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Long-term efficacy of ritlecitinib up to Month 24 from the ALLEGRO phase 2b/3 and long-term phase 3 clinical studies in alopecia areata

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Introduction & Objectives: Ritlecitinib, an oral JAK3/TEC family kinase inhibitor, demonstrated efficacy and safety up to 48 weeks in patients aged ≥12 years with alopecia areata (AA) in the ALLEGRO phase 2b/3 study (NCT03732807). ALLEGRO-LT (NCT04006457) is an ongoing, phase 3, open-label study investigating the long-term safety and efficacy of ritlecitinib in AA. Here we report updated interim efficacy results of ritlecitinib up to Month 24 from the ALLEGRO phase 2b/3 study and ALLEGRO-LT study.

Materials & Methods: Patients aged ≥12 years with AA and ≥50% scalp hair loss who rolled over to ALLEGRO-LT after completing ALLEGRO-2b/3 were included. Data are reported for patients who received daily ritlecitinib 50-mg with an initial 4-week 200-mg daily loading dose in ALLEGRO-2b/3 and daily ritlecitinib 50-mg in ALLEGRO-LT ("200/50-mg" group) as well as for patients who received daily ritlecitinib 50-mg in ALLEGRO-2b/3 and ALLEGRO-LT ("50-mg" group). Outcomes include the proportions of patients with response (based on Severity of Alopecia Tool [SALT] score ≤20, SALT score ≤10, and Patients' Global Impression of Change [PGI-C] score of "moderately improved" or "greatly improved") through Month 24, and the proportions of patients who sustained SALT ≤20 response from Month 12 through Month 24. Observed and imputed (modified last observation carried forward [mLOCF]) data, to account for missing data values, are reported at the time of data cutoff (December 9, 2022).

Results: The 200/50-mg and 50-mg groups included 194 and 191 patients, respectively, of whom 127 (65.5%) and 111 (58.1%) were ongoing at the time of data cutoff. At Month 12, 45.9% and 45.1% (observed) and 41.8% and 40.3% (mLOCF) of patients in the 200/50-mg and 50-mg groups, respectively, had SALT scores ≤20; the proportions increased to 63.1% and 60.8% (observed) and 50.8% and 46.1% (mLOCF), respectively, at Month 24. SALT score ≤10 response rates increased from 39.4% to 51.1% (observed) and from 35.6% to 40.9% (mLOCF) between Months 12 and 24 for the 200/50-mg group and from 34.2% to 50.8% (observed) and from 30.9% to 37.7% (mLOCF) for the 50-mg group. Of patients who achieved SALT score ≤20 response at Month 12 with ritlecitinib 200/50-mg and 50-mg, 92.8% and 79.7% (observed) sustained this response through Month 24, respectively. PGI-C response rates were maintained from Month 12 (200/50-mg: 69.4% [observed], 65.3% [mLOCF]; 50-mg: 61.6% [observed], 57.7% [mLOCF]) to Month 24 (200/50-mg: 76.4% [observed], 65.4% [mLOCF]; 50-mg: 70.0% [observed], 56.6% [mLOCF]).

Conclusion: Ritlecitinib 50-mg (with or without a 200-mg loading dose) demonstrated clinically meaningful and sustained clinician- and patient-reported efficacy through Month 24, which supports its long-term use in patients aged ≥12 years with severe AA.