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Antipruritic action vs vehicle and was well tolerated in patients with AD 1 and JAK2

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Table 1. Adverse Events According to the Type of Previous Medication Among Patients Who Applied Ruxolitinib Cream in the Phase 3 Studies (TC 78% LTE Period)

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Figure 3. Mean-Affected BSA Stratified by the Type of Previous Medication Among Patients Who Applied (A) 0.75% or (B) 1.5% Ruxolitinib Cream

Assessments

Patients

Statistical Analysis

Ruxolitinib cream was well tolerated across all subgroups of previous treatment: the frequency of treatment-emergent adverse events (TEAEs), treatment-related adverse events (TRAEs), and adverse events (AEs) leading to treatment discontinuation was low. In the overall population, the most common TEAEs through Week 52 were arthropathy (0.9%), upper respiratory tract infections (0.9%), and herpes zoster (0.9%). TRAEs, n (%)

Study Design and Patients

In the event the predicted risk estimate from this trial became a threat to the health of the patients, the investigator would be asked to stop treatment. – No risk associated with a relationship to systemic exposure were observed

Truncating the LTE period, patients were instructed to stop using RUX and stop treatment 3 days after lesion clearance in the LTS period; patients initially randomized to vehicle were rerandomized 1:1 (blinded) to either 0.75% or 1.5% RUX

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• Ruxolitinib cream, used as maintenance therapy, demonstrated effective long-term disease control, regardless of the type of previous therapy

• Ruxolitinib cream was well tolerated over a period up to 52 weeks, regardless of the type of previous therapy

• Ruxolitinib cream was well tolerated across all subgroups of previous treatment: the frequency of treatment-emergent adverse events (TEAEs), treatment-related adverse events (TRAEs), and adverse events (AEs) leading to treatment discontinuation was low. In the overall population, the most common TEAEs through Week 52 were arthropathy (0.9%), upper respiratory tract infections (0.9%), and herpes zoster (0.9%). TRAEs, n (%)

Patient and investigator initiated, n (%) skin cancer (0.1% or 0.3% of total treated patients); the frequency of all systemic TEAEs was low (1.3% and 1.6% of patients who received 0.75% RUX and 1.5% RUX, respectively). No deaths, discontinuations, or serious AEs were reported as possibly, likely, or definitely related to systemic exposure.

The data were summarized using descriptive statistics. Disease control was assessed by the proportion of patients who achieved no or minimal skin lesions (IGA score of 0 or 1 [clear or almost clear skin]) and mean percentage of BSA affected by lesions (IGA score of 0 or 1 [clear or almost clear skin]) and mean percentage of BSA affected by lesions (IGA score of 0 or 1 [clear or almost clear skin]). The mean percentage of BSA affected by lesions did not decrease in the overall population (Supplementary Digital Content 1, http://links.lww.com/DERM/A175).

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