

# 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<sup>1</sup>
- 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<sup>2</sup>
  - 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,<sup>3</sup> 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<sup>4,5</sup>

## 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<sup>2</sup>
- 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
<i>De novo group (n=447)</i>				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 Group 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)

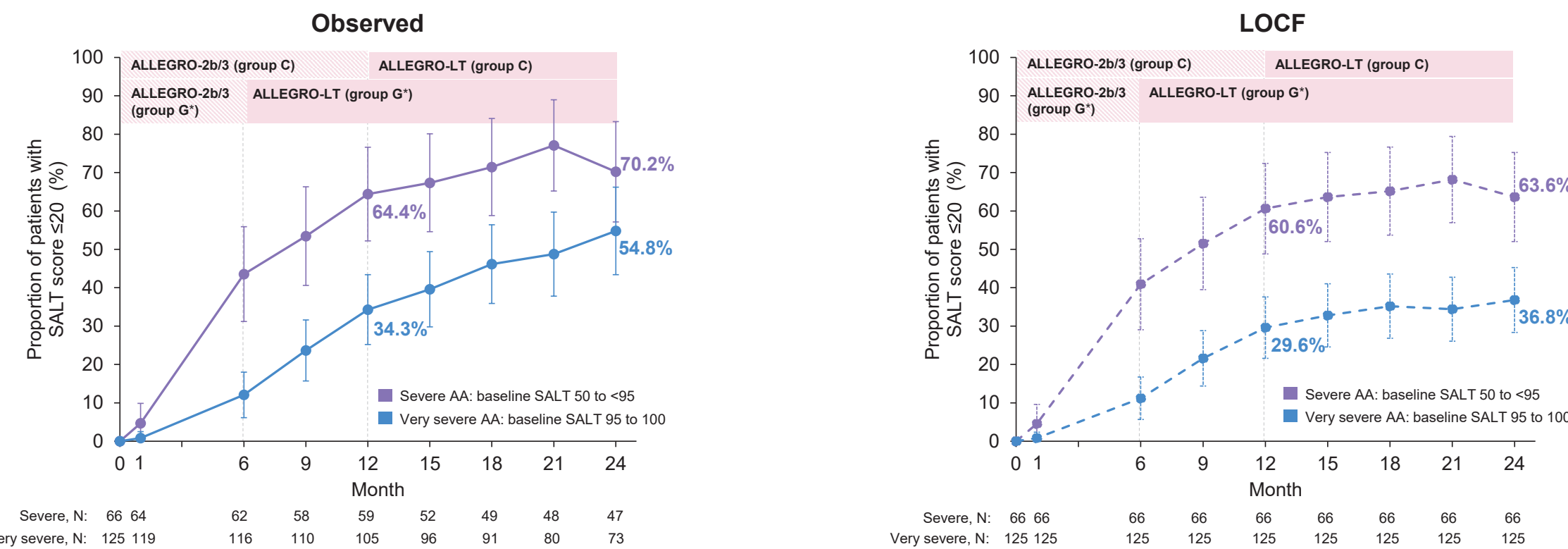
Table 1. Baseline characteristics of patients receiving ritlecitinib 50 mg, by baseline extent of hair loss

	Severe AA: Baseline SALT 50 to <95 (N=66)	Very Severe AA: Baseline SALT 95 to 100 (N=125)
<b>Age</b>		
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)
<b>Female, n (%)</b>	48 (72.7)	59 (47.2)
<b>White, n (%)</b>	41 (62.1)	82 (65.6)
<b>SALT score</b>		
Median (range)	74.0 (51.0-94.2)	100.0 (95.0-100.0)
Mean (SD)	74.5 (12.9)	99.5 (1.1)
<b>Duration of current AA episode, median (range), years</b>	1.6 (0.2-9.2)	2.7 (0.0-10.0)
<b>Duration of AA since diagnosis, median (range), years</b>	8.0 (0.5-53.3)	6.3 (0.3-58.2)
<b>Abnormal EBA (0-2), n (%)</b>	36 (54.5)	118 (94.4)
<b>Abnormal ELA (0-2), n (%)</b>	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

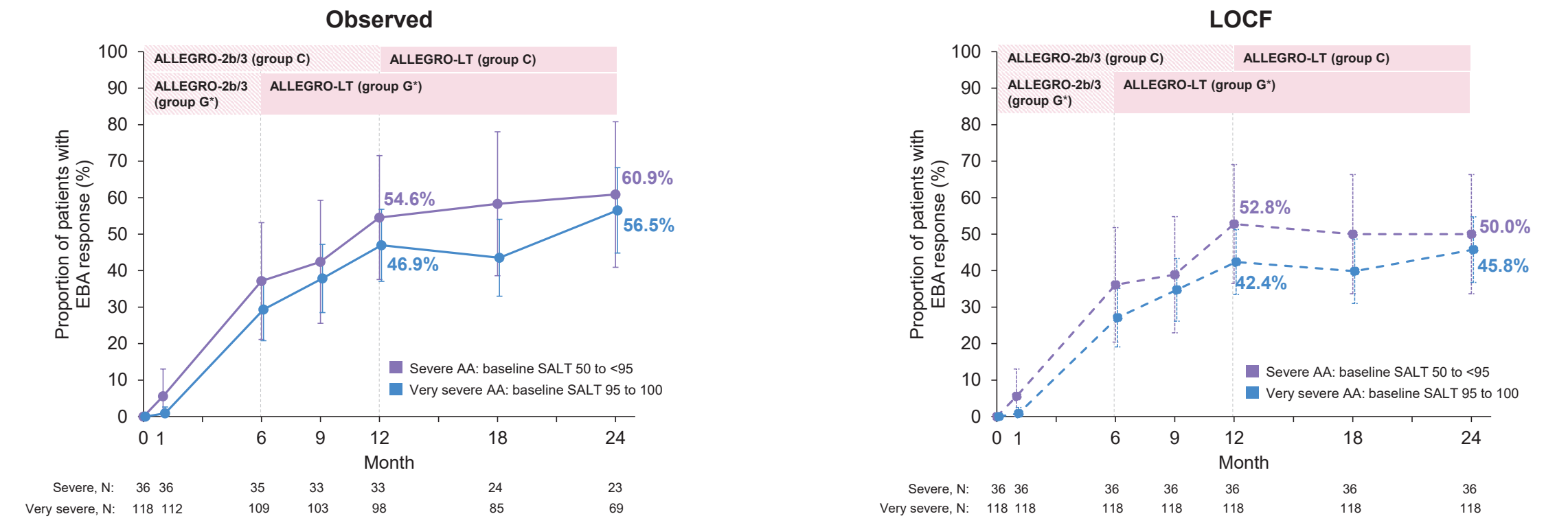


LOCF, last observation carried forward; SALT, Severity of Alopecia Tool.

\*Data while on placebo were not included in this analysis; data from patients in Group 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

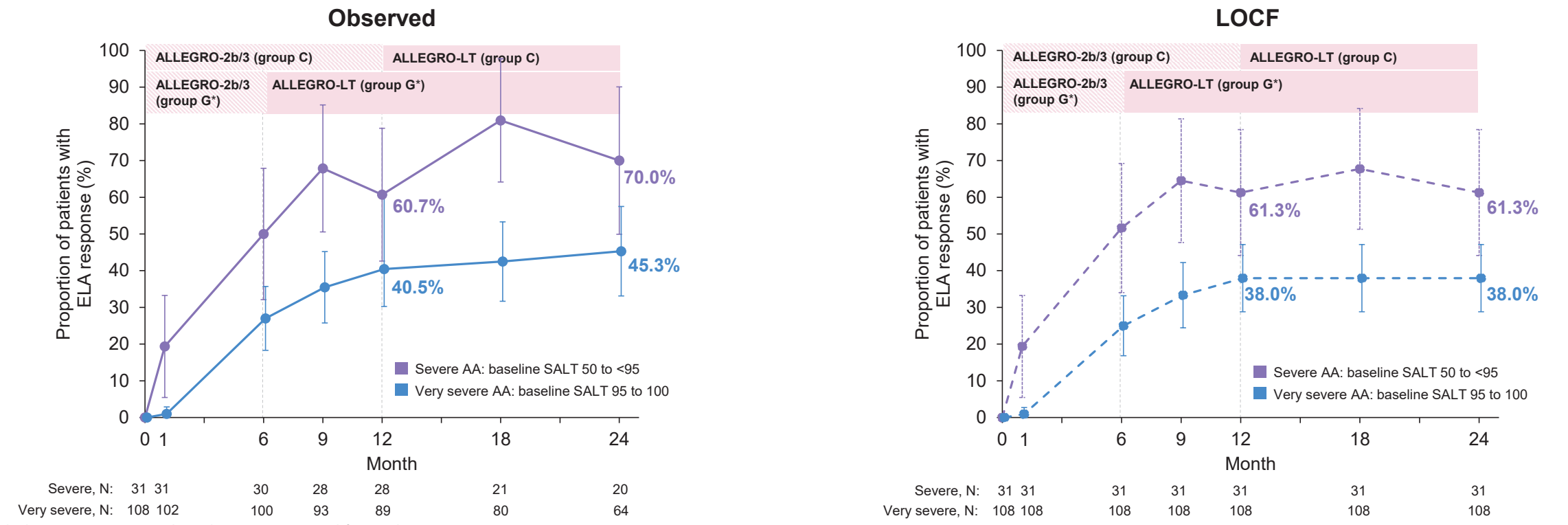


EBA, eyebrow assessment; LOCF, last observation carried forward.

\*Data while on placebo were not included in this analysis; data from patients in Group 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 Group 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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## DISCLOSURES

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