PIGMENTATION

EFFICACY AND SAFETY OF RUXOLITINIB CREAM FOR THE TREATMENT OF VITILIGO: RESULTS OF A 24-WEEK RANDOMIZED, DOUBLE-BLIND, DOSE-RANGING, VEHICLE-CONTROLLED STUDY

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Introduction: Vitiligo is an autoimmune disease of the skin characterized by patches of depigmentation. Preclinical and translational studies suggest interferon gamma (IFN-γ) drives disease pathogenesis by signaling through Janus kinases (JAKs) 1 and 2. Previously, 20-week, open-label application of 1.5% ruxolitinib cream, a selective JAK1/JAK2 inhibitor, significantly improved facial vitiligo area severity index (F-VASI) scores from baseline.

Objective: To report efficacy, safety, and dose response of ruxolitinib cream in patients with vitiligo after 24 weeks of treatment

Materials and Methods: This 24-week, double-blind, vehicle-controlled component of a 3-part, 104-week, phase 2 study (NCT03099304) enrolled patients with vitiligo aged 18–75 years, with depigmented areas including ≥0.5% of body surface area (BSA) on the face and ≥3% of BSA on nonfacial areas. Eligible patients were equally randomized to receive ruxolitinib cream 1.5% twice daily, 1.5% once daily (QD), 0.5% QD, 0.15% QD, or vehicle for 24 weeks. The primary endpoint was the proportion of patients treated with ruxolitinib cream who achieved ≥50% improvement from baseline in F-VASI score (F VASI50) at

Week 24 versus vehicle. Secondary endpoints included the proportion of patients who achieved a facial physician global vitiligo assessment (F-PhGVA) of clear or almost clear at Week 24 and treatment safety. Exploratory endpoints included percentage change in chemokine ligand (CXCL) 10, CXCL9, and IFN-γ.

Results: 157 patients were enrolled (mean [SD] age, 48.3 [12.9] years); 46.5% of patients were male, and 84.1% were white. Baseline mean percentage (SD) of total- and facial-BSA involvement was 22.05% (18.38%) and 1.48% (0.86%) of total body, respectively. Baseline mean (SD) total-VASI was 17.95 (15.46), and F-VASI was 1.26 (0.82). Data analysis is currently ongoing.

Conclusions: Comparison of ruxolitinib cream to vehicle for improvement in facial repigmentation (measured by F-VASI50), the primary endpoint of the study, will be presented.