Effects of Ruxolitinib Cream on Work Productivity and Activity Impairment in Patients With Atopic Dermatitis: 52-Week Pooled Results From Two Phase 3 Studies

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Atopic dermatitis (AD) is a chronic inflammatory skin disease that can negatively impact work productivity and daily activities. Ruxolitinib cream, a selective Janus kinase (JAK) 1/JAK2 inhibitor, was investigated in two phase 3 randomized AD studies of identical design (TRuE-AD1 [NCT03745638]; TRuE-AD2 [NCT03745651]). Ruxolitinib cream was well tolerated and demonstrated significant improvement vs vehicle in work productivity and activity impairment at Week 8 in the phase 3 studies. In these studies, patients aged ≥12 years with AD for ≥2 years, an Investigator’s Global Assessment score of 2 or 3, and 3%-20% affected body surface area (excluding scalp) were randomized (2:2:1) to twice-daily (BID) 0.75% ruxolitinib, 1.5% ruxolitinib, or vehicle cream for an 8-week, double-blind, vehicle-controlled (VC) period of continuous treatment. Patients subsequently continued in a double-blind, long-term safety (LTS) period (as-needed treatment) up to Week 52. Patients initially randomized to ruxolitinib cream remained on their regimen during the LTS period; patients initially on vehicle were rerandomized (1:1) to either ruxolitinib cream strength. During the LTS period (starting at Week 8), patients treated areas with active AD only, stopped treatment 3 days after lesion clearance, and restarted treatment upon recurrence. In this analysis,
data from the VC and LTS periods using the Work Productivity and Activity Impairment Questionnaire-Specific Health Problem version 2.0 (WPAI:SHP v2.0) are reported for employed patients. Work time missed owing to AD (absenteeism), impairment while working with AD (presenteeism), overall AD-related work impairment, and AD-related activity impairment were assessed. Scores are expressed as a percentage of impairment, with higher scores indicating more impairment. Of 1249 randomized patients, 1072 (85.8%) continued into the LTS period; 1031 were evaluated for efficacy (0.75% ruxolitinib cream, n=409; 1.5% ruxolitinib cream, n=428; vehicle to 0.75% ruxolitinib cream, n=98; vehicle to 1.5% ruxolitinib cream, n=96). Median (range) age was 33.0 (12–85) years, 61.7% of patients were female, 70.3% were White, and 22.8% were Black. Baseline values for absenteeism were relatively low across all groups (7.3%, 3.3%, 4.0%, and 5.7% for 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, vehicle to 0.75% ruxolitinib cream, vehicle to 1.5% ruxolitinib cream, respectively; n=231/243/53/49). At Week 8, mean changes from baseline in absenteeism scores were 1.1, 4.6, 13.5, and 1.0. During as-needed application of ruxolitinib cream in the LTS period, mean changes from baseline were 1.2, 4.2, 6.3, and 4.4. Mean presenteeism values ranged from 29.5%–36.3% across groups at baseline (n=229/242/53/49). At Week 8, mean changes from baseline in presenteeism among patients who applied ruxolitinib cream (0.75%/1.5%) were −19.2/−20.1 and −13.0/−12.1 in the vehicle to 0.75%/vehicle to 1.5% ruxolitinib cream groups. The improved presenteeism was maintained with as-needed ruxolitinib cream among patients initially randomized to 0.75%/1.5% ruxolitinib cream (Week 52, −21.9/−22.4); similar improvements at Week 52 were observed for patients who switched to ruxolitinib cream.
(0.75%/1.5%) in the LTS period (Week 52, −25.3/−28.3). Similar trends were reported among patients in the 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, vehicle to 0.75% ruxolitinib cream, and vehicle to 1.5% ruxolitinib cream groups for overall work impairment (mean baseline values across group, 31.7%–39.5% [n=229/242/53/49]; Week 8 mean change from baseline, −17.5/−15.6/−1.8/−10.3; Week 52 mean change from baseline, −19.1/−18.5/−19.2/−21.8) and daily activities (mean baseline values across groups, 31.6%–33.9% [n=408/427/97/96]; Week 8 mean change from baseline, −21.0/−21.7/−9.0/−13.2; Week 52 mean change from baseline, −22.9/−25.5/−22.7/−27.8). In summary, work productivity and daily activities were substantially improved with 8 weeks of ruxolitinib cream BID application, and these improvements were maintained for 44 weeks with as-needed ruxolitinib cream. Patients who switched from vehicle to either ruxolitinib cream strength during the LTS period had similar improvements in work productivity and activity impairment at Week 52 compared with patients initially randomized to ruxolitinib cream. Improvement in work productivity with ruxolitinib cream treatment may result in improved QoL and previously unrecognized indirect cost-benefits.

**Author Disclosures**

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