Efficacy of Ritlecitinib in Patients With Alopecia Areata by Extent of Hair Loss: Results From the Phase 2b/3 and Phase 3 ALLEGRO Clinical Trials

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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 loss of scalp, face, and/or body hair[1]
- Ritlecitinib, an oral, dual JAK3/TEC family kinase inhibitor, demonstrated efficacy and safety in patients ≥12 years old with AA and ≥50% scalp hair loss in the phase 2b/3 ALLEGRO study[2]
  - Ritlecitinib 50 mg once daily (QD) is approved for the treatment of severe AA in adults and adolescents ≥12 years of age
- The Alopecia Areata Investigators Global Assessment™ (AA-IGA)™ defines the severity of AA by the extent of scalp hair loss,[3] where:
  - 50-94% scalp hair loss = "severe AA"
  - 95-100% scalp hair loss = "very severe AA"
  - Patients with more extensive hair loss as baseline may be less likely to have a robust response to treatment[4-7]

OBJECTIVE

- This post hoc, pooled analysis of the ALLEGRO-2b/3 and phase 3 ALLEGRO-LT studies evaluated the efficacy of ritlecitinib in patients with AA by extent of baseline scalp hair loss through Month 24

METHODS

Study design and patient population

- ALLEGRO-2b/3 (NCT03732807) was a pivotal, phase 2b/3, double-blind, dose-ranging, placebo-controlled trial in patients aged ≥12 years with AA and ≥50% scalp hair loss[2]
- ALLEGRO-LT (NCT04006457) is an ongoing, phase 3, open-label study in patients who received study intervention in the ALLEGRO phase 2a study or ALLEGRO-2b/3 and in de novo patients who had not received treatment in any other ALLEGRO study
- This post hoc analysis includes pooled data from patients who received ritlecitinib 50 mg QD in ALLEGRO-2b/3 and subsequently rolled over to ALLEGRO-LT, where they continued to receive ritlecitinib 50 mg QD (**Figure 1**)

Figure 1. Study design and patient population

	ALLEGRO phase 2b/3				ALLEGRO-LT	
	Loading (4 weeks)	Maintenance (20 weeks)	Extension (24 weeks)		Long-term study (60 months)	
Group A (n=131)	200 mg	50 mg	50 mg		50 mg	
Group B (n=129)	200 mg	30 mg	30 mg		50 mg	
Group C (n=130)	50 mg	50 mg	50 mg		50 mg	
Group D (n=132)	30 mg	30 mg	30 mg		50 mg	
Group E (n=61)	10 mg	10 mg	10 mg		50 mg	
Group F (n=63)	Placebo	Placebo	200 mg	50 mg	50 mg	
Group G* (n=61)	Placebo	Placebo	50 mg		50 mg	
***De novo* group** (n=447)					200 mg	50 mg

→ **Combined ritlecitinib 50 mg group** (N=191)

*Data while on placebo were not included in this analysis; data from patients in Groub G were rebaselined from the start of treatment with ritlecitinib.

Outcomes

- Outcomes included the proportion of patients with response through Month 24 based on:
  - Severity of Alopecia Tool (SALT) score ≤20 (≤20% scalp hair loss)
  - A ≥2-grade improvement from baseline or a normal score (score of 3) in the Eyebrow Assessment (EBA) and Eyelash Assessment (ELA) among patients with an abnormal score at baseline

Statistical analysis

- Data are presented as observed and imputed (last observation carried forward [LOCF]) to account for missing data values
  - LOCF was applied to each visit for all participants with missing data, except for those who had not yet reached that analysis visit
- Data are reported to the cutoff date of December 9, 2022

RESULTS

- 191 patients who received ritlecitinib 50 mg QD were included: 66 (34.6%) were categorized as severe AA and 125 (65.4%) were categorized as very severe AA at baseline (**Table 1**)
- Patients categorized as very severe AA had longer median duration of current AA episode and a higher percentage of patients categorized as very severe AA had eyebrow and eyelash involvement at baseline than patients categorized as severe AA (**Table 1**)

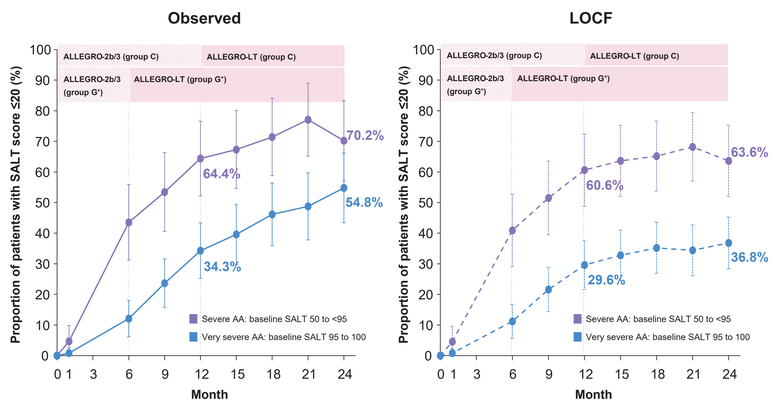
Table 1. Baseline characteristics of patients receiving ritlecitinib 50 mg, by baseline extent of hair loss

	Severe AA: Baseline SALT 50 to <95 (N=66)	Very Severe AA: Baseline SALT 95 to 100 (N=125)
Age		
Median (range), years	32.5 (12-68)	29.0 (12-70)
12-17 years, n (%)	10 (15.2)	17 (13.6)
≥18 years, n (%)	56 (84.8)	108 (86.4)
Female, n (%)	48 (72.7)	59 (47.2)
White, n (%)	41 (62.1)	82 (65.6)
SALT score		
Median (range)	74.0 (51.0-94.2)	100.0 (95.0-100.0)
Mean (SD)	74.5 (12.9)	99.5 (1.1)
Duration of current AA episode, median (range), years	1.6 (0.2-9.2)	2.7 (0.0-10.0)
Duration of AA since diagnosis, median (range), years	8.0 (0.5-53.3)	6.3 (0.3-58.2)
Abnormal EBA (0-2), n (%)	36 (54.5)	118 (94.4)
Abnormal ELA (0-2), n (%)	31 (47.0)	108 (86.4)

AA, alopecia areata; EBA, Eyebrow Assessment; ELA, eyelash assessment; SALT, Severity of Alopecia Tool.

- At Month 12, 64.4% and 34.3% (observed) and 60.6% and 29.6% (LOCF) of patients categorized as severe AA and very severe AA, respectively, achieved SALT ≤20 (**Figure 2**)
  - At Month 24, these proportions increased to 70.2% and 54.8% (observed) and 63.6% and 36.8% (LOCF), respectively

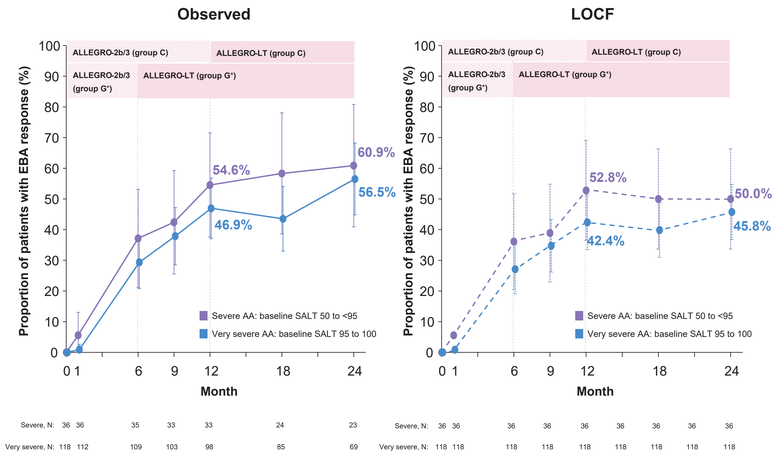
Figure 2. Proportion of patients with SALT ≤20 response at each visit, in participants who received ritlecitinib 50 mg



LOCF, last observation carried forward; SALT, Severity of Alopecia Tool.
*Data while on placebo were not included in this analysis; data from patients in Groub G were rebaselined from the start of treatment with ritlecitinib.

- EBA response was achieved in 54.6% and 46.9% (observed) and 52.8% and 42.4% (LOCF) of patients categorized as severe AA and very severe AA, respectively, at Month 12 (**Figure 3**)
  - At Month 24, the proportions were 60.9% and 56.5% (observed) and 50.0% and 45.8% (LOCF)

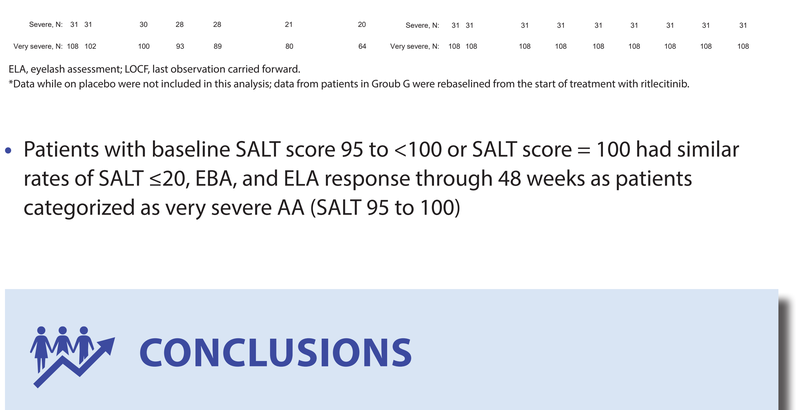
Figure 3. Proportion of patients with EBA response at each visit, among patients with abnormal EBA score at baseline who received ritlecitinib 50 mg



EBA, eyebrow assessment; LOCF, last observation carried forward.
*Data while on placebo were not included in this analysis; data from patients in Groub G were rebaselined from the start of treatment with ritlecitinib.

- ELA response was achieved in 60.7% and 40.5% (observed) and 61.3% and 38.0% (LOCF) of patients categorized as severe AA and very severe AA, respectively, at Month 12 (**Figure 4**)
  - At Month 24, the proportions were 70.0% and 45.3% (observed) and 61.3% and 38.0% (LOCF)

Figure 4. Proportion of patients with ELA response at each visit, among patients with abnormal ELA score at baseline who received ritlecitinib 50 mg



ELA, eyelash assessment; LOCF, last observation carried forward.
*Data while on placebo were not included in this analysis; data from patients in Groub G were rebaselined from the start of treatment with ritlecitinib.

- Patients with baseline SALT score 95 to <100 or SALT score = 100 had similar rates of SALT ≤20, EBA, and ELA response through 48 weeks as patients categorized as very severe AA (SALT 95 to 100)

CONCLUSIONS

- Patients with AA categorized as severe or very severe had scalp, eyebrow, and eyelash hair regrowth over 24 months with ritlecitinib treatment
- Treating AA with ritlecitinib before hair loss becomes more extensive may elicit better response to treatment.

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