Efficacy of Ritlecitinib in Patients with Alopecia Areata by Extent of Hair Loss at Baseline: Post Hoc Analysis of the Phase 3 Long-Term ALLEGRO-LT Study

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BACKGROUND

Alopecia areata (AA) is an autoimmune disease with an underlying immune-inflammatory pathogenesis characterized by non-scarring hair loss occurring in severity from small patches to complete loss of scalp, face, and/or beard hair. Ritlecitinib, an oral, JAK3/TEC family kinase inhibitor, demonstrated efficacy in placebo-controlled patients aged ≥12 years with ≥25% scalp hair loss at baseline in the ALLEGRO phase 3/4 study. ALLEGRO-LT is an ongoing phase 4 open-label study investigating the long-term safety and efficacy of ritlecitinib in patients aged ≥12 years with AA.

OBJECTIVE

This analysis included only patients with baseline SALT score ≥95-100 who were enrolled in the ALLEGRO-LT study and had at least 15 months of follow-up since completion of Phase 3/4. The primary objective of this post hoc analysis was to evaluate the efficacy of ritlecitinib through Month 15 for patients with AA by extent of scalp hair loss baseline.

METHODS

Study design

- ALLEGRO-2: an open-label, phase 1, open-label, multicenter, long-term study of ritlecitinib
- This analysis included only new participants

RESULTS

Patient baseline and disease characteristics

- Almost 44% of patients with baseline SALT score of 90-100 (≥90% scalp hair loss) achieved SALT score ≤10 (reflecting at least 90% scalp hair coverage) at Month 15 (Figure 1).
- Of patients with baseline SALT score of ≥90-100%, 80% reached at least 80% scalp hair coverage at baseline in the Phase 3 study (Data Supplement) (Figure 1).
- More than 30% of those with extensive hair loss (SALT score ≥75%) achieved at least 80% scalp hair coverage at Month 15 (Figure 1).
- The safety profile was consistent with that of the primary ALLEGRO phase 2/3 study.

Conclusions

Ritlecitinib was efficacious in patients with AA with ≥25% scalp hair loss at baseline, including those with extensive hair loss.

After 15 months of treatment with ritlecitinib, patients with >50% scalp hair loss at baseline achieved almost complete scalp hair regrowth (median SALT score reflecting 97%-98% scalp hair coverage).

For patients with very extensive scalp hair loss at baseline (SALT score ≥90%), over one-third achieved clinically meaningful SALT response at Month 15.

The safety profile was consistent with that of the primary ALLEGRO phase 2/3 study.