Scalp, eyebrow, and eyelash hair regrowth with continued ritlecitinib treatment among patients with alopecia areata without target efficacy response at Week 24: post hoc analysis of the ALLEGRO phase 2b/3 study

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BACKGROUND

- Alopecia areata (AA) is an autoimmune disease that has an underlying immuno-inflammatory pathogenesis and is characterized by nonscarring hair loss ranging from small patches to complete scalp, face, and/or body hair loss[1]
- Ritlecitinib, an oral JAK3/TEC family kinase inhibitor, demonstrated efficacy and safety in patients aged ≥12 years with AA and ≥50% scalp hair loss in the ALLEGRO phase 2b/3 trial (NCT03732807)[2]
  - Significant improvements in the proportion of patients with Severity of Alopecia Tool (SALT) score ≤20 (≤20% of scalp without hair) and SALT score ≤10 (≤10% of scalp without hair) at Week 24 were observed in the 50 mg and 30 mg ritlecitinib treatment groups (± 200 mg loading dose) vs placebo

OBJECTIVE

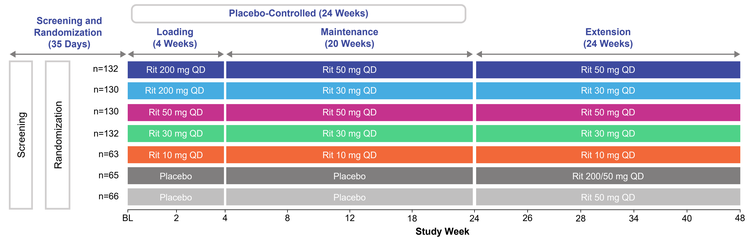
- To assess response to ritlecitinib between Weeks 28–48 among subpopulations of patients with AA who did not achieve target efficacy response criteria at Week 24

METHODS

Study design

- The ALLEGRO phase 2b/3 trial was a randomized, double-blind, placebo-controlled, combined dose-ranging and pivotal study (**Figure 1**)

Figure 1. ALLEGRO-2b/3 Study Design



BL, baseline; QD, once daily; Rit, ritlecitinib. No other therapies for AA were allowed during the study.

Study population

- Inclusion criteria:
  - Age ≥12 years
  - AA with ≥50% scalp hair loss, including patients with alopecia totalis (AT) and alopecia universalis (AU)
  - Current AA episode duration of 6 months to 10 years
- Patients with other causes of alopecia or previous use of any JAK inhibitor were excluded
- This post hoc analysis included patients who received ritlecitinib 200/50, 200/30, 50, or 30 mg and did not have a clinical response at Week 24

Outcomes

- This post hoc analysis assessed the proportions of ritlecitinib-treated patients who achieved clinical response between Weeks 28 and 48, among those who did not meet clinical response criteria at Week 24

Separate criteria for non-response at Week 24 were determined for each cohort:

- SALT score >20, or
- SALT score >10, or
- No improvement in eyebrow assessment (EBA) score (abnormal or <2-grade improvement from baseline) in patients with abnormal EBA scores at baseline, or
- No improvement in eyelash assessment (ELA) score (abnormal or <2-grade improvement from baseline) in patients with abnormal ELA scores at baseline

Clinical response at each timepoint was defined separately for each endpoint:

- SALT score ≤20, or
- SALT score ≤10, or
- EBA score (normal or ≥2-grade improvement from baseline) in patients with abnormal EBA scores at baseline, or
- ELA score (normal or ≥2-grade improvement from baseline) in patients with abnormal ELA scores at baseline

Statistical Analysis

- Descriptive analyses were used to summarize the proportion of patients who achieved response at Week 28, 34, 40, or 48, among those who did not meet clinical response criteria at Week 24
- 95% CIs were calculated based on normal approximation
- Post hoc analyses were based on observed data; patients with missing data at each timepoint were excluded from that timepoint

RESULTS

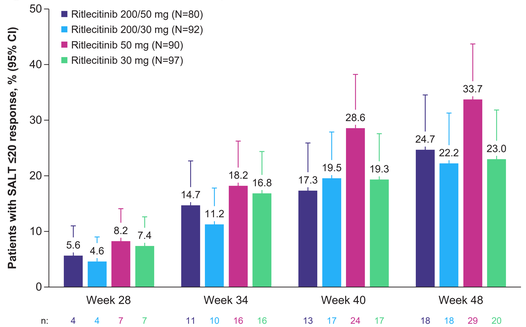
Table 1. Baseline characteristics of SALT score ≤20 non-responders at Week 24

	Ritlecitinib QD			
	200/50 mg (n=80)	200/30 mg (n=92)	50 mg (n=90)	30 mg (n=97)
Age				
Mean (SD), years	34.9 (15.3)	34.3 (13.9)	31.9 (12.8)	32.8 (14.7)
12-17 years, n (%)	13 (16.3)	14 (15.2)	10 (11.1)	15 (15.5)
≥18 years, n (%)	67 (83.8)	78 (84.8)	80 (88.9)	82 (84.5)
Female, n (%)	44 (55.0)	57 (62.0)	43 (47.8)	55 (56.7)
White, n (%)	56 (70.0)	65 (70.7)	54 (60.0)	63 (64.9)
Patients with AT/AU*, n (%)	45 (56.3)	49 (53.3)	49 (54.4)	48 (49.5)
Baseline SALT score, mean (SD)				
All patients	93.3 (13.5)	92.9 (12.4)	93.6 (11.9)	92.1 (13.0)
Non-AT/AU	84.7 (17.0)	84.9 (14.4)	86.0 (14.4)	84.3 (14.7)
Duration of disease since AA diagnosis, mean (SD), years	9.2 (10.7)	11.6 (12.2)	9.2 (8.6)	8.5 (9.1)
Duration of current AA episode, mean (SD), years	3.7 (3.0)	3.5 (2.8)	3.5 (2.8)	3.6 (2.8)

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; QD, once daily; SALT, Severity of Alopecia Tool; yrs, years.
*Patients in the AT/AU category had a SALT score of 100 at baseline (regardless of the category in the AA history case report form).

- Of patients in the ritlecitinib groups who did not meet SALT ≤20 response at Week 24, 4.6–8.2% had a response at Week 28, with rates increasing to 22.2–33.7% at Week 48 (**Figure 2**)

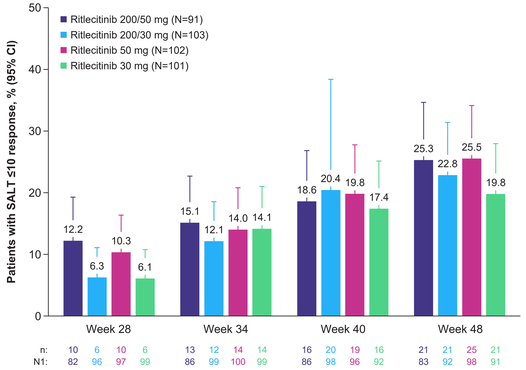
Figure 2. SALT score ≤20 response over time after Week 24



SALT, Severity of Alopecia Tool.
n/N1 indicated for each timepoint; n: number of patients with response. N1: number of patients with SALT score data at each timepoint.

- Of patients in the ritlecitinib groups who did not meet SALT ≤10 response at Week 24, 6.1–12.2% had a response at Week 28, with rates increasing to 19.8–25.5% at Week 48 (**Figure 3**)

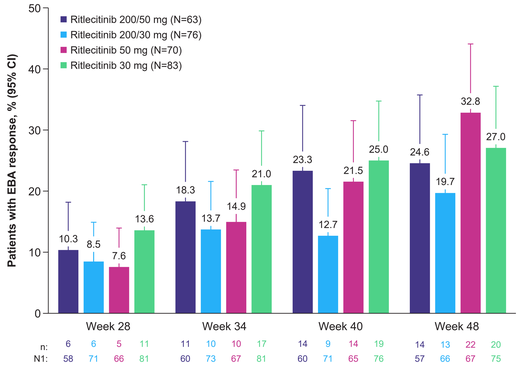
Figure 3. SALT score ≤10 response over time after Week 24



SALT, Severity of Alopecia Tool.
n/N1 indicated for each timepoint; n: number of patients with response. N1: number of patients with SALT score data at each timepoint.

- Of EBA non-responders at Week 24, 7.6–13.6% achieved response at Week 28 and 19.7–32.8% at Week 48 (**Figures 4**)

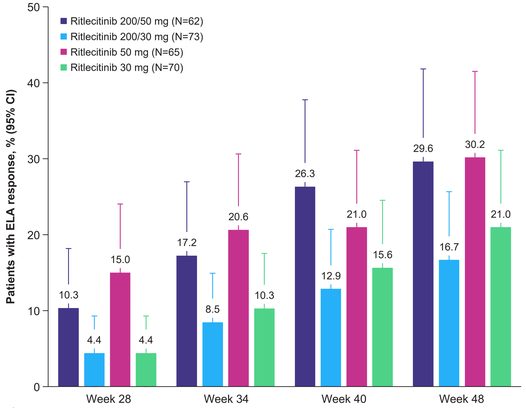
Figure 4. EBA responses over time after Week 24*



EBA, eyebrow assessment.
n/N1 indicated for each timepoint; n: number of patients with response. N1: number of patients with EBA data at each timepoint.
*EBA response defined as a normal score (3) or ≥2-grade improvement from baseline in the EBA scale in patients without normal EBA scores at baseline.

- Of ELA non-responders at Week 24, 4.4–15.0% achieved response at Week 28 and 16.7–30.2% at Week 48 (**Figure 5**)

Figure 5. ELA responses over time after Week 24*



ELA, eyelash assessment.
n/N1 indicated for each timepoint; n: number of patients with response. N1: number of patients with ELA data at each timepoint.
*ELA response defined as a normal score (3) or ≥2-grade improvement from baseline in the ELA scale in patients without normal ELA scores at baseline.

Safety

- Ritlecitinib was well tolerated through Week 48 in patients with AA
- Among patients who did not meet clinical response at Week 24, the most common AEs (≥5% of patients in any treatment group) were nasopharyngitis, nausea, headache, and folliculitis

CONCLUSIONS

- Target hair regrowth responses may be achieved at later time points with continued ritlecitinib treatment in patients with AA who do not initially achieve target response at Week 24

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REFERENCES

1. Islam N, et al. *Autoimmun Rev.* 2015;14:81-89.
2. King B, et al. *Lancet* 2023;401:1518-1529.

DISCLOSURES

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