Presented at the
Dermatology Nurses’ Association 48th Annual Convention
Las Vegas, NV, USA
February 23–25, 2022

Efficacy and Safety of Ruxolitinib Cream for the Treatment of Vitiligo: 24-Week Results From 2 Randomized, Double-Blind Phase 3 Studies

David Rosmarin, MD,1 Amit G. Pandya, MD,2,3 Pearl Grimes, MD,4 John E. Harris, MD, PhD,5 Seemal R. Desai, MD, MD,6,7 Mark Lebwohl, MD,2
Mireille Ruer-Mulard, MD,2 Thierry Passeron, MD, PhD,9,10 Julien Seneschal, MD, PhD,11 Albert Wolkerstorfer, MD, PhD,12 Deanna Kornacki, PhD,13
Kang Sun, PhD,14 Kathleen Butler, MD,12 Khaled Ezzeddine, MD, PhD15

Introduction
- Vitiligo is an autoimmune disease that targets melanocytes, causing skin depigmentation.
- Disease characteristics are largely regulated by interferon-α (IFN-α) signaling pathways.
- A common form of vitiligo, a skin-lightening blister, is under investigation for the treatment of vitiligo.

Objective
- To evaluate the efficacy and safety of ruxolitinib cream in adolescents and adults with vitiligo involving ≥20% of body surface area (BSA) over 24 weeks, randomized, double-blind phase 3 studies (TRU-V1 [NCT02451984] and TRU-V2 [NCT02457074]) of vehicle design.

Methods
Patients and Study Design
- Patients aged 12 years or older diagnosed with nonsegmental vitiligo with depigmented lesions involving ≥20% of BSA were included in the 2 randomization phases (TRU-V1 and TRU-V2). Patients were further stratified by lesion size (≤50% or >50% BSA) and lesion location (face, nonface).

Results
Assessments
- The primary endpoint was the proportion of patients achieving improvement from baseline in the Vitiligo Area Scoring Index (VASI) at Week 24.

Efficacy
- At Week 24, the primary endpoint of F-VASI<50 was achieved by a significantly greater proportion of patients applying ruxolitinib cream on vehicle (192/229 [84.5%]) vs vehicle (109/115 [94.6%]) at baseline (P<0.001).
- At Week 24, the proportions of patients achieving a VASI response (Figure 4) and least squares mean percentage change from baseline in VASI (Figure 5) were significantly greater with application of ruxolitinib cream on vehicle (P<0.01).

Figure 5. Representative Clinical Images of Patients Who Applied Ruxolitinib Cream During 24 Weeks of Double-Blind Treatment

Figure 4. F-VASI Responses at Week 24

Conclusions
- Ruxolitinib cream demonstrated clinical and functional superiority to vehicle for the primary and all key secondary endpoints in the two phase 3, randomized, double-blind studies, confirming phase 2 findings.
- Adolescent and adult patients with nonsegmental vitiligo achieved substantial facial and total body repigmentation at 24 weeks.
- Ruxolitinib cream was well tolerated, and no serious TEAEs were considered related to treatment.

Disclosures
- All authors have provided Disclosures related to this article. The corresponding author is responsible for confirming these disclosures.

References