Vitiligo Biomarker CXCL10 Correlates With Clinical Response in the TRuE-V Mechanism of Action Study

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Introduction

- Ruxolitinib cream is a topical formulation of the selective Janus kinase (JAK) 1/2JAK inhibitor ruxolitinib and is the first and only regenerative treatment approved in the United States.
- The TRuE-V mechanism of action (MOA) study (NCT04963835) was designed to evaluate ruxolitinib cream MOA in adult patients with vitiligo by assessing treatment-associated changes in biomarkers.

Objective

- Using data from the TRuE-V MOA study, we evaluated changes from baseline in local and systemic immune biomarkers at Weeks 4, 12, 24, and 40, including serum C-X-C motif chemokine ligand 10 (CXCL10) protein levels, which are known to correlate with vitiligo disease severity in patients with vitiligo.

Methods

- Adults aged ≥18 y with nonsegmental vitiligo with depigmented areas covering ≥50% total body surface area (BSA), including nonfacial areas, and who met the eligibility criteria were randomized 2:1 to apply 1.5% ruxolitinib cream twice daily (BID) or vehicle BID for 24 weeks.
- Change in local and systemic immune biomarkers at all time points was compared with baseline.

Results

- A reduction (ie, improvement) in facial Vitiligo Area Scoring Index (F-VASI) with ruxolitinib cream was observed as early as Week 12 (Figure 2A), whereas a decrease in total Vitiligo Area Scoring Index (T-VASI) was significant at Week 24 (Figure 2B).

- Changes in T-VASI scores significantly correlated with a change in serum CXCL10 levels (Table 2).
- Changes in skin CXCL10 gene expression correlated significantly with F-VASI and T-VASI scores.

Conclusions

- The TRuE-V MOA study was designed to evaluate biomarker responses in skin and serum of patients with vitiligo who applied 1.5% ruxolitinib cream BID to nonfacial areas, and
- Serum CXCL10 levels decreased significantly in patients who applied ruxolitinib cream, which correlated with T-VASI improvement.
- Skin CXCL10 levels were also significantly reduced after 12 weeks of treatment with ruxolitinib cream.
- The correlation of clinical scores (F-VASI and T-VASI) to CXCL10 was stronger for skin than for serum.
- With the exception of CXCL10, most systemic protein analytes did not correlate or only weakly correlated with F-VASI and T-VASI scores.

Disclosures

- All authors are employees and shareholders of Incyte Corporation.

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References