Effects of Ruxolitinib Cream on Pruritus and Sleep in Atopic Dermatitis: 52-Week Pooled Results From Two Phase 3 Studies

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Introduction
Atopic dermatitis (AD) is a highly pruritic inflammatory skin disease. Quality of life in patients with AD can significantly be reduced by itch and sleep disturbance.1

Janssen biomarkers playbook probability classifies in the pathogenesis of AD.2

Ruxolitinib cream is a topical formulation of ruxolitinib, a selective JAK1/JAK2 inhibitor.3

In two phase 3 randomized studies of identical design (TRU-AD Q1 POCP056500 and TRU-AD Q2 POCP056500), ruxolitinib cream was well-tolerated and demonstrated substantial improvement in itch in both studies during the vehicle-controlled period (VC) (0% pruritus assessment and adults with AD).4

Objective
To evaluate the effects of ruxolitinib cream on itch and sleep over 52 weeks using the Patient-Reported Outcomes Measurement Information System (PROMIS) during the daytime period and reported on perceptions of sleep quality, sleep depth, and restoration during usual daily activities, use of AD systemic therapies during the washout period and at home during the VC period, and a 7-day recall period using a tablet at study visits.

Methods
Patients and Study Design
Eligible patients aged 12+ years with AD for ≥2 years and had an Investigator’s Global Assessment score of 4 or 5 (severe or very severe body involvement) were enrolled.

Key exclusion criteria were unstable course of AD, other types of eczema, inflammatory conditions, use of AD topical therapies (percutaneous bland emollients) during the washout period and during the study, and any history of an experience that could interfere with study contact, interpretation of data, or patient well-being.

TRU-AD Q1 and TRU-AD Q2 had identical design (Figure 1). In both studies, patients were randomized (2:2:1) to either of 2 ruxolitinib cream strength regimens (0.75% twice daily [BID], 1.5% BID) or vehicle cream BID throughout the study. Patients were randomized to receive either 12 mo continuous treatment or 8 weeks of treatment with ruxolitinib cream, respectively (Figure 2). Patients reported the number of days of itchy skin due to eczema in the past week using the Patient-Oriented Eczema Measure (POEM) and were stratified by AD severity. In the LTS period, itch relief was maintained for patients who remained in the study or switched from vehicle to 0.75% RUX cream. These proportions were maintained to Week 22 (31.6% and 43.2%) (Figure 4).

Results
Sleep Assessment With PROMIS
Sleep disturbance scores were maintained or slightly decreased in all groups from Week 8 to Week 52 (Table 3, Figure 3). Among patients who applied ruxolitinib cream in the VC period, PROMIS sleep disturbance mean scores had decreased by the beginning of the LTS period, indicating improvement; scores decreased slightly in all groups from Week 52 to Week 22 (Table 4). Among patients who applied ruxolitinib cream in the LTS period, itch relief was maintained for patients who remained in the study or switched from vehicle to 1.5% RUX cream, and these scores were maintained to Week 22 (31.6% and 43.2%) (Figure 4).

Conclusions
Itch and sleep were improved with ruxolitinib cream use during the VC period.

Sleep improvement was demonstrated by the increasing proportions of patients reporting no nights of disturbed sleep per POEM Q2 and the decreasing scores in PROMIS sleep-related impairment and sleep disturbance.

Improvements in itch and sleep were maintained for 44 weeks with as-needed ruxolitinib cream use.

Patient with switched from vehicle to ruxolitinib cream at Week 8 quickly attained itch and sleep scores similar to patients initially randomized to ruxolitinib cream, and these scores were maintained to Week 52.

Assessments
At each visit, patients were asked to report whether they had skin lesions that itch or scratch (yes/no). Patient assessments included sleep disturbance and itch in VC and LTS assessed by PRO. Patients reported the number of days of itchy skin due to eczema in the past week using the POEM and were stratified by AD severity. In the LTS period, itch relief was maintained for patients who remained in the study or switched from vehicle to 0.75% RUX cream. These proportions were maintained to Week 22 (31.6% and 43.2%).

Figure 1. Study Design

Figure 2. POEM

Figure 3. PROMIS Sleep Disturbance Score

Figure 4. Week 22 PROMIS Sleep-Related Impairment Scores

References

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