Introduction

Atopic dermatitis (AD) is a highly pruritic inflammatory skin disease.

The severity of AD is often stratified using objective (Investigator’s Global Assessment [IGA], Eczema Area and Severity Index [EASI], body surface area [BSA]) and subjective (itch numerical rating scale [NRS]) criteria.

Topical therapies are the standard of care for most patients with AD.

For patients with more severe AD, systemic therapies may be considered, such as systemic steroid therapy or biologics.

TRU-EAD1 and TRU-EAD2 had identical study designs (TRU-EAD [NCT07045536] & TRU-EAD2 [NCT07308551]), ruxolitinib cream demonstrated and maintained efficacy, and patients continued treatment in the treatment arm of AD.

Methods

Study Design and Patients

 Eligible patients were age 18–72 years, had a recent history (±1 year) of AD with an IGA score of 3, 4, or 5, and a body surface area (BSA) affected by AD of ≥10% at baseline.

Key exclusion criteria were unstable cardiovascular disease, use of AD topical therapies during the washout period and during the study, use of topical therapies (except bland emollients) during the washout period and during the study, and any other medical or psychological condition that could interfere with study conduct.

TRU-EAD1 and TRU-EAD2 had baseline-defined subgroups (Table 1).

Figure 1. Study Design

Results

Patients

 A total of 1249 patients (median age, 32 years) were randomized.

 Efficacy

Distribution of baseline demographics and characteristics of all randomized patients are shown in Table 2.

The definition of more severe AD (IGA score of 3, EASI 16, and affected BSA ≥10%) at baseline was based on IGA, EASI, and BSA criteria for trialing of systemic therapies (eg, dupilumab) and oral JAK.

Among patients with a baseline IGA score of 3, EASI 16, and BSA ≥10% in the pooled population, 31 and 28 patients continued from the VC to the LTP period in the 0.75% and 1.5% ruxolitinib cream, respectively, and were evaluated for disease control.

Safety

No AEs suggestive of a relationship to systemic exposure were observed.

Conclusions

The subset of patients meeting various thresholds for more severe disease at baseline achieved effective long-term disease control with ruxolitinib cream monotherapy during the 52-week study period.

Ruxolitinib cream was well tolerated in the long-term setting in the subset of patients who may be eligible for both systemic and topical therapies.

This data suggest that ruxolitinib cream may delay or prevent the need for systemic therapy in a subset of patients with more severe AD.

Although these patients met various thresholds for more severe disease at baseline, failure of topical therapy was not a requirement for entering the studies.

Disclosures

E.L. Lilly and Company, AstraZeneca, Galderma, Incyte Corporation, Janssen, Menlo, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. MEK was an employee of Galderma, Incyte Corporation, Janssen, Menlo, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. MEK served as a scientific advisor and/or clinical study investigator for Almirall, AstraZeneca, Galderma, Incyte Corporation, Janssen, Menlo, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. MEK was an employee and shareholder of Galderma, Incyte Corporation, Janssen, Menlo, Novartis, Ortho Dermatologics, Pfizer, Regeneron, and Sanofi Genzyme.

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References


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Long-Term Safety and Disease Control with Ruxolitinib Cream in Patients With More Severe Atopic Dermatitis: Pooled Results From Two Phase 3 Studies

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Table 1. Patient Demographics and Baseline Clinical Characteristics

Table 2. Summary of Mean Percentage of BSA Affected by AD During the LTS Period Using Different Criteria Among All Patients With Clear or Almost Clear Skin at Baseline

Table 3. Summary of Mean Percentage of BSA Affected by AD During the LTS Period Using Different Criteria Among All Patients With Clear or Almost Clear Skin at Baseline

Table 4. Adverse Events Among Patients With IGA=3, BSA ≥10%, and EASI ≥16 at Baseline

Table 5. Summary of Mean Percentage of BSA Affected by AD During the LTS Period Using Different Criteria Among All Patients With Clear or Almost Clear Skin at Baseline

Table 6. Summary of Mean Percentage of BSA Affected by AD During the LTS Period Using Different Criteria Among All Patients With Clear or Almost Clear Skin at Baseline

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