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# Patient-Reported Satisfaction with Hair Regrowth in a Study of Ritlecitinib in Alopecia Areata: Results from ALLEGRO-2b/3

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## Keywords

Alopecia areata · Patient-reported outcomes · Ritlecitinib · Satisfaction

## Abstract

**Introduction:** Patients with alopecia areata (AA) report high levels of dissatisfaction with commonly used treatments. Patient-reported outcomes are essential to understanding patients' experiences with AA treatments. The objective of this study was to evaluate patient-reported satisfaction with hair growth among patients with AA receiving ritlecitinib or placebo and the correlation between clinician-assessed efficacy and patient-reported satisfaction. **Methods:** In the ALLEGRO-2b/3 (NCT03732807) trial, patients with AA and  $\geq 50\%$  scalp hair loss were randomized to daily ritlecitinib or placebo for 24 weeks, with a 24-week extension of continued ritlecitinib or switch from placebo to ritlecitinib. The Patient Satisfaction with Hair Growth (P-Sat) measure evaluated patients' satisfaction with hair growth in 3 domains: amount, quality, and overall satisfaction with hair growth. The prespecified analysis evaluated the proportion of patients who were slightly, moderately, or very satisfied with hair growth. Several post hoc analyses assessed the proportion of patients who were moderately/very satisfied

and moderately/very dissatisfied and calculated polyserial correlations between change from baseline (CFB) in Severity of Alopecia Tool (SALT) and P-Sat scores at weeks 24 and 48. **Results:** At week 24, the proportion of patients ( $N = 718$ ) reporting satisfaction (slightly, moderately, or very satisfied) overall with their hair growth ranged from 36.4% in the ritlecitinib 10-mg group (evaluated for dose ranging only) to 67.5% in the 200/50-mg group versus 22.6% in the placebo groups. In patients randomized to ritlecitinib, the proportion who were satisfied increased or was maintained at week 48. A substantially greater proportion of placebo patients who switched to ritlecitinib reported satisfaction at week 48 than at week 24. Similar results were observed for patient satisfaction with the amount and quality of hair growth. In the post hoc analyses defining satisfaction as moderately/very satisfied and dissatisfaction as moderately/very dissatisfied, the benefit of ritlecitinib was also observed. All P-Sat domain scores strongly correlated with CFB-SALT scores at weeks 24 (range 0.73–0.76;  $p < 0.05$ ) and 48 (0.74–0.77;  $p < 0.05$ ). **Conclusions:** Patients receiving active ritlecitinib doses reported favorable results versus placebo in satisfaction with

Trial Registration: ClinicalTrials.gov NCT0373280.

hair growth up to week 48. High concordance was observed between improvement in scalp hair growth evaluated by clinicians and patient-reported satisfaction.

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### Plain Language Summary

Alopecia areata (AA) is a disease which causes small or large areas of hair loss on the scalp and/or body. AA affects about 145 million people worldwide and occurs in children and adults. AA can have a large impact on a person's mental health and cause damage to self-esteem. AA can also cause worry or feelings of sadness. Therefore, it is important to understand if people are satisfied with their treatments for AA. Our study looked at a medicine called ritlecitinib that was taken as a pill by mouth. People in the study had lost at least half of the hair on their scalp and were at least 12 years old. A total of 718 people in 18 countries were included. The purpose of this study was to compare ritlecitinib with a placebo (medicine that looks the same but does not have active ingredients). It was decided by chance what treatment people would take. We looked at how many people were satisfied with the amount and quality of their hair and how satisfied they were overall with hair growth during the 1-year study. After 6 months, many more people taking ritlecitinib were satisfied with their hair growth than people taking placebo. After people who were taking placebo switched to ritlecitinib, more were satisfied with their hair growth than before switching. The satisfaction that people reported with hair growth agreed with the improvement in hair growth reported by doctors involved in the study.

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### Introduction

Alopecia areata (AA) is an autoimmune disease that has underlying immuno-inflammatory pathogenesis and is characterized by nonscarring hair loss involving the scalp, face, and/or body [1]. Hair loss may occur in one or many patches, or there may be complete scalp hair loss (alopecia totalis [AT]) or complete loss of scalp, facial, and body hair (alopecia universalis [AU]) [1]. Hair loss in patients with AA is unpredictable; relapse and remission may occur, although extensive hair loss is more likely to be persistent [2–4]. The global prevalence of AA has been estimated at approximately 2% [5], and patients with AA may experience psychological and psychosocial symp-

toms that have a negative impact on their quality of life [6–14].

The underlying pathogenesis of AA involves the collapse of immune privilege at the hair follicle, followed by recognition of exposed hair follicle autoantigens by T-cell receptors on cytotoxic CD8<sup>+</sup> T cells [15–17]. Downstream signaling from the T-cell receptor involves the tyrosine kinase expressed in hepatocellular carcinoma (TEC) kinase family, which may contribute to the autoimmune reaction that characterizes AA [18–22]. Interferon- $\gamma$ , produced by multiple active immune cells, including CD8<sup>+</sup> T cells, induces interleukin-15 production; both interferon- $\gamma$  and interleukin-15 signal through Janus kinases (JAKs), perpetuating an inflammatory feed-forward loop, leading to the collapse of hair follicle immune privilege [23–25].

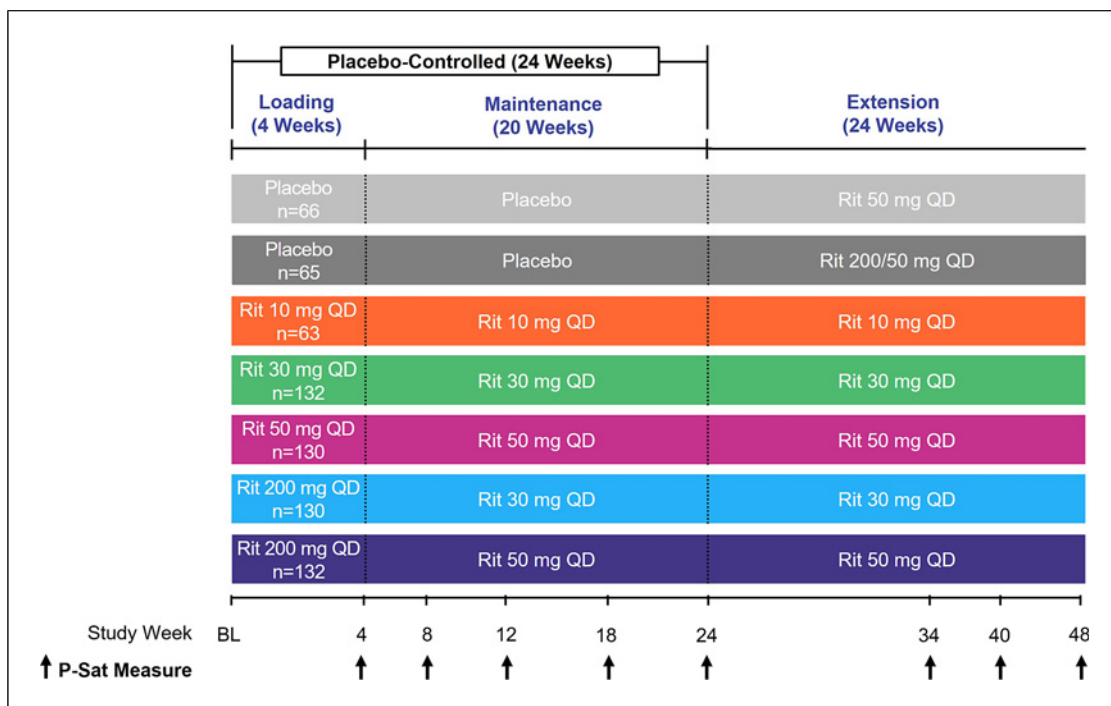
Patients report high levels of dissatisfaction with commonly used treatment options due to ineffectiveness and adverse effects [6, 11, 26]; however, new treatment options for AA have recently been approved. Currently, 2 therapies are approved for the treatment of severe AA. Baricitinib is a JAK1/2 inhibitor approved in the USA, Japan, EU, China, and several other countries for adults with severe AA [2]. Ritlecitinib is a selective dual inhibitor of JAK3 and all 5 members of the TEC family kinases that is approved for adolescent (12–17 years of age) and adult patients with severe AA in the USA, Japan, EU, China, and several other countries [4].

The ALLEGRO phase 2b/3 trial (NCT03732807) demonstrated significantly greater scalp hair growth per clinician-assessed Severity of Alopecia Tool (SALT) score with ritlecitinib compared with placebo over 24 weeks among patients aged  $\geq 12$  years with AA [4]. Patient-reported outcomes (PROs), including treatment satisfaction, are essential to understand the patient's experience with ritlecitinib. The objective of this study was to evaluate patient-reported satisfaction with hair growth among patients with AA receiving ritlecitinib or placebo and the correlation between clinician-assessed efficacy and patient-reported satisfaction.

### Materials and Methods

#### Study Design and Patient Population

ALLEGRO-2b/3 was an international, randomized, double-blind, placebo-controlled, combined dose-ranging and pivotal, phase 2b/3 study (Fig. 1) that enrolled both adult and adolescent patients with AA. The study design, including inclusion and exclusion criteria, has been published previously [4]. Briefly, patients  $\geq 12$  years of age with  $\geq 50\%$  scalp hair loss, including AT and AU, without evidence of terminal hair growth within 6



**Fig. 1.** Study design. BL, baseline; P-Sat, Patient Satisfaction with Hair Growth; QD, once daily; Rit, ritlecitinib.

months, were included. The maximum duration of current episode of hair loss was restricted to  $\leq 10$  years.

Patients received once-daily ritlecitinib for 24 weeks  $\pm$  an initial 4-week 200-mg loading dose: 10 mg, 30 mg, 50 mg, 200/30 mg, 200/50 mg, or placebo. After week 24, patients assigned to placebo switched to ritlecitinib 200/50 mg or 50 mg once daily for an additional 24 weeks; patients assigned to ritlecitinib continued their assigned maintenance dose.

This study was approved by the Institutional Review Boards or Ethics Committees of the participating institutions (including the Western Institutional Review Board [now known as Western Institutional Review Board-Copernicus Group]; reference number 20182828); online suppl. Table 1; for all online suppl. material, see <https://doi.org/10.1159/000539536>). The study was conducted in accordance with the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences, 2002), International Council for Harmonisation Guideline for Good Clinical Practice, and the Declaration of Helsinki. Written informed consent was obtained from each patient, parent, or patient's legal representative.

#### P-Sat Measure

The Patient Satisfaction with Hair Growth (P-Sat) measure (Fig. 2) was developed by Pfizer Inc through qualitative interviews with patients with AA. The measure evaluated patients' satisfaction with hair growth since the start of the trial in 3 domains: amount, quality, and overall satisfaction. The P-Sat measure was administered at weeks 4, 8, 12, 18, 24, 34, 40, and 48.

#### Outcomes and Statistical Analysis

A prespecified analysis evaluated the proportion of patients reporting any satisfaction (slightly, moderately, or very satisfied) with hair growth. Post hoc analyses included (1) defining satisfaction as proportion of patients who were moderately or very satisfied with hair growth, (2) evaluating dissatisfaction defined as proportion of patients who reported they were moderately or very dissatisfied with hair growth, and (3) calculating polyserial correlations between change from baseline (CFB) in SALT scores and the 3 P-Sat domain scores at weeks 24 and 48 for all patients combined. Proportions were reported for all treatment groups up to and including week 48. *p* values were not controlled for multiplicity, and analyses were based on observed data without any imputations.

## Results

### Patients

A total of 718 patients in 18 countries were randomized (placebo,  $n = 131$ , 10 mg,  $n = 63$ ; 30 mg,  $n = 132$ ; 50 mg,  $n = 130$ ; 200/30 mg,  $n = 130$ ; 200/50 mg,  $n = 132$ ). Baseline demographic and clinical characteristics were generally balanced across treatment groups; the majority of patients in each group were female and White (Table 1) [4]. The mean duration of current AA episode ranged from 3.2 to 3.6 years across the groups. The proportion of

*Instructions: For each question below, please select the box that best describes your experiences since the start of the study.*

**1. How satisfied are you with the amount of hair that has grown back since the start of the study?**

Very satisfied                       Neither satisfied or dissatisfied

Moderately satisfied                       Slightly dissatisfied                       Very dissatisfied

Slightly satisfied                       Moderately dissatisfied

**2. How satisfied are you with the quality of the new hair regrowth you have experienced since the start of the study?**

Very satisfied                       Neither satisfied or dissatisfied

Moderately satisfied                       Slightly dissatisfied                       Very dissatisfied

Slightly satisfied                       Moderately dissatisfied

**3. How satisfied are you overall with the hair that has grown back since the start of the study?**

Very satisfied                       Neither satisfied or dissatisfied

Moderately satisfied                       Slightly dissatisfied                       Very dissatisfied

Slightly satisfied                       Moderately dissatisfied

**Fig. 2.** P-Sat measure. P-Sat, Patient Satisfaction with Hair Growth.

patients in each group with AT/AU (defined as a SALT score of 100 at baseline) was  $\geq 45\%$ ; for patients without AT/AU, the mean SALT score ranged from 78.3 to 87.0 across groups.

*Prespecified Analysis of P-Sat*

At week 24, the proportion of patients reporting satisfaction (primary outcome: slightly, moderately, or very satisfied) overall with their hair growth ranged from 36.4% in the ritlecitinib 10-mg group to 67.5% in the 200/50-mg ritlecitinib group compared with 22.6% in the placebo groups (30.6% in the placebo to ritlecitinib 200/50-mg group and 14.5% in the placebo to ritlecitinib 50-mg group; Fig. 3a). The proportion of patients satisfied with the amount of hair growth ranged from 30.9% in the ritlecitinib 10-mg group to 67.5% in the ritlecitinib 200/50-mg and 50-mg groups compared with 22.6% in the placebo groups (29.0% in the placebo to ritlecitinib 200/50-mg group and 16.1% in the placebo to ritlecitinib 50-mg group; Fig. 3b). The proportion of patients satisfied with the quality of hair growth ranged from 32.7% in the ritlecitinib 10-mg group to 65.8% in the 200/50-mg group compared with 23.4% in the placebo groups (30.6% in the placebo to ritlecitinib 200/50-mg group and 16.1% in the placebo to ritlecitinib 50-mg group; Fig. 3c).

Among patients who were randomized to active treatment with ritlecitinib (200/50, 50, 200/30, or 30 mg), the proportion who were satisfied overall and with the amount and quality of hair growth continued to increase or was maintained to week 48; satisfaction remained low in patients receiving ritlecitinib 10 mg (Fig. 3). Among patients who received placebo until week 24 and then switched to ritlecitinib 200/50 mg or 50 mg, a substantially greater proportion reported satisfaction overall (75.0% and 61.0%, respectively) and with the amount (75.0% and 64.4%) and quality of hair growth (73.3% and 57.6%) at week 48 than at week 24. At week 48, the proportion of patients in the placebo to ritlecitinib 200/50-mg group reporting satisfaction was similar to that of patients who had been receiving ritlecitinib 200/50 mg or 50 mg for the entire study.

*Post Hoc Analysis of P-Sat*

Approximately half of patients randomized to receive active ritlecitinib treatment reported being moderately to very satisfied in all 3 P-Sat domains (amount, quality, and overall satisfaction) at week 24, with the overall proportion of patients moderately or very satisfied increasing or maintained to week 48 (Fig. 4).

**Table 1.** Baseline characteristics [4]

	Placebo <sup>a</sup> (n = 131)	Ritlecitinib QD				
		10 mg (n = 63)	30 mg (n = 132)	50 mg (n = 130)	200/30 mg (n = 130)	200/50 mg (n = 132)
Age						
Mean (SD), years	34.0 (15.0)	34.3 (13.9)	33.7 (14.8)	32.4 (13.4)	33.7 (13.8)	34.5 (15.0)
12–17 y, n (%)	19 (14.5)	9 (14.3)	20 (15.2)	18 (13.8)	19 (14.6)	20 (15.2)
≥18 y, n (%)	112 (85.5)	54 (85.7)	112 (84.8)	112 (86.2)	111 (85.4)	112 (84.8)
Female, n (%)	86 (65.6)	43 (68.3)	80 (60.6)	71 (54.6)	85 (65.4)	81 (61.4)
Race, n (%)						
White	94 (71.8)	42 (66.7)	91 (68.9)	79 (60.8)	90 (69.2)	92 (69.7)
Asian	31 (23.7)	17 (27.0)	34 (25.8)	43 (33.1)	28 (21.5)	33 (25.0)
Black or African American	4 (3.1)	2 (3.2)	3 (2.3)	5 (3.8)	7 (5.4)	6 (4.5)
Multiracial	2 (1.5)	0	2 (1.5)	1 (0.8)	3 (2.3)	0
American Indian or Alaska Native	0	0	2 (1.5)	0	1 (0.8)	0
Native Hawaiian or Other Pacific Islander	0	1 (1.6)	0	0	0	0
Not reported	0	1 (1.6)	0	2 (1.5)	1 (0.8)	1 (0.8)
Severity of AA, n (%)						
AT/AU <sup>b</sup>	60 (45.8)	29 (46.0)	61 (46.2)	60 (46.2)	60 (46.2)	60 (45.5)
Baseline SALT score, mean (SD)						
Non-AT/AU <sup>b</sup>	87.0 (12.9)	78.3 (17.6)	81.5 (16.3)	82.0 (15.9)	82.4 (15.4)	82.2 (16.5)
Duration of current AA episode, mean (SD), years	3.2 (2.7)	3.3 (2.7)	3.6 (2.8)	3.2 (2.7)	3.4 (2.9)	3.4 (2.9)

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; QD, once daily; SALT, Severity of Alopecia Tool. <sup>a</sup>Placebo alone for 24 weeks (and later switched to ritlecitinib). <sup>b</sup>Patients in the AT/AU category had a SALT score of 100% at baseline as assessed by the investigator (regardless of the category in the AA history case report form).

Among patients receiving placebo until week 24 and then switching to ritlecitinib 200/50 mg or 50 mg, a substantially greater proportion were moderately or very satisfied in all 3 domains at week 48 than at week 24. At week 48, the proportion of patients in the placebo to ritlecitinib 200/50-mg group who were moderately or very satisfied was similar to that of patients who had been receiving ritlecitinib 200/50 mg or 50 mg for the entire study. The placebo group was twice as likely to report being dissatisfied (moderately or very dissatisfied) compared with active ritlecitinib treatment groups at week 24; dissatisfaction decreased by week 48 after patients switched over to active ritlecitinib treatment (Fig. 4).

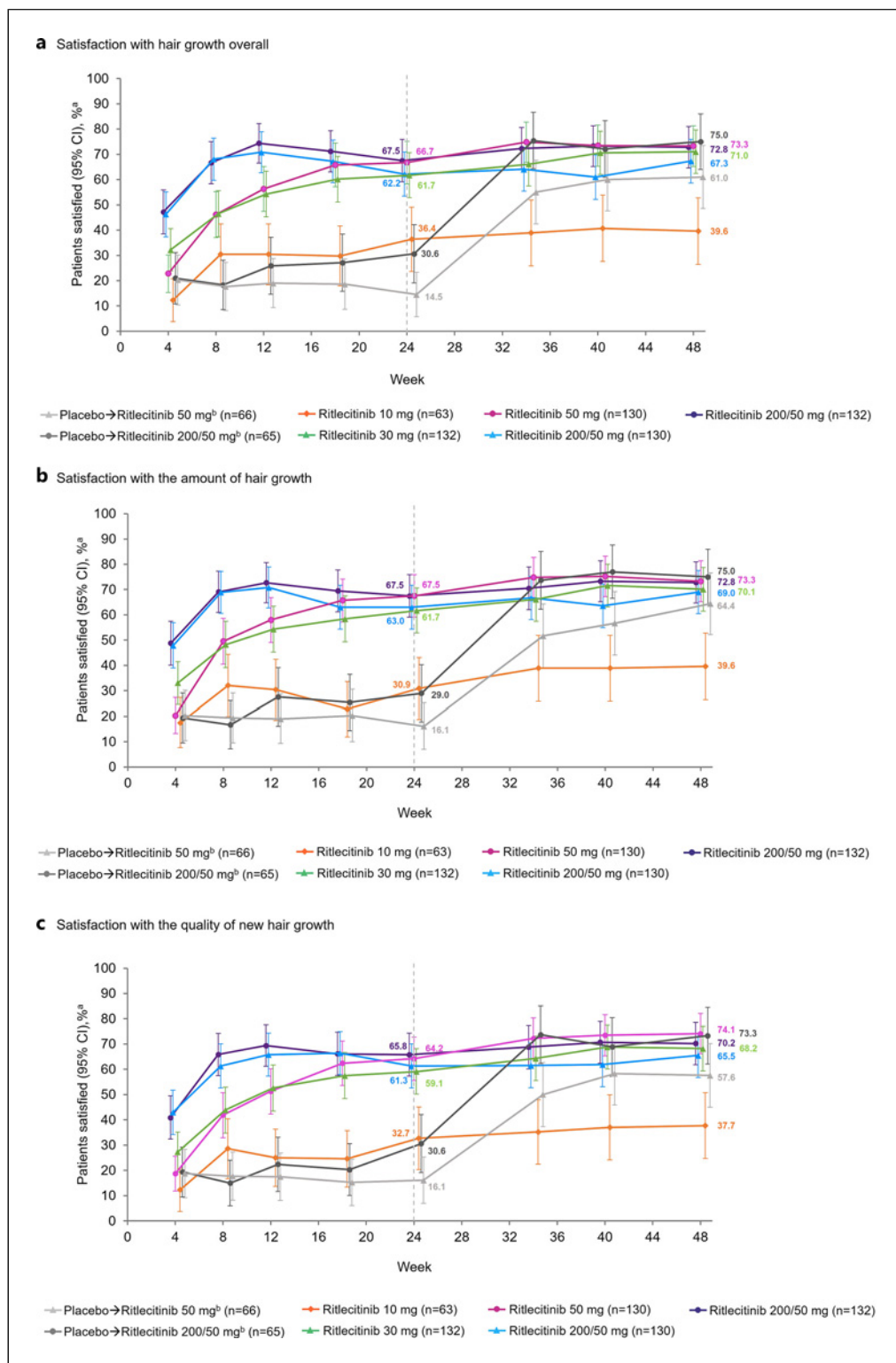
#### *Correlations between CFB-SALT Scores and the 3 P-Sat Domain Scores*

All P-Sat domain scores were strongly correlated with CFB-SALT scores at week 24 (range, 0.73–0.76;  $p < 0.05$ ) and week 48 (range, 0.74–0.77;  $p < 0.05$ ) (Table 2).

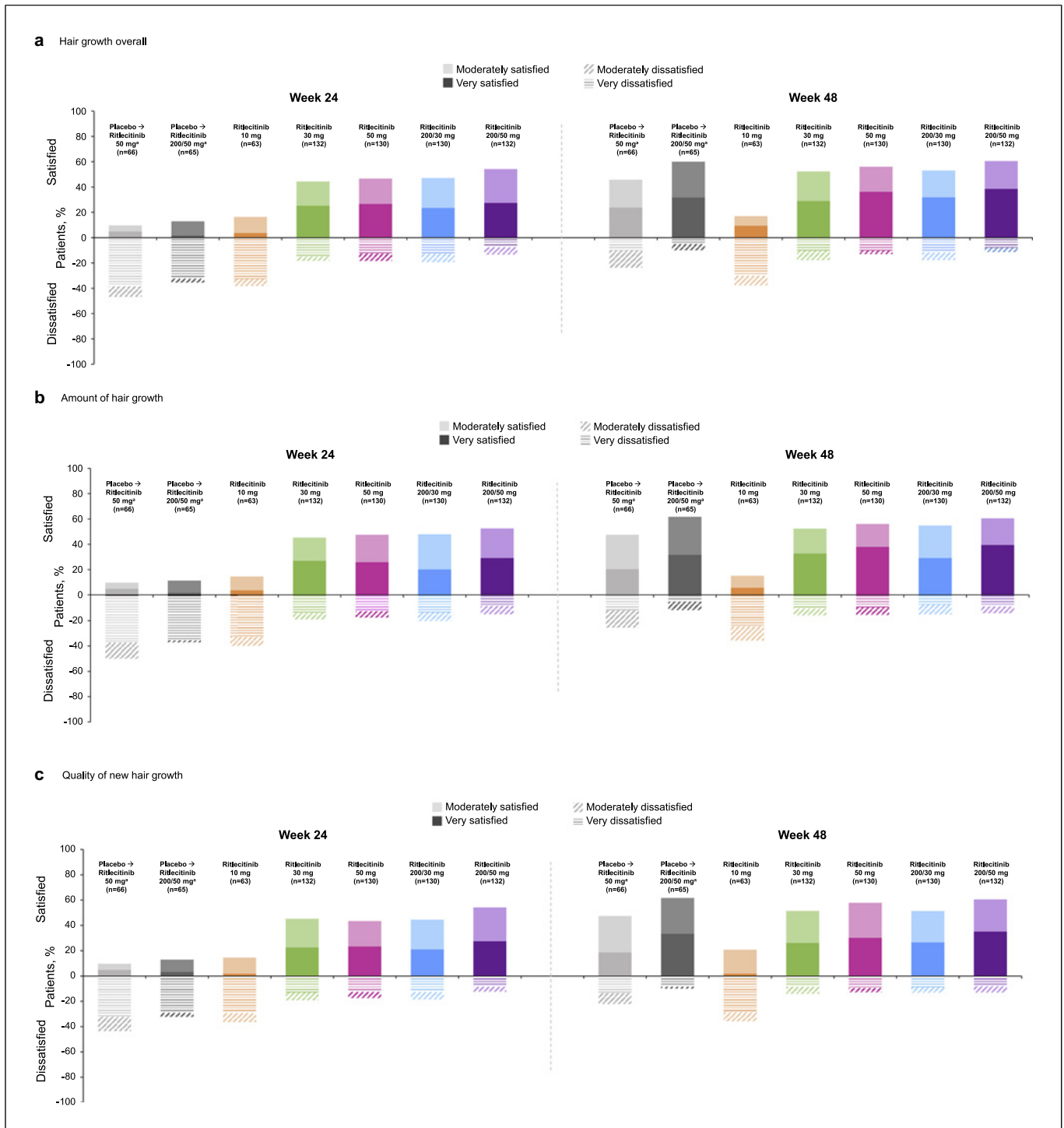
## Discussion

In this analysis of the ALLEGRO-2b/3 trial, the proportion of patients reporting satisfaction (slightly, moderately, or very satisfied) overall and with the amount and quality of hair growth at week 24 was 2- to almost 3-fold higher in patients who received ritlecitinib doses >10 mg daily than in those who received placebo. Satisfaction increased or was maintained at week 48 among patients who were initially assigned to ritlecitinib and continued it in the extension period. A substantially greater proportion of patients in the placebo to ritlecitinib groups were moderately or very satisfied at week 48 than at week 24 (before switching from placebo); however, the proportion of patients in the placebo to ritlecitinib 200/50-mg group reporting satisfaction was ≈30% across the 3 P-Sat domains at week 24. In the secondary analysis defining satisfaction as moderately or very satisfied, the benefit of ritlecitinib on patient satisfaction with hair growth was also observed.





**Fig. 3.** Proportion of patients reporting satisfaction (slightly, moderately, or very satisfied)<sup>a</sup> (a) with hair growth overall, (b) with the amount of hair growth, and (c) with the quality of new hair growth. <sup>a</sup>P-Sat response is defined as “slightly,” “moderately,” or “very satisfied.” <sup>b</sup>Patients received placebo until week 24 and then were switched to active ritilecitinib treatment.



**Fig. 4.** Proportion of patients reporting moderately/very satisfied and moderately/very dissatisfied (a) with hair growth overall, (b) with the amount of hair growth, and (c) with the quality of new hair growth at weeks 24 and 48. <sup>a</sup> Patients received placebo until week 24 and then were switched to active ritlecitinib treatment.

The benefit of ritlecitinib was also seen in the smaller proportion of patients who received ritlecitinib reporting dissatisfaction (moderately or very dissatisfied)

compared with placebo. The strong correlations observed between CFB-SALT scores and P-Sat indicated a high concordance between improvement in scalp hair



**Table 2.** Correlation between P-Sat domains and CFB-SALT scores at weeks 24 and 48

Measure	P-Sat domains, correlation coefficient (95% CI)		
	satisfaction with overall hair growth	satisfaction with amount of hair growth	satisfaction with quality of new hair growth
CFB-SALT at week 24 ( <i>n</i> = 647)	0.76 (0.72–0.79)	0.76 (0.72–0.79)	0.73 (0.69–0.77)
CFB-SALT at week 48 ( <i>n</i> = 621)	0.77 (0.73–0.80)	0.77 (0.73–0.80)	0.74 (0.71–0.78)

CFB-SALT, change from baseline in Severity of Alopecia Tool; P-Sat, Patient Satisfaction with Hair Growth. *p* < 0.05 for all.

growth as evaluated by clinicians and patient-reported satisfaction. These are the first randomized clinical trial data demonstrating a higher proportion of patients reporting satisfaction with a treatment compared with placebo, as directly assessed by a patient-reported instrument measuring patient satisfaction with hair growth.

Patients with AA may experience psychological and psychosocial symptoms such as depression, anxiety, anger, social withdrawal, embarrassment, and low self-esteem due to their hair loss, which can have a substantial negative impact on their quality of life [6–8, 11, 14]. Furthermore, patients report high levels of dissatisfaction with commonly used treatment options due to ineffectiveness and adverse effects [6, 11, 26]. A survey conducted by the National Alopecia Areata Foundation in 1083 patients with AA reported that >75% of patients were unsatisfied with current medical treatments (63% [*n* = 682] were very unsatisfied and 15% [*n* = 164] were somewhat unsatisfied) [26]. Therefore, a need for safe and effective treatments for AA exists due to the significant burden on patients combined with the ineffectiveness of commonly used treatments.

Evaluation of therapies for AA should include PRO measures in addition to clinician-reported outcomes. Understanding treatment outcomes that are important to patients is recommended for the development of clinical trial endpoints [6, 27]. The P-Sat measure was developed based on qualitative patient input and includes patient satisfaction with not only overall hair growth and amount of hair growth but also the quality of hair growth. Quality of hair growth may be a concern for some patients with AA because hair that regrows may not have the same color or texture as hair that was lost [28–30]. Results from the analysis of both the prespecified and post hoc definitions (slightly, moderately, or very satisfied and moderately or very satisfied, respectively) of patient satisfaction with ritlecitinib

treatment were consistent across all 3 of the P-Sat domains evaluated.

Patient satisfaction with hair growth may be affected by multiple factors, including the extent of hair loss at the start of treatment, duration of hair loss, level of acceptance of and coping strategies for hair loss, experience with previous treatments, and expectations of treatment results. Expectations for hair growth following treatment have been shown to vary based on patients' current hair loss [31], and nonlinear relationships between health-related quality of life measures and AA severity have been demonstrated [32]. In addition, coping strategies in patients with AA may evolve over time [33]. In the present analysis, high satisfaction rates were observed in a population of patients that had no hair growth in the previous 6 months (46% of whom had AT/AU) and had a mean duration of current AA episode of >3 years. The proportion of patients in the ritlecitinib 10-mg group who reported satisfaction did not significantly differ from the placebo to ritlecitinib 200/50-mg group while these patients were receiving placebo; there was a substantial increase in proportion of patients in the placebo to ritlecitinib 200/50-mg group reporting satisfaction once treatment with ritlecitinib was initiated after week 24. The favorable results with ritlecitinib versus placebo in patient satisfaction with hair regrowth were consistent with improvements in other PROs in the ALLEGRO-2b/3 trial, including patient perception of treatment benefit as measured by the Patient Global Impression of Change (PGI-C) [4] and Alopecia Areata Patient Priority Outcomes (AAPPO) measure of hair loss experienced by patients [34].

Limitations of this study include the majority of patients being White, with <6% of Black or African American patients in all treatment groups; thus, these results may not be representative of all patients with AA. The P-Sat measure was designed to encapsulate

all areas of hair growth and did not evaluate patient satisfaction by area of the body, and as a result, the effect of specific areas of hair growth (e.g., scalp hair vs. eyebrow/eyelash growth) on patient satisfaction with hair growth was not evaluated. Differences in growth of scalp hair versus eyebrows/eyelashes may affect patient satisfaction because eyebrow and eyelash growth are important to patients with AA [6, 35, 36]. However, in ALLEGRO-2b/3, improvement in eyebrows or eyelash growth was associated with a higher likelihood of SALT response [37]; therefore, a difference in patient-reported satisfaction would not be expected.

## Conclusions

Patients receiving ritlecitinib reported overwhelmingly higher rates of satisfaction with hair growth compared with placebo. This is the first study using placebo-controlled clinical data demonstrating the impact of a treatment for AA on patient satisfaction that includes overall satisfaction and satisfaction with the quality and amount of hair. These results confirm the benefit to patients of treatment of their AA.

## Key Message

Patients receiving ritlecitinib reported higher satisfaction rates with their hair growth compared with placebo.

## Acknowledgments

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## Statement of Ethics

This study was approved by the Institutional Review Boards or Ethics Committees of the participating institutions. The study was conducted in accordance with the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences, 2002), ICH Guideline for Good Clinical Practice, and the Declaration of Helsinki. Written informed consent was obtained from each patient, parent, or the patient's legal representative.

## Conflict of Interest Statement

R.S. has provided professional services to AbbVie, Aerotech, Amgen, Arena, Arcutis, Aksebio, AstraZeneca, Ascend, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Coherus Biosciences, Cutanea, Connect, Demira, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, MedImmune, Merck, MSD, Novartis, Oncobiologics, Pfizer, Regeneron, Reistone, Roche, Sanofi, Samson Clinical, Sun Pharma, and UCB. E.H.L. and L.N. are employees of and hold stock or stock options in Pfizer Inc. F.Z. and S.H.Z. were employees of and held stock or stock options in Pfizer Inc at the time of the study and manuscript preparation. X.Z.: no disclosures to report. B.K. has received honoraria and/or consultation fees from AbbVie, AltruBio Inc, Almirall, AnaptysBio, Arena Pharmaceuticals, Aslan Pharmaceuticals, Bioniz Therapeutics, Bristol Myers Squibb, Concert Pharmaceuticals Inc, Equillium, Horizon Therapeutics, Eli Lilly and Company, Incyte Corp, Janssen Pharmaceuticals, LEO Pharma, Merck, Otsuka/Visterra Inc, Pfizer Inc, Q32 Bio Inc, Regeneron, Sanofi Genzyme, Sun Pharmaceutical, TWi Biotechnology Inc, Viela Bio, and Ventyx Biosciences Inc. He has served on speaker bureaus for AbbVie, Incyte, Eli Lilly, Pfizer, Regeneron, and Sanofi Genzyme. N.M. has provided professional services to AbbVie, Arena Pharmaceuticals, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly, La Roche-Posay, and Pfizer.

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## Author Contributions

Ernest H. Law, Lynne Napatalung, and Samuel H. Zwillich contributed conceptualization, methodology, data curation, formal analysis (supporting), investigation, writing – original draft, and writing – review and editing. Xingqi Zhang, Rodney Sinclair, Natasha Mesinkovska, and Brett King contributed data curation, formal analysis (supporting), investigation, and writing – review and editing. Fan Zhang contributed conceptualization, methodology, data curation, formal analysis (lead), investigation, and writing – review and editing.

## Data Availability Statement

The data that support the findings of this study are not publicly available for the protection of study participant privacy; however, upon request, and subject to review, Pfizer will provide the data that support the findings of this study. Subject to certain criteria, conditions and exceptions, Pfizer may also provide access to the related individual de-identified participant data. See <https://www.pfizer.com/science/clinical-trials/trial-data-and-results> for more information.

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