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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Introduction/Background: The oral JAK3/TEC family kinase inhibitor ritlecitinib demonstrated efficacy and safety in patients aged ≥12 years with alopecia areata (AA) with ≥50% hair loss in the ALLEGRO phase 2b/3 study. ALLEGRO-LT is an ongoing phase 3 open-label study investigating the long-term safety and efficacy of ritlecitinib in patients aged ≥12 years with AA with ≥25% hair loss.

Objectives: This post hoc analysis of ALLEGRO-LT evaluated the efficacy of ritlecitinib through Month 15 in patients with AA by the extent of scalp hair loss at baseline.

Methods: The open-label, multicenter, long-term ALLEGRO-LT study (NCT04006457) enrolled patients into two arms: (1) roll-over patients who had received study intervention in
either the ALLEGRO phase 2a study (NCT02974868) or phase 2b/3 study (NCT03732807), and (2) de novo patients who were aged ≥12 years with AA with ≥25% scalp hair loss at baseline and had not participated in either study. This post hoc analysis only included patients in the de novo cohort. All patients received an initial 4-week loading dose of ritlecitinib 200 mg once-daily (QD) followed by ritlecitinib 50 mg QD. Outcomes included median Severity of Alopecia Tool (SALT) score over time and the proportions of patients with SALT score ≤20 (≤20% scalp hair loss) and ≤10 at Month 15. Patients were stratified by extent of scalp hair loss at baseline (measured by SALT score) as follows: 25 to <50, 50 to <75, 75 to <90, 90 to <95, and 95 to 100. Analyses were based on observed data.

Results: 1052 patients were enrolled in ALLEGRO-LT, of whom 447 patients received ritlecitinib in the de novo arm. Of the 447 de novo patients, 26.6% (n=119), 16.8% (n=75), 9.2% (n=41), 2.9% (n=13), and 44.5% (n=199) had baseline SALT scores 25 to <50, 50 to <75, 75 to <90, 90 to <95, and 95 to 100, respectively. Patients with baseline SALT score ≥95 generally had longer mean duration of AA episode (3.47 years) and disease duration (10.86 years) than patients with SALT score <50 at baseline (2.53 and 8.79 years, respectively). A greater proportion of patients with baseline SALT score <50 had active shedding at baseline (49.6%) vs patients with baseline SALT score ≥95 (11.6%). Across all groups, median SALT scores improved (decreased) from baseline through Month 15 (Figure 1). At Month 15, median SALT scores were 1.0, 1.2, 1.4, 2.4, and 30.9 for the 25 to <50, 50 to <75, 75 to <90, 90 to <95, and 95 to 100 groups, respectively. At Month 15, 93.0% (93/100), 87.7% (57/65), 88.2% (30/34), 83.3% (10/12), and 43.9% (68/155) of patients, respectively, achieved SALT scores ≤20, and 81.0% (81/100), 76.9% (50/65), 73.5% (25/34), 75.0% (9/12), and 33.5% (52/155) of patients, respectively, achieved SALT score ≤10.

Conclusions: After 15 months of ritlecitinib treatment, patients with less than 95% hair loss at baseline reached median SALT scores of <2.4, reflecting almost complete scalp hair
regrowth. More refractory disease was seen in the subset of patients with extensive (≥95%) hair loss at baseline; however, over one third of these patients achieved clinically meaningful SALT response (SALT ≤20 and SALT ≤10) at Month 15. Overall, ritlecitinib was efficacious in patients with AA with ≥25% hair loss including those with extensive hair loss at baseline.

**Keywords:** ritlecitinib, alopecia areata, SALT score, hair loss, JAK inhibitor
**Figure 1.** Median SALT scores through Month 15 by baseline SALT score

IQR, interquartile range; SALT, Severity of Alopecia Tool.

Patients in ALLEGRO-LT had SALT score ≥25 at baseline.

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