Atopic dermatitis (AD) is a highly pruritic, inflammatory skin disease. Quality of life can be significantly reduced by pruritus and sleep disturbances. Ruxolitinib cream is a topical formulation of ruxolitinib, a selective Janus kinase (JAK) 1/JAK2 inhibitor. In two phase 3 randomized AD studies of identical design (TRuE-AD1 [NCT03745638] and TRuE-AD2 [NCT03745651]), ruxolitinib cream was well tolerated and demonstrated significant improvement vs vehicle in itch and sleep (TRuE-AD1) at Week 8. 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 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, or vehicle cream for an 8-week, double-blind, vehicle-controlled period (VC; continuous treatment). Patients subsequently continued in a double-blind, long-term safety period (LTS; as-needed treatment) up to Week 52. Patients initially randomized to ruxolitinib cream remained on their regimen during the LTS; patients initially on vehicle were rerandomized (1:1) to either ruxolitinib cream strength. During the LTS, patients treated
areas with active AD only, stopped treatment 3 days after lesion clearance, and
restarted treatment upon recurrence. Here, the effects of ruxolitinib cream on itch and
sleep during the LTS are reported using pooled results from the 2 studies. Itch and
sleep were assessed using questions 1 and 2 of the Patient-Oriented Eczema Measure
(POEM Q1 and Q2), in which patients reported the number of days/ nights of itchy skin
or disturbed sleep, respectively, due to eczema in the past week. Sleep-related
impairment and sleep disturbance were also assessed using items 8a and 8b,
respectively, of the Patient-Reported Outcomes Measurement Information System
(PROMIS), with a recall period of 24 hours for the VC and 7 days for the LTS. Of 1249
randomized patients, 1072 (85.8%) continued into the LTS; 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. At Week 8, the proportions of patients reporting no days of itch per
POEM Q1 were 27.7%, 32.7%, 9.2%, and 9.5% for 0.75% ruxolitinib cream, 1.5%
ruxolitinib cream, vehicle to 0.75% ruxolitinib cream, and vehicle to 1.5% ruxolitinib
cream, respectively. During as-needed application of ruxolitinib cream in the LTS, itch
relief was maintained for patients who remained in the 0.75%/1.5% ruxolitinib cream
groups (Week 52: 28.0%/36.2% reported no days of itch). In the vehicle to 0.75%/1.5%
ruxolitinib cream groups, more patients reported no days of itch at Week 52
(36.1%/43.2%) vs Week 8. The proportions of patients reporting no nights of disturbed
sleep per POEM Q2 at Week 8 were 64.9%, 71.8%, 48.0%, and 41.1% for 0.75%
ruxolitinib cream, 1.5% ruxolitinib cream, vehicle to 0.75% ruxolitinib cream and vehicle
to 1.5% ruxolitinib cream, respectively. At Week 52, patients who remained in the 0.75%/1.5% ruxolitinib cream groups maintained undisturbed sleep (74.5% for both groups). More patients who switched from vehicle to as-needed 0.75%/1.5% ruxolitinib cream reported no nights of disturbed sleep at Week 52 (73.6%/80.2%) vs Week 8. At baseline, PROMIS sleep-related impairment mean scores were 17.3, 17.4, 17.0, and 16.6 for 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, vehicle to 0.75% ruxolitinib cream, and vehicle to 1.5% ruxolitinib cream, respectively. Overall, scores had decreased slightly in the ruxolitinib cream groups by the beginning of the LTS, indicating less impairment (15.2, 15.2, 16.0, 16.7), and decreased slightly in all groups to Week 52 (14.4, 14.4, 14.8, 13.8). PROMIS sleep disturbance mean scores at baseline were 18.9, 19.2, 18.2, and 18.9; had decreased slightly in the ruxolitinib cream groups by the beginning of the LTS (17.4, 17.4, 18.8, 19.6); and were maintained or slightly decreased in all groups to Week 52 (16.8, 17.2, 17.0, 16.2). In summary, itch and sleep were improved with ruxolitinib cream, and these improvements were maintained for 44 weeks with as-needed ruxolitinib cream use. Patients who switched from vehicle to ruxolitinib cream at Week 8 had similar itch and sleep scores at Week 52 to patients initially randomized to ruxolitinib cream.

Author Disclosures

ELS is an investigator for AbbVie, Eli Lilly, Galderma, Kyowa Hakko Kirin, LEO Pharma, Merck, Pfizer, and Regeneron and is a consultant with honorarium for AbbVie, Eli Lilly, Forte Bio, Galderma, Incyte Corporation, LEO Pharma, Menlo Therapeutics, Novartis, Pfizer, Regeneron, Sanofi Genzyme, and Valeant. MB is an investigator for Incyte
Corporation. DT has served as an investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Asana Biosciences, Biogen Idec, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Galapagos, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi, Target-Solution, and UCB and has received grants from AbbVie, Celgene, LEO Pharma, and Novartis. LM is an investigator for AbbVie, Eli Lilly, Galderma, Incyte Corporation, LEO Pharma, Pfizer, and Sanofi and is a consultant with honorarium for AbbVie, Eli Lilly, Galderma, LEO Pharma, Menlo Therapeutics, Novartis, Pfizer, and Sanofi. AWA has served as a research investigator and/or scientific advisor to AbbVie, Bristol Myers Squibb, Dermavant, Dermira, Incyte Corporation, Janssen, LEO Pharma, Lilly, Modmed, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. JIS has received honoraria for advisory board, speaker, and consultant services from AbbVie, Asana BioSciences, Bluefin, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly, Galderma, GlaxoSmithKline, Glenmark, Incyte Corporation, Kiniksa, LEO Pharma, Menlo Therapeutics, Novartis, Pfizer, Realm, Regeneron, and Sanofi and research grants for investigator services from Galderma and GlaxoSmithKline. MEV, HK, and JG are employees and shareholders of Incyte Corporation. JCS has served as an advisor for AbbVie, LEO Pharma, Menlo Therapeutics, Novartis, Pierre Fabre, and Trevi; has received speaker honoraria from AbbVie, Eli Lilly, Janssen-Cilag, LEO Pharma, Novartis, Sanofi-Genzyme, and Sun Pharma; and has received clinical trial funding from AbbVie, Almirall, Amgen, Galapagos, Holm, Incyte Corporation, InflaRX, Janssen-Cilag, Menlo Therapeutics, Merck, Novartis, Pfizer, Regeneron, Trevi, and UCB.