitinib cream (range for TCS, 60.7%–77.1%; TCI, 68.2%–81.7%; TCS+TCI, 69.0%–83.1%; systemic therapies, 58.2%–70.0%; phototherapy, 60.0%–80.0%) or 1.5% ruxolitinib cream (range for TCS, 71.4%–79.5%; TCI, 70.7%–80.5%; TCS+TCI, 71.2%–81.5%; systemic therapies, 69.7%–80.6%; phototherapy, 66.7%–82.9%). Furthermore, mean affected BSA was low from Weeks 12 through 52 in all subgroups among patients who received 0.75% ruxolitinib cream (range for TCS, 1.8%–3.2%; TCI, 2.4%–3.8%; TCS+TCI, 2.2%–3.5%; systemic therapies, 2.7%–4.1%; phototherapy, 2.3%–3.3%) or 1.5% ruxolitinib cream (range for TCS, 1.3%–2.1%; TCI, 1.8%–2.8%; TCS+TCI, 1.7%–2.6%; systemic
therapies, 1.7%–2.7%; phototherapy, 1.6%–2.5%). A pooled safety analysis included patients who received 0.75%/1.5% ruxolitinib cream in either study period (TCS, n=461/461; TCI, n=134/121; TCS+TCI, n=121/109; systemic therapies, n=106/110; phototherapy, n=42/48). Among patients who received 0.75%/1.5% ruxolitinib cream, treatment-emergent adverse events (TEAEs) that were considered related to treatment occurred in 7.8%/7.6% of patients in the TCS subgroup, 13.4%/15.7% in the TCI subgroup, 12.4%/17.4% in the TCS+TCI subgroup, 12.3%/13.6% in the systemic therapies subgroup, and 19.0%/14.6% in the phototherapy subgroup. The frequency of application site reactions was low regardless of previous therapy (TCS, 3.3%/2.0%; TCI, 3.7%/3.3%; TCS+TCI, 3.3%/3.7%; systemic therapies, 2.8%/3.6%; phototherapy, 4.8%/4.2%). TEAEs resulting in discontinuation were noted in 1.7%/0.9% of patients in the TCS subgroup, 0.7%/0.8% in the TCI subgroup, 0.8%/0.9% in the TCS+TCI subgroup, 2.8%/0.9% in the systemic therapies subgroup, and 2.4%/0% in the phototherapy subgroup. In summary, ruxolitinib cream maintained long-term disease control and was well tolerated over a period up to 52 weeks, regardless of previous therapy.

Author Disclosures

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