Updated Integrated Efficacy Analysis of Ritlecitinib Up to 3 Years in Adolescents With Alopecia Areata From the ALLEGRO Clinical Trials

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SYNOPSIS

- Alopecia areata (AA) is an autoimmune disease characterized by patchy or complete nonscarring hair loss on the scalp, with or without additional loss of facial and/or body hair[1]
- Ritlecitinib is an oral, selective dual inhibitor of JAK3/TEC family kinases approved for the treatment of severe AA in adults and adolescents ≥12 years of age
- In the ALLEGRO phase 2b/3 study, ritlecitinib demonstrated efficacy and safety in patients ≥12 years of age with AA up to 48 weeks[2,3]
- ALLEGRO-LT is an ongoing, open-label extension, phase 3 study investigating the safety and efficacy of long-term treatment with ritlecitinib in adults and adolescents with AA

OBJECTIVE

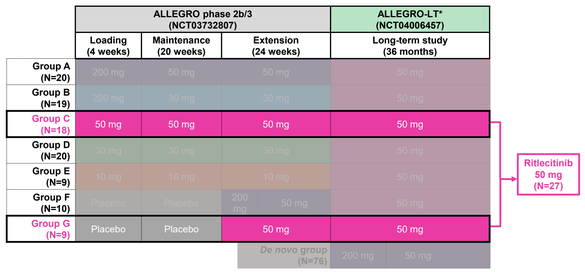
- To report updated efficacy results of ritlecitinib up to 3 years in adolescents with AA from the ALLEGRO phase 2b/3 and open-label ALLEGRO-LT phase 3 studies

METHODS

Study design and patients

- Adolescents (aged 12-17 years) from ALLEGRO-2b/3 and/or ALLEGRO-LT were included (**Figure 1**)
  - Adolescents with ≥50% scalp hair loss and a current AA episode duration of 6 months to 10 years were included in ALLEGRO-2b/3
  - Per study protocol, continuation criteria for rollover adolescents in ALLEGRO-LT required ≥50% improvement in Severity of Alopecia Tool (SALT) score by Month 3 and SALT score ≤20 by Month 6
- Adolescents received ritlecitinib 50 mg once-daily (QD) without a 200 mg loading dose in ALLEGRO-2b/3 and rolled over to ALLEGRO-LT, in which they continued to receive 50 mg QD

Figure 1. Study design



*Data cutoff for the ongoing ALLEGRO LT was 25 June 2024.

Outcomes

- Proportion of adolescents with response through Month 36 based on:
  - SALT score ≤20 (≤20% scalp hair loss)
  - SALT score ≤10 (≤10% scalp hair loss)
  - Eyebrow Assessment (EBA) response and eyelash assessment (ELA) response
  - Patients' Global Impression of Change (PGI-C) score of "moderately improved" or "greatly improved" from baseline

Statistical analyses

- Patients who received placebo and switched to ritlecitinib were re-baselined to align time points across groups
- Data are reported as observed and imputed; last observation carried forward (LOCF) was applied to each visit for all participants with missing data
- Confidence intervals (CIs) are calculated based on normal approximation
- The data cutoff was 25 June 2024

RESULTS

Baseline characteristics and patient disposition

- Overall, 27 patients were included (**Table 1**)
- At baseline, the mean (SD) SALT score was 91.8 (13.1), 19 patients (70.4%) had abnormal EBA score, and 17 patients (63.0%) had abnormal ELA score (**Table 1**)

Table 1. Baseline characteristics

	Ritlecitinib 50 mg (N=27)
Age, mean (SD), years	14.8 (1.6)
Female, n (%)	12 (44.4)
Race, n (%)	
White	20 (74.1)
Black or African American	4 (14.8)
Asian	3 (11.1)
Weight, mean (SD), kg	59.5 (17.1)
BMI, mean (SD), kg/m²	21.9 (4.1)
Patients with AT/AU,* n (%)	12 (44.4)
Baseline SALT score	
All adolescents, mean (SD)	91.8 (13.1)
Non-AT/AU, mean (SD)	85.2 (14.6)
EBA, total abnormal (0-2),† n (%)	19 (70.4)
ELA, total abnormal (0-2),‡ n (%)	17 (63.0)
Duration of AA since diagnosis, mean (SD), years	6.1 (4.7)
Duration of current AA episode, mean (SD), years	2.3 (2.1)

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; BMI, body mass index; EBA, eyebrow assessment; ELA, eyelash assessment; SALT, Severity of Alopecia Tool.
*Participants in the AT/AU category had a SALT score of 100 (complete scalp hair loss) at baseline.
†Abnormal is EBA score <3. Response is ≥2-grade improvement from baseline or a score of 3 at the analysis visit.
‡Abnormal is ELA score <3. Response is ≥2-grade improvement from baseline or a score of 3 at the analysis visit.

- Among the 27 patients, 1 was ongoing at the data cutoff, 8 discontinued from ALLEGRO-LT due to availability of commercial drug, 1 completed ALLEGRO-2b/3 and did not rollover to ALLEGRO-LT, and 17 discontinued for other reasons (5 due to not meeting continuation criteria; **Table 2**)

Table 2. Patient disposition

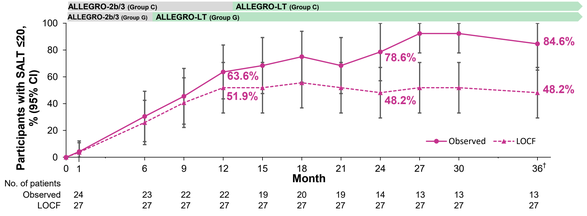
	Ritlecitinib 50 mg (N=27)
Ongoing at the data cutoff date, n (%)	1 (3.7)
Completed, n (%)	
Completed the study*	1 (3.7)
Removed from the study per protocol as commercial drug became available	8 (29.6)
Discontinued, n (%)	17 (63.0)
No longer meets eligibility criteria†	5 (18.5)
AE‡	3 (11.1)
Lost to follow-up	3 (11.1)
Withdrawal by patient	3 (11.1)
Other	2 (7.4)
Lack of efficacy	1 (3.7)

AE, adverse event.
*Completed ALLEGRO-2b/3 and did not rollover to ALLEGRO-LT.
†Per study protocol, continuation criteria for rollover adolescents in ALLEGRO-LT required ≥50% improvement in SALT score by Month 3 and SALT score ≤20 by Month 6.
‡Per study protocol, treatment discontinuation and participant withdrawal from the study occurred for the following AEs: serious infections (defined as any infection requiring parenteral antimicrobial therapy or hospitalization for treatment or meeting other criteria that require the infection to be classified as a SAE), treatment-related SAEs, or other SAEs or severe AEs (at the discretion of the investigator or sponsor); clinically meaningful and treatment-emergent declines in hearing from baseline were discussed with the sponsor for possible withdrawal from study.

Efficacy Analysis

- At 3 years, 84.6% (11/13 observed) and 48.2% (13/27 LOCF) of adolescents had SALT score ≤20 (**Figure 2**)

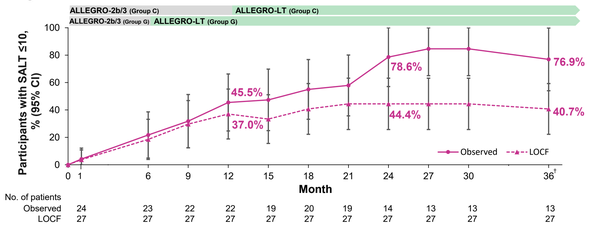
Figure 2. SALT score* ≤20 response



LCOF, last observation carried forward; SALT, Severity of Alopecia Tool.
*A SALT score of 100 represents full scalp hair loss and a SALT score of 0 represents full scalp hair coverage.
†The "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (N=18) and patients in group G were treated with ritlecitinib for 38 months (N=9).

- At 3 years, SALT score ≤10 response rates were 76.9% (10/13 observed) and 40.7% (11/27 LOCF; **Figure 3**)

Figure 3. SALT score* ≤10 response



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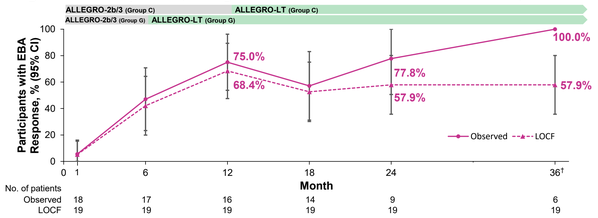
†The "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (N=18) and patients in group G were treated with ritlecitinib for 38 months (N=9).

- Among adolescents with abnormal EBA at baseline, EBA response rates were 100.0% (6/6 observed) and 57.9% (11/19 LOCF) at 3 years (**Figure 4**)

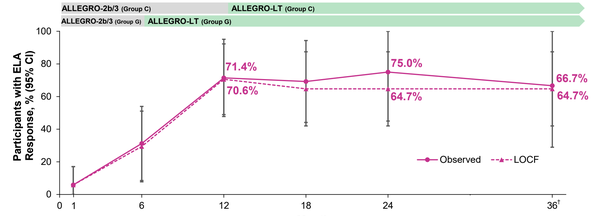
Figure 4. EBA response* (among adolescents with abnormal EBA at baseline)



EBA, eyebrow assessment; LOCF, last observation carried forward.
*Abnormal is EBA score <3; response is ≥2-grade improvement from baseline or a score of 3 at the analysis visit.
†The "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (N=18) and patients in group G were treated with ritlecitinib for 38 months (N=9).

- At 3 years, among adolescents with abnormal ELA at baseline, ELA response rates were 66.7% (4/6 observed) and 64.7% (11/17, LOCF; **Figure 5**)

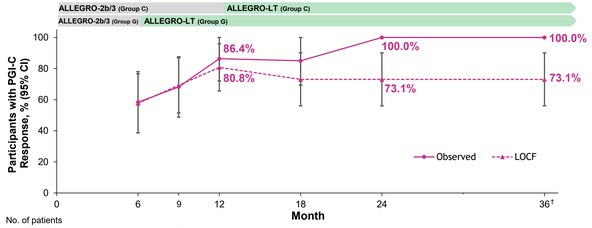
Figure 5. ELA response* (among adolescents with abnormal ELA at baseline)



ELA, eyelash assessment; LOCF, last observation carried forward.
*Abnormal is ELA score <3; response is ≥2-grade improvement from baseline or a score of 3 at the analysis visit.
†The "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (N=18) and patients in group G were treated with ritlecitinib for 38 months (N=9).

- PGI-C response ("moderately" or "greatly" improved) rates were 100.0% (9/9 observed) and 73.1% (19/26 LOCF) at 3 years (**Figure 6**)

Figure 6. PGI-C response*



LOCF, last observation carried forward; PGI-C, patient global impression of change.
*PGI-C response is defined as "moderately improved" or "greatly improved".
†The "Month 36" timepoint includes patients in Group C who were treated with ritlecitinib for 36 months (N=18) and patients in group G were treated with ritlecitinib for 38 months (N=9).

Limitations

- The decreasing number of adolescents who reached later study time points limits data interpretation

CONCLUSIONS

- In adolescents with AA, ritlecitinib 50 mg had long-term clinician- and patient-reported efficacy up to 3 years as reported by SALT score ≤20, SALT score ≤10, EBA response, ELA response, and PGI-C response

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3. Hordinsky M, et al. *Pediatr Dermatol*. 2023;40:1003-1009.

DISCLOSURES

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