Long-Term Safety and Disease Control With Ruxolitinib Cream Among Patients With Atopic Dermatitis Based on Previous Medication History: Pooled Results From Two Phase 3 Studies

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1. Introduction
- Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by itching, dryness, and redness.
- Treatment for AD includes topical corticosteroids (TCS), topical calcineurin inhibitors (TCI), and systemic immunomodulatory agents.
- Current treatment regimens may be insufficient because of limited efficacy, delayed onset of beneficial effects, and potential steroid- or psoriasis-like side effects. This may contribute to poor treatment adherence and persistence in patients with AD.
- In the present study, patients treated with ruxolitinib cream demonstrated sustained disease control and were well tolerated when used as a continuous treatment regimen from the vehicle-controlled period through the long-term safety period.

2. Methods
- **Study Design and Patients**
  - Patients were aged ≥18 years and had ≥10 years of AD history who had not responded to ≥2 prior therapies. All patients had ≥2 prior topical AD therapies, one TCS plus an intermittent TCI treatment, and ≥2 weeks of failure on any previous therapy or ≥2 weeks of treatment-free period.
  - Patients were randomized to either ruxolitinib cream (0.75% or 1.5%) or vehicle for 8 weeks (vehicle-controlled period).
  - Patients were then randomized to either a placebo-controlled period (with either active medication or placebo treatment) and a long-term safety period (44 weeks).
- **Assessments**
  - Disease control was assessed by the proportion of patients who achieved an Investigator’s Global Assessment (IGA) score of 0 or 1 (clear or almost clear skin) and mean percentage of body surface area (BSA) affected by AD at 0 or 6 weeks during the 12-week period.
- **Safety and Tolerability**
  - Safety and tolerability were assessed in terms of new drug-related adverse events (TEAEs), drug-related moderate adverse events, and adverse events (AEs) leading to treatment discontinuation.

3. Results
- **Patients**
  - A total of 1,290 patients (male, n=612; female, n=678) were treated with ruxolitinib cream (0.75%, n=646; 1.5%, n=644) in the vehicle-controlled period and then randomized to either placebo-controlled period (vehicle-controlled [VC] period) or ruxolitinib cream (0.75% or 1.5%) through the long-term safety period (LTS period).
  - Patients were instructed to continue treating their AD lesions (IGA score of 0 or 1 [clear or almost clear skin]) and mean percentage of BSA affected by AD at 0 or 6 weeks during the 12-week period.

4. Conclusions
- **Ruxolitinib cream, used as maintenance therapy, demonstrated effective long-term control, regardless of the type of previous therapy.**

**References**

**Acknowledgments**
- The authors thank the patients, investigators, and enrollment sites whose participation made the study possible.
- Supported by the study sponsor, Galderma, and the authors.

**Disclosures**
- GB serves as a consultant/advisor to AbbVie, Janssen, LEO Pharma, Galderma, and Glenmark; received honoraria from AbbVie, Janssen, LEO Pharma, Galderma, and Glenmark; and has received research grant support from AbbVie, Janssen, Galderma, and Glenmark.
- EF has served as a consultant/advisor to AbbVie, Janssen, LEO Pharma, Galderma, and Glenmark; received research grant support from AbbVie, Janssen, Galderma, and Glenmark; and has received honoraria from AbbVie, Janssen, Galderma, and Glenmark.

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**Conflict of interest**
- GB served as a consultant/advisor/lecturer to Almirall, AbbVie, Asana, Asana Skin Science, BC: BioCure, BMS, Galderma, Coram, Dermagraft, Dermira, Enzon, Exilex, Galderma, Incyte Corporation, Janssen, Kala Pharmaceuticals, LEO Pharma, Menlo, Momenta, Novartis, Pfizer, Regeneron, Rapt, Sanofi, Santen, Sun Pharma, and UCB Pharma. GB received research support from Asana, BC: BioCure, BMS, Galderma, Coram, Dermagraft, Dermira, Enzon, Exilex, Galderma, Incyte Corporation, Janssen, Kala Pharmaceuticals, LEO Pharma, Menlo, Momenta, Novartis, Pfizer, Regeneron, Rapt, Sanofi, Santen, Sun Pharma, and UCB Pharma. CJS served as a consultant/advisor to Almirall, AbbVie, Asana, Asana Skin Science, BC: BioCure, BMS, Galderma, Coram, Dermagraft, Dermira, Enzon, Exilex, Galderma, Incyte Corporation, Janssen, Kala Pharmaceuticals, LEO Pharma, Menlo, Momenta, Novartis, Pfizer, Regeneron, Rapt, Sanofi, Santen, Sun Pharma, and UCB Pharma. SC served as a consultant/advisor to Almirall, AbbVie, Asana, Asana Skin Science, BC: BioCure, BMS, Galderma, Coram, Dermagraft, Dermira, Enzon, Exilex, Galderma, Incyte Corporation, Janssen, Kala Pharmaceuticals, LEO Pharma, Menlo, Momenta, Novartis, Pfizer, Regeneron, Rapt, Sanofi, Santen, Sun Pharma, and UCB Pharma. KCL served as a consultant/advisor to Almirall, AbbVie, Asana, Asana Skin Science, BC: BioCure, BMS, Galderma, Coram, Dermagraft, Dermira, Enzon, Exilex, Galderma, Incyte Corporation, Janssen, Kala Pharmaceuticals, LEO Pharma, Menlo, Momenta, Novartis, Pfizer, Regeneron, Rapt, Sanofi, Santen, Sun Pharma, and UCB Pharma.