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

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Safety

- The safety profile of ruxolitinib cream in the LTS period was consistent with the VC period.
- Ruxolitinib cream was well-tolerated, and the frequency and nature of application site reactions were low.

Results

- The proportion of patients with clearance of skin lesions (GA score of 0 or 1) increased during the LTS period with an achieved use of ruxolitinib cream (Figure 3).
- The proportion of patients who achieved an IGA score of 0 or 1 increased after switching from vehicle to either ruxolitinib cream strength in the LTS period (Figure 4).

Conclusions

- The majority of patients who entered the LTS period completed the study.
- Ruxolitinib cream was well tolerated over 52 weeks, with a consistent safety profile throughout the study.
- A high proportion of patients maintained clear or almost clear skin using ruxolitinib cream as needed.
- Mean affected BSA decreased during the LTS period.

Disclosures


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References

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Assessments

- Safety and tolerability assessments included the frequency of reported treatment-emergent adverse events (TEAEs), treatment-related adverse events, and adverse events (AEs) leading to treatment discontinuation.
- Disease clearance was assessed by the proportion of patients who achieved no or minimal skin lesions (GA score of 0 or 1) or almost clear skin and mean percentage of BSA affected by AD at end visit (every 4 weeks) during the LTS period.

Statistical Analyses

- Data were analyzed by descriptive statistics.
- The safety analyses included patients who received at least 1 dose of RUX in the VC and/or LTS period.

Methods

- Safety and tolerability assessments included the frequency of reported treatment-emergent adverse events (TEAEs), treatment-related adverse events, and adverse events (AEs) leading to treatment discontinuation.
- Disease clearance was assessed by the proportion of patients who achieved no or minimal skin lesions (GA score of 0 or 1) or almost clear skin and mean percentage of BSA affected by AD at end visit (every 4 weeks) during the LTS period.
- Data were analyzed by descriptive statistics.
- The safety analyses included patients who received at least 1 dose of RUX in the VC and/or LTS period.

Objective

- To evaluate the long-term safety and disease control of ruxolitinib cream in patients with AD.

Introduction

- Atopic dermatitis (AD) is a highly pruritic inflammatory skin disease.
- The pathogenesis of AD involves Janus kinases (JAKs) acting downstream of proinflammatory cytokines, leading to skin barrier defects.
- Ruxolitinib cream is a topical formulation of ruxolitinib, a selective inhibitor of JAK1 and JAK2.

In two phase 3 randomized studies of identical design (TRuE-AD1 [NCT01780346] and TRuE-AD2 [NCT01780348]), ruxolitinib cream demonstrated superior efficacy and tolerability initially with self-applied action on vehicle and was well-tolerated in patients with AD. (Figures 1 and 2). Figure 1. History and the Key Secondary Endpoint at Week 8 of the Vehicle-Controlled Period is TRuE-AD1 and TRuE-AD2.