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Long-term efficacy and safety of ritlecitinib in adults and adolescents with alopecia areata (AA): 3-year results from the ALLEGRO-LT phase 3, open-label study

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DISCLOSURES: This study was sponsored by Pfizer Inc. Maryanne Senna has served on advisory boards and/or is a consultant and/or is a clinical trial investigator or a speaker for Abbvie, Arena Pharmaceuticals, Concert Pharmaceuticals Inc, Eli Lilly and Company, Inmagene, LEO Pharma, Merck, Pfizer Inc, Sun Pharmaceutical, and Kintor. She is a scientific advisor for BiologicsMD. Ignasi Figueras has served as an advisory board member, consultant, and/or investigator for AbbVie, Eli Lilly and Company, LEO Pharma, L'Oréal, Pfizer, Novartis, Sanofi, Celgene, Amgen, Galderma and Gebro Pharma, and speaker for AbbVie, Eli Lilly and Company, LEO Pharma, Pfizer, Sanofi, Novartis, Sobi, Pierre Fabre, La Roche Possay, Galderma and Gebro Pharma. Misaki Kinoshita-Ise is a clinical trial investigator for AbbVie, Eli Lilly Japan, Pfizer, Bristol Myers Squibb, and a speaker for Eli Lilly Japan and Pfizer. Sameh Hanna is a clinical trialist with Abbvie, Lilly, Lumenis, and Pfizer, and has received honoraria for speaking/consulting from AbbVie, Lilly, and Pfizer. Wenyu Wu is a clinical trial investigator and a speaker for Abbvie, Eli Lilly and Pfizer. Dalia Wajsbrot, Deborah Woodworth, Robert Wolk, Alanna Chaudhry, Alex Lejeune, and Helen Tran employees of, and may hold stock or stock option in, Pfizer Inc. Third-party medical writing assistance, provided by Nucleus Global, an Inizio Company, was funded by Pfizer Inc.

BACKGROUND

- Alopecia areata (AA) is an autoimmune disease with an underlying immuno-inflammatory pathogenesis characterized by non-scarring hair loss of the scalp, face, and/or body[1]
- In the ALLEGRO phase 2b/3 study, ritlecitinib, a selective dual JAK3/TEC kinase family inhibitor, demonstrated efficacy and safety up to 48 weeks in patients with AA[2]

OBJECTIVE

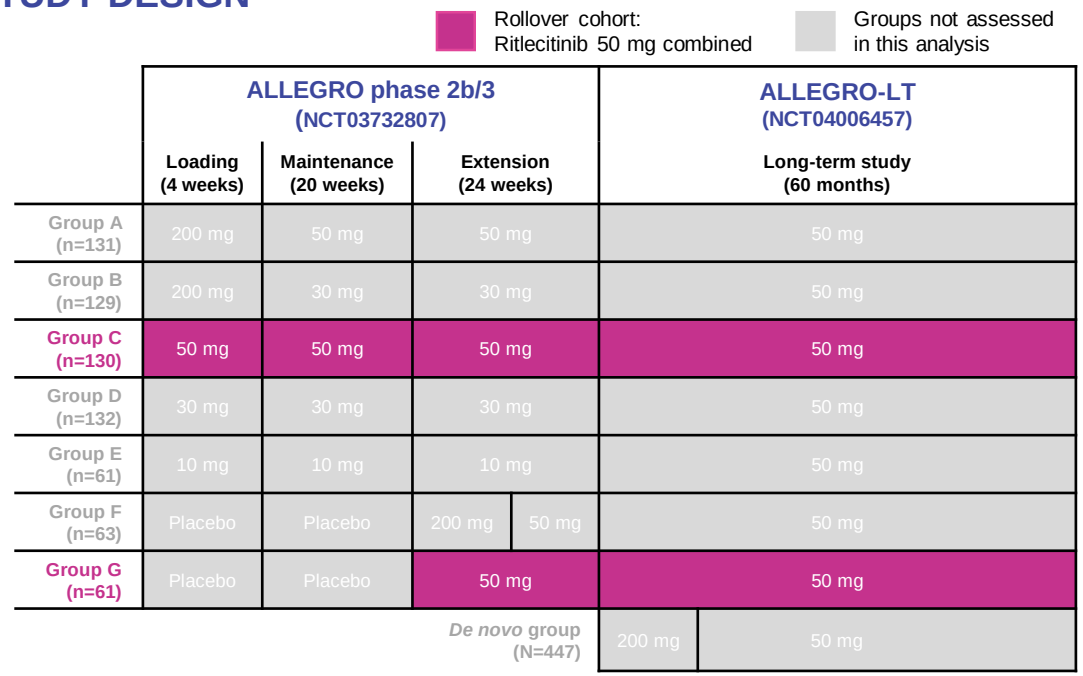
- This analysis investigated the efficacy and safety of ritlecitinib up to 3 years in patients with AA from ALLEGRO-2b/3 and the ongoing, phase 3, open-label ALLEGRO-LT studies

JAK3, Janus kinase 3; QD, once daily; TEC, tyrosine kinase expressed in hepatocellular carcinoma.

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

METHODS

STUDY DESIGN



ANALYSIS POPULATION

- Key inclusion criteria (ALLEGRO-2b/3):
  - Aged ≥12 years
  - Diagnosed with AA with ≥50% scalp hair loss due to AA, (including AT and AU)
  - Maximum duration of current episode of hair loss ≤10 years
- Patients received ritlecitinib 50 mg QD in ALLEGRO-2b/3 and continued the same dosage in the ALLEGRO-LT study*

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
  - PGI-C score of “moderately improved” or “greatly improved” from baseline
- Incidence of AEs, SAEs, severe AEs and AEs leading to discontinuation

STATISTICAL METHODS

- Efficacy data are presented as:
  - Observed data
  - Imputed data (last observation carried forward [LOCF]), to account for missing data values†
- Data while on placebo were not included in this analysis; data from patients in Group G were re-baselined from the start of treatment with ritlecitinib
- Visits were calculated as time since the first ritlecitinib dose, thus resulting in different months for some visits‡
- Timepoints presented in this summary are those where all groups in the cohort had planned assessments for the efficacy endpoint under analysis
- Data are reported to the cutoff date of June 25, 2024

AA, alopecia areata; AE, adverse event; AT, alopecia totalis; AU, alopecia universalis; PGI-C, Patient Global Impression of Change; QD, once daily; SAE, severe adverse event; SALT, Severity of Alopecia Tool.
*Adolescents in ALLEGRO-LT were required to have an improvement in SALT score of ≥ 50% from baseline in ALLEGRO-2b/3 at Month 3 and a SALT score of ≤ 20 by Month 6 to continue in ALLEGRO-LT. †LOCF was applied to each visit for all participants with missing data, except for those who have not yet reached that analysis 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 were treated with ritlecitinib for 38 months (n=61).

BASELINE CHARACTERISTICS & PATIENT DISPOSITION

Baseline characteristics[1]

- 191 patients were included in the **ritlecitinib 50 mg combined group**

Table. Baseline characteristics

	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 among all patients, mean (SD)	90.8 (14.1)
Duration of AA since diagnosis (years), median (range)	6.9 (0.3-58.2)
Duration of current AA episode (years), median (range)	2.2 (0.0-10.0)
Prior pharmalogical treatment for AA, n (%)	145 (75.9)

Patient disposition

- At the date of data cutoff, 27 (14.1%) patients were ongoing treatment, and 62 (32.5%) patients had completed the study

Table. Patient disposition

	Ritlecitinib 50 mg (N=191)
Ongoing treatment at the date of datacut	27 (14.1)
Completed	62 (32.5)
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)

Data are presented as n (%).

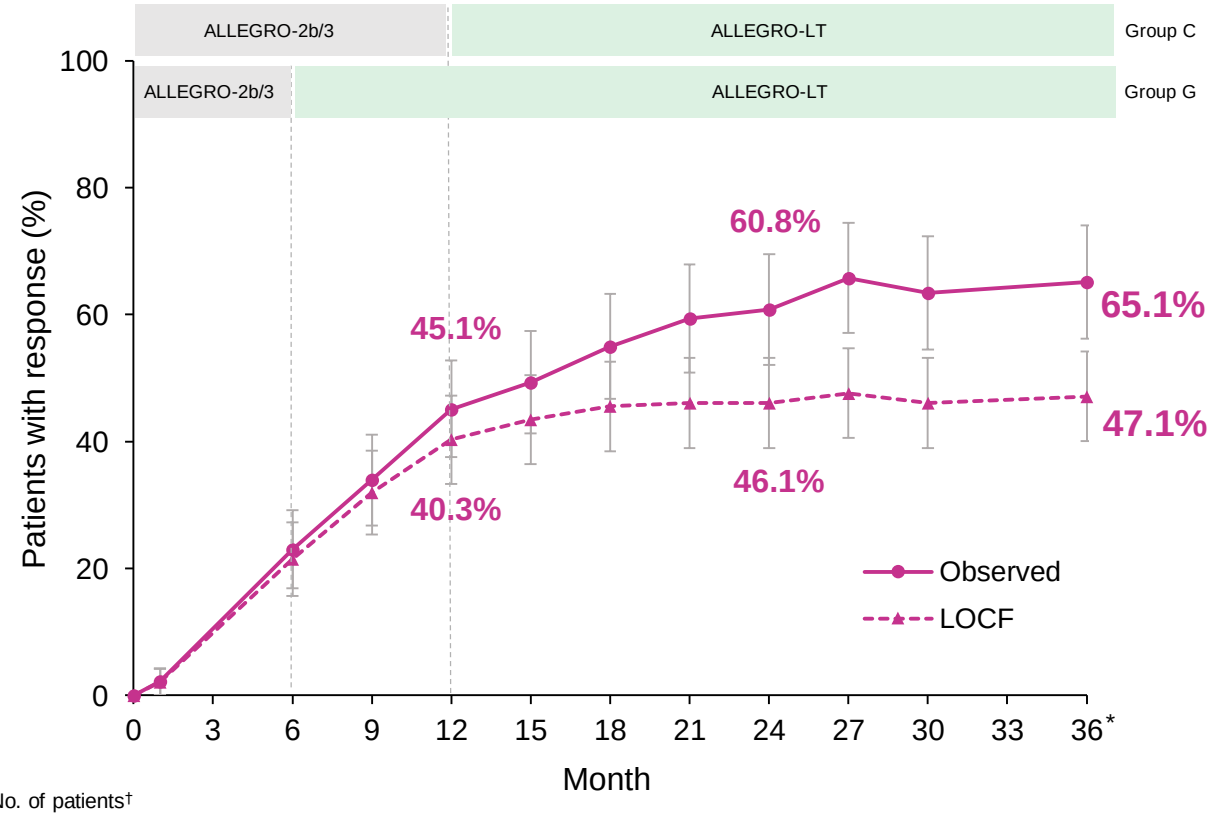
AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; SALT, Severity of Alopecia Tool.
Interim results are subject to change as additional data are collected and analyzed in the ongoing study.
*Patients in the AT/AU group had a SALT score of 100 at baseline regardless of the category in the alopecia areata history case report form. †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 from baseline at Month 3 in ALLEGRO 2b/3, nor a SALT score of ≤20 at Month 6) and one adult who was diagnosed with scarring alopecia.

1. Piliang M, et al. *Br J Dermatol.* 2025;192:215-227.

RESULTS

SALT ≤20 response over time

- 65.1% (71/109 observed) and 47.1% (90/191 LOCF) of patients had SALT score <20 at Month 36*

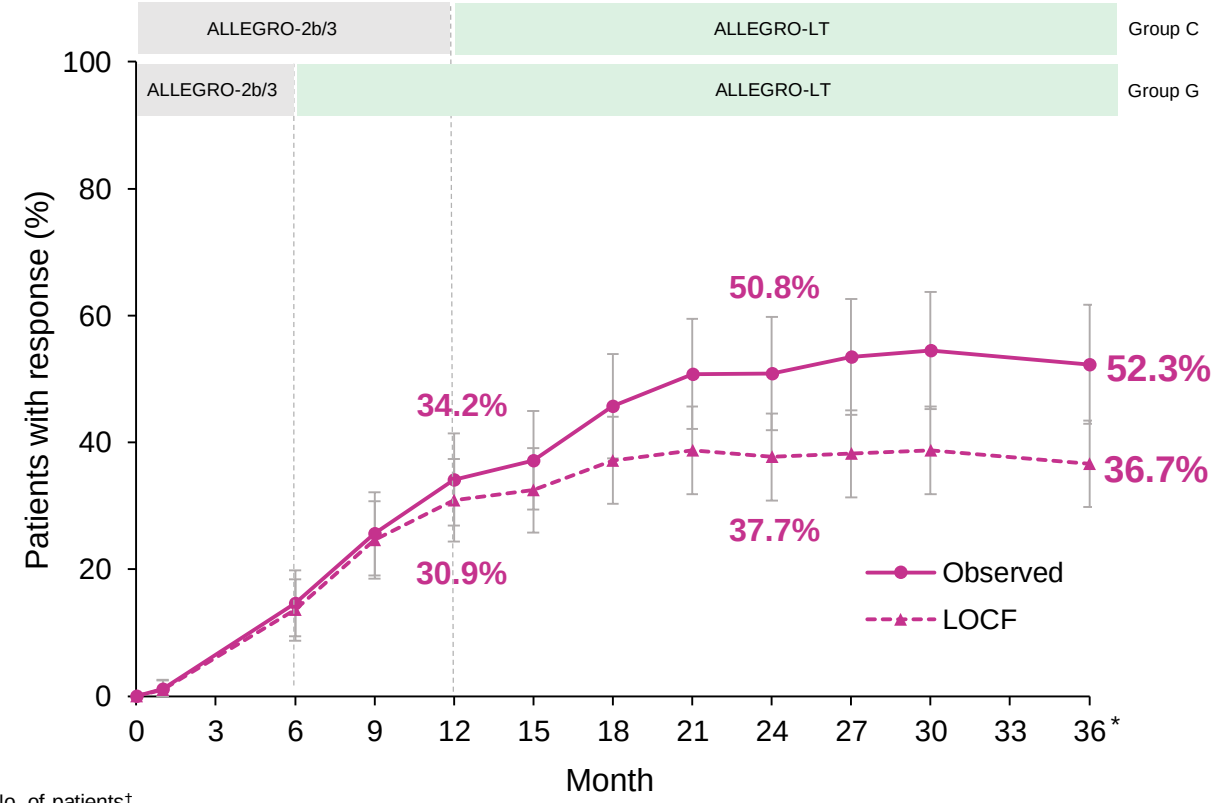


No. of patients†

Observed	183	178	168	164	148	140	128	120	114	112	109
LOCF	191	191	191	191	191	191	191	191	191	191	191

SALT ≤10 response over time

- 52.3% (57/109 observed) and 36.7% (70/191 LOCF) of patients had SALT score <10 at Month 36*



No. of patients†

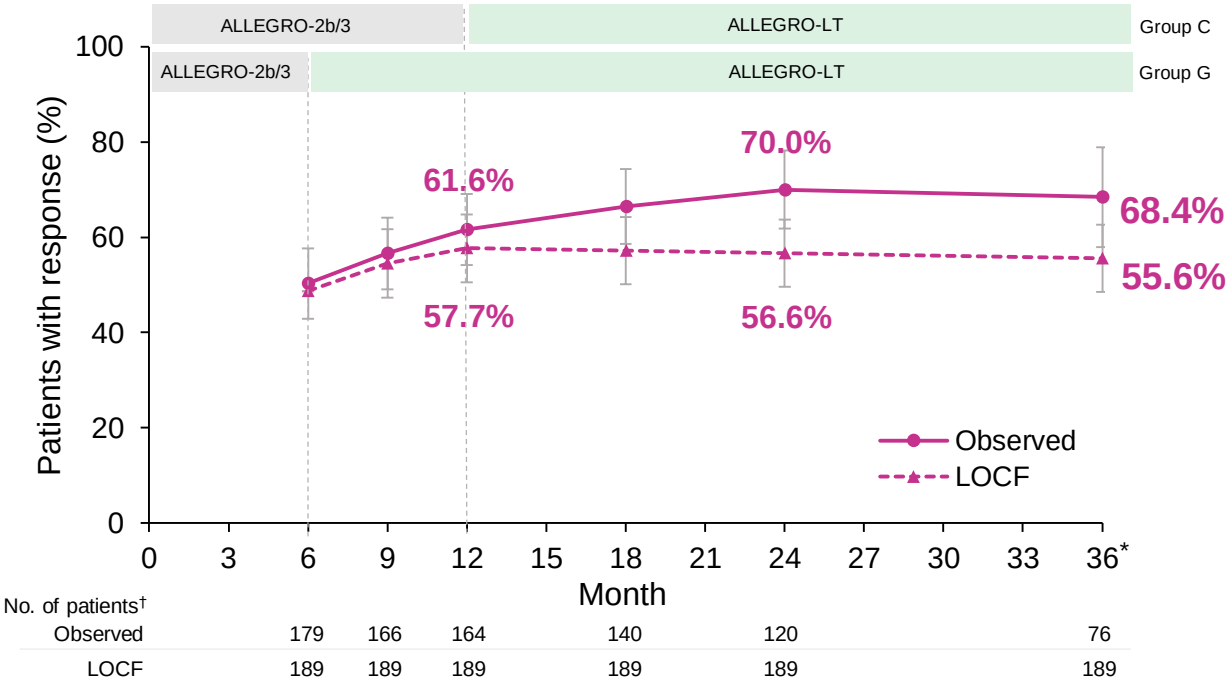
Observed	183	178	168	164	148	140	128	120	114	112	109
LOCF	191	191	191	191	191	191	191	191	191	191	191

LOCF, last observation carried forward; SALT, Severity of Alopecia Tool.
Interim results are subject to change as additional data are collected and analyzed in the ongoing study.
*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 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.

RESULTS & CONCLUSIONS

PGI-C response over time

- 68.4% (52/76 observed) and 55.6% (105/189 LOCF) of patients reported "moderately" or "greatly" improved PGI-C response at Month 36*



SAFETY

Table. Safety overview

n (%)	Ritlecitinib 50 mg (N=191)
Patients with AEs	186 (97.4)
Patients with serious AEs	13 (6.8)
Patients discontinued from study or study drug due to AEs‡	24 (12.6)
Patients with temporary drug discontinuation due to AEs	70 (36.6)

- Ritlecitinib was generally well tolerated through Month 36* in patients with AA
- The long-term safety profile of ritlecitinib 50 mg was consistent with that reported previously[1]
- The findings represent a partial view of the overall safety profile that has been characterized in an integrated safety analysis of the ALLEGRO clinical programme[2,3]

CONCLUSIONS

- Ritlecitinib 50-mg demonstrated meaningful clinician- and patient-reported efficacy up to 3 years
- These data are the longest duration of ritlecitinib treatment to be reported to date and support the long-term use of ritlecitinib in patients aged ≥12 years with AA

AA, alopecia areata; AE, adverse event; LOCF, last observation carried forward; PGI-C, Patient Global Impression of Change; SAE, serious adverse event.
Interim results are subject to change as additional data are collected and analyzed in the ongoing study.
*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 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. ‡Participants with a record that indicated that the AE caused the participant to be discontinued from the study or study drug.

1. Piliang M, et al. *Br J Dermatol.* 2025;192:215-227; 2. King B, et al. *Am J Clin Dermatol.* 2024; 25:299-314; 3. Senna M, et al. Poster presented at the Annual AAD Meeting; March 9, 2024.