Long-Term Efficacy and Complete Scalp Hair Regrowth in Patients with Alopecia Areata Receiving Ritlecitinib 50 mg QD Up to 3 Years in the ALLEGRO Clinical Trial Program

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BACKGROUND

- Alopecia areata (AA) is an autoimmune disease characterized by nonscarring hair loss on the scalp, with or without loss of facial and/or body hair[1]
- Ritlecitinib is an oral, selective, JAK3/TEC family kinase inhibitor approved to treat patients aged ≥12 years with severe AA[2,3]
- In clinical trials, achievement of Severity of Alopecia Tool (SALT) score ≤20 and ≤10 (≤20% and ≤10% scalp hair loss) are commonly reported, but reporting achievement of SALT score 0, among the most stringent endpoints, is less common

OBJECTIVE

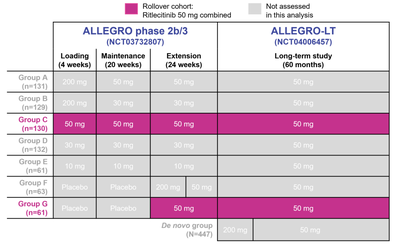
- To report efficacy results through 3 years, including achievement of SALT score 0, in patients with AA receiving ritlecitinib in the ALLEGRO phase 2b/3 (ALLEGRO-2b/3; NCT03732807) and ongoing, phase 3, open-label ALLEGRO-LT (NCT04006457) studies

METHODS

Study design and patients

- Key inclusion criteria in ALLEGRO-2b/3:
  - Aged ≥12 years
  - Diagnosis of AA with ≥50% scalp hair loss due to AA
  - Maximum duration of current episode of hair loss ≤10 years
- This post hoc analysis included patients treated with ritlecitinib 50 mg once daily (QD) in ALLEGRO-2b/3 who rolled over to the open-label phase 3 ALLEGRO-LT study and continued to receive ritlecitinib 50 mg (**Figure 1**)

Figure 1. Study design



Outcomes

- The proportions of patients treated with ritlecitinib 50 mg QD with response through 3 years were assessed based on:
  - SALT score ≤20, SALT score ≤10, and SALT score 0
  - Eyebrow Assessment (EBA) and Eyelash Assessment (ELA) responses

Statistical analysis

- Efficacy data are presented as observed and imputed (last observation carried forward [LOCF]) to account for missing data values
- Data from patients in Group G were rebaselined from the start of treatment with ritlecitinib at Week 24 of the ALLEGRO-2b/3 study
- Visits were calculated as time since the first ritlecitinib dose, thus resulting in different months for some visits
  - The "Month 36" timepoint includes patients in group C (n=130) who were treated with ritlecitinib for 36 months and patients in group G (n=61) who were treated with ritlecitinib for 38 months
- Data are reported to the cutoff date of June 25, 2024

RESULTS

Baseline characteristics and patient disposition

- 191 patients treated with ritlecitinib 50 mg QD were included in this post hoc analysis (**Table 1**)
- Mean SALT score was 90.8 (corresponding to ~91% scalp hair loss), and the median duration of current AA episode was 2.2 years
- At the date of data cutoff, 27 (14.1%) patients were ongoing treatment (**Table 2**)

Table 1. Demographic and baseline characteristics[4]

	Ritlecitinib 50 mg (N=191)
Age, years	
Median (range)	31.0 (12.0-65.0)
12-17 years, n (%)	27 (14.1)
≥18 years, n (%)	164 (85.9)
≥65 years, n (%)	6 (3.1)
Female, n (%)	107 (56.0)
White, n (%)	123 (64.4)
AT/AU,* n (%)	86 (45.0)
SALT score, mean (SD)	90.8 (14.1)
Duration of AA since diagnosis, median (range), years	6.9 (0.3-58.2)
Duration of current AA episode, median (range), years	2.2 (0.0-10.0)
Prior pharmalogical treatment for AA, n (%)	145 (75.9)

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

Table 2. Patient disposition

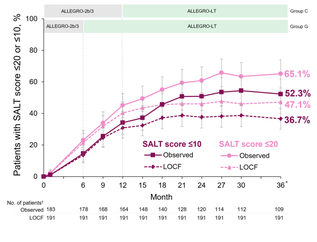
n (%)	Ritlecitinib 50 mg (N=191)
Ongoing treatment at the date of datacut	27 (14.1)
Completed the study	9 (4.7)
Removed from study per protocol as commercial drug became available	53 (27.8)
Discontinued	102 (53.4)
Adverse event	21 (11.0)
Lack of efficacy	17 (8.9)
Lost to follow-up	8 (4.2)
Physician decision	3 (1.6)
Pregnancy	1 (0.5)
Protocol deviation	0
Withdrawal by subject	35 (18.3)
No longer meets eligibility criteria*	6 (3.1)
Other	11 (5.8)

SALT, Severity of Alopecia Tool.
*Adolescents (n=5) who did not meet the protocol continuation criteria in ALLEGRO-LT (i.e., did not achieve a ≥50% improvement in SALT score at Month 3 from baseline in ALLEGRO 2b/3 or a SALT score of ≤20 at Month 6) and one adult who was diagnosed with scarring alopecia.

SALT score ≤20 and ≤10 responses

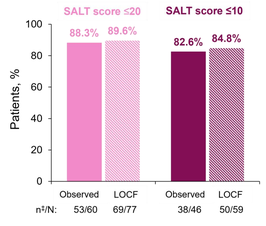
- At Month 36 (**Figure 2**):
  - **65.1%** (observed) and **47.1%** (LOCF) of patients had **SALT score ≤20**
  - **52.3%** (observed) and **36.7%** (LOCF) of patients had **SALT score ≤10**
- Among patients with **SALT score ≤20** at Month 12, **88.3%** (observed) and **89.6%** (LOCF) maintained this response at Month 36 (**Figure 3**)
- Among patients with **SALT score ≤10** at Month 12, **82.6%** (observed) and **84.8%** (LOCF) maintained this response at Month 36 (**Figure 3**)

Figure 2. SALT score ≤20 and ≤10 responses over time



LOCF, last observation carried forward; SALT, Severity of Alopecia Tool.
*To align timepoints across groups for summarization, visits are calculated as time since the first ritlecitinib dose; the "Month 36" timepoint includes patients in group C who were treated with ritlecitinib for 36 months (n=130) and patients in Group G who were treated with ritlecitinib for 38 months (n=61).
†Number of patients with valid data at that analysis visit. LOCF was applied to each visit for all participants with missing data, except for those who have not yet reached that analysis visit. Interim results are subject to change as additional data are collected and analyzed in the ongoing study.

Figure 3. SALT score ≤20 and ≤10 responses at Month 12 maintained* up to Month 36†

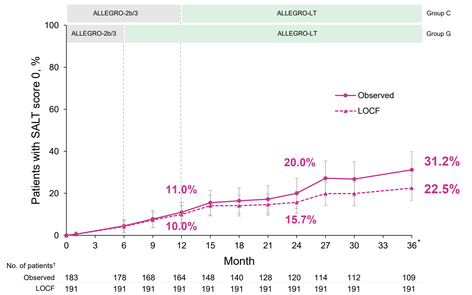


LOCF, last observation carried forward; SALT, Severity of Alopecia Tool.
*Maintained SALT score ≤20 and ≤10 responses were defined as having a response at Month 12 and maintaining this response through the Month 36 visit. †To align timepoints across groups for summarization, visits are calculated as time since the first ritlecitinib dose; the "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (n=130) and patients in Group G who were treated with ritlecitinib for 38 months (n=61).
‡Number of patients with valid data at that analysis visit. LOCF was applied to each visit for all participants with missing data, except for those who have not yet reached that analysis visit.

SALT score 0 responses

- **31.2%** (34/109 observed) and **22.5%** (43/191 LOCF) of patients had complete scalp hair regrowth (SALT score 0) at Month 36 (**Figure 4**)

Figure 4. SALT score 0 response over time



LOCF, last observation carried forward; SALT, Severity of Alopecia Tool.
*To align timepoints across groups for summarization, visits are calculated as time since the first ritlecitinib dose; the "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (n=130) and patients in Group G who were treated with ritlecitinib for 38 months (n=61). †Number of patients with valid data at that analysis visit. LOCF was applied to each visit for all participants with missing data, except for those who have not yet reached that analysis visit. Interim results are subject to change as additional data are collected and analyzed in the ongoing study.

EBA and ELA responses

- Among patients with an abnormal EBA score at baseline, **63%** (observed) and **49%** (LOCF) had an EBA response at Month 36, and among patients with an abnormal ELA score at baseline, **60%** (observed) and **50%** (LOCF) had an ELA response at Month 36 (**Figures 5 and 6**)

Figure 5. EBA response* over time (among patients with abnormal EBA at baseline)

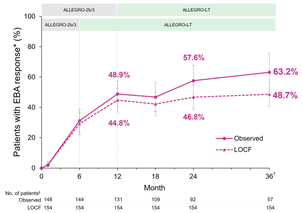
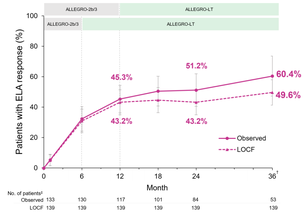


Figure 6. ELA response* over time (among patients with abnormal ELA at baseline)

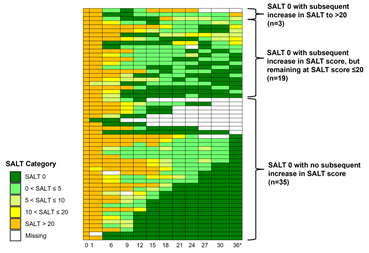


EBA, eyebrow assessment; ELA, eyelash assessment; LOCF, last observation carried forward.
*EBA and ELA responses are defined as at least 2-grade improvement in EBA or ELA, respectively, from baseline or a score of 3 (normal) among patients with an abnormal EBA or ELA score at baseline.
†To align timepoints across groups for summarization, visits are calculated as time since the first ritlecitinib dose; the "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (n=130) and patients in Group G who were treated with ritlecitinib for 38 months (n=61).
‡Number of patients with valid data at that analysis visit. LOCF was applied to each visit for all participants with missing data, except for those who have not yet reached that analysis visit. Interim results are subject to change as additional data are collected and analyzed in the ongoing study.

SALT score 0 during at least one time point

- Of a total of 191 patients, 57 (29.8%) achieved complete scalp hair regrowth (SALT score 0) at ≥1 time point through Month 36 and are depicted in each row in **Figure 7**
- Of these 57 patients with SALT score 0 during ≥1 visit:
  - 35 (61.4%) did not have an increase in SALT score at later visits
  - 19 (33.3%) had an increase in SALT score at a subsequent visit but remained at SALT score ≤20
  - 3 (5.2%) had a SALT score >20 at a subsequent visit

Figure 7. Visualization of patients with SALT score 0 at ≥1 visit

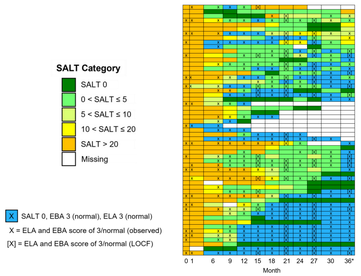


SALT, Severity of Alopecia Tool.
In the heatmap visualization, each row represents 1 patient and shows their SALT score at each visit.
*Visits are calculated as time since the first ritlecitinib dose; the "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (n=130) and patients in Group G who were treated with ritlecitinib for 38 months (n=61).

Complete scalp hair regrowth and normal eyebrow and eyelash hair

- 45/57 (78.9%) patients had normal eyebrow and eyelash score during ≥1 visit when SALT score 0 was reached (**Figure 8**)

Figure 8. Visualization of patients with SALT score 0 and normal EBA and ELA at ≥1 visit



EBA, eyebrow assessment; ELA, eyelash assessment; SALT, Severity of Alopecia Tool.
In the heat map visualization, each row represents 1 patient and shows their SALT score at each visit.
*Visits are calculated as time since the first ritlecitinib dose; the "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (n=130) and patients in Group G who were treated with ritlecitinib for 38 months (n=61).

CONCLUSIONS

- Ritlecitinib 50 mg QD demonstrated clinically meaningful clinician-reported efficacy up to 3 years, supporting the long-term use of ritlecitinib in patients aged ≥12 years with AA
- Almost one-third of patients achieved complete scalp hair regrowth (SALT score of 0) at ≥1 timepoint, with the majority sustaining that response at later visits or remaining at SALT score ≤5
- Almost one-quarter of patients achieved complete scalp hair regrowth and normal eyebrow and eyelash hair at ≥1 timepoint

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DISCLOSURES

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