Distribution of SALT scores with ritlecitinib treatment up to 24 months from the ALLEGRO phase 2b/3 and long-term phase 3 clinical studies in alopecia areata

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BACKGROUND

- Alopecia areata (AA) is an autoimmune disease that has an underlying immuno-inflammatory pathogenesis and is characterized by non-scarring hair loss ranging from small patches to complete scalp, face, and/or body hair loss[1]
- Ritlecitinib, an oral JAK3/TEC family kinase inhibitor, demonstrated efficacy and safety up to 48 weeks in patients aged ≥12 years with AA in the ALLEGRO phase 2b/3 study (NCT03732807; "ALLEGRO-2b/3")[2]
- The long-term efficacy of ritlecitinib in patients who rolled over from ALLEGRO-2b/3 to the ongoing phase 3, open-label ALLEGRO-LT study (NCT04006457) has been reported in terms of the proportions of patients with Severity of Alopecia Tool (SALT) scores of ≤20 and ≤10 (≤20% or ≤10% scalp without hair) at Month 24[3]
- However, the distribution of SALT scores in the overall population, including patients not reaching the SALT score ≤20 and ≤10 thresholds, has not yet been described

OBJECTIVE

- This study describes changes in the distribution of SALT scores over 24 months of ritlecitinib treatment in the overall population and in age and disease severity subgroups

METHODS

Study design and patients

- Key inclusion criteria in ALLEGRO-2b/3:
  - Age ≥12 years
  - Diagnosis of AA with ≥50% scalp hair loss due to AA (including alopecia totalis [AT] and alopecia universalis [AU])
  - Maximum duration of current episode of hair loss ≤10 years
- This analysis includes patients who received ritlecitinib 50 mg once daily (QD) without a loading dose in ALLEGRO-2b/3 and who subsequently rolled over into ALLEGRO-LT where they continued to receive ritlecitinib 50 mg QD (**Figure 1**)
  - Continuation criteria for adolescents (aged 12-17 years) in ALLEGRO-LT: ≥50% improvement from baseline in SALT score by Month 3 for rollover patients from ALLEGRO-2b/3 and SALT score ≤20 by Month 6 in ALLEGRO-LT

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	
De novo group (n=447)					200 mg	50 mg

Combined ritlecitinib 50 mg group (N=191) [Groups C and G]

*Data while on placebo were not included in this analysis; data from patients in Groub G were rebaselined from the start of treatment with ritlecitinib.

Assessments and statistical analysis

- The distribution of patients according to SALT score (as observed) was assessed through Month 24 for the overall population and subgroups based on age (adults [≥18 years] vs adolescents [12-17 years]) and disease severity (patients with AT/AU vs those without AT/AU)
- The data cutoff date was December 9, 2022

RESULTS

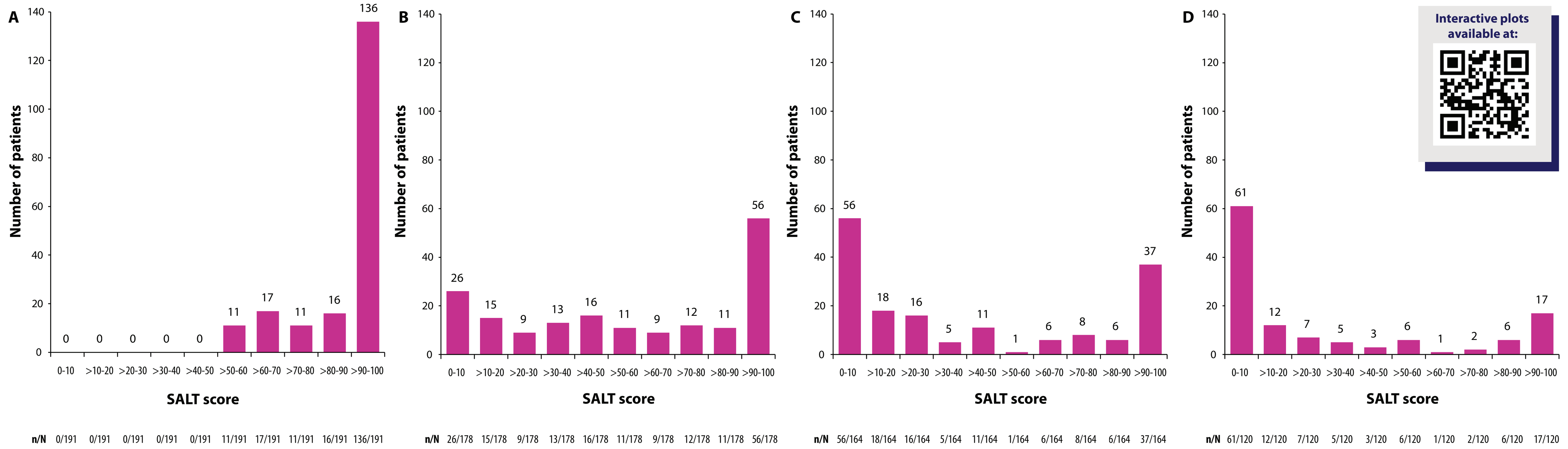
- The analysis included 191 patients (27 adolescents and 164 adults) (**Table 1**)
- At the time of data cutoff, 71 patients had discontinued; withdrawal by patient (n=19), adverse events (n=18), and lack of efficacy (n=14) were the most common reasons for discontinuation
- The distribution of participants by SALT score (as observed) at baseline, Month 12, and Month 24 are presented for the overall population (**Figure 2**) (Interactive dynamic plot)
- Per the inclusion criteria, all participants had a SALT score of ≥50 at baseline; 136/191 patients (71.2%) had SALT >90
- Among patients who had a nonmissing SALT score, 56/178 (31.5%), 37/164 (22.6%), and 17/120 (14.2%) were in the SALT >90-100 category at Months 6, 12, and 24, respectively
- Reductions in the number of patients in the other SALT >50 categories were observed from baseline through Month 24
- At Month 12, 56/164 (34.2%) and 18/164 (11.0%) patients were in the SALT 0-10 and >10-20 categories, respectively, with 61/120 (50.8%) and 12/120 (10.0%) patients in these categories at Month 24
- Among the patients with AT/AU at baseline, 18/69 (26.1%) and 6/69 (8.7%) were in the SALT 0-10 and >10-20 categories, respectively, at Month 12; 25/47 (53.2%) and 3/47 (6.4%) were in these categories, respectively, at Month 24 (**Figure 3**) (Interactive dynamic plot)
- For the adolescent participants, 10/22 (45.5%) and 4/22 (18.2%) were in the SALT 0-10 and >10-20 categories, respectively, at Month 12, and 11/14 (78.6%) and 0/14 (0%) were in these categories at Month 24 (**Figure 4**) (Interactive dynamic plot)

Table 1. Baseline demographic and disease characteristics in rollover patients treated with ritlecitinib 50 mg QD

	Ritlecitinib 50 mg QD (n=191)
Age, mean (SD), years	33.2 (14.4)
12-17 years, n (%)	27 (14.1)
≥18 years, n (%)	164 (85.9)
Female, n (%)	107 (56.0)
White, n (%)	123 (64.4)
BMI, mean (SD), kg/m²	24.9 (5.8)
AT, n (%)*	37 (19.4)
AU, n (%)*	41 (21.5)
Mean baseline SALT score (SD)	90.8 (14.1)
Baseline SALT score ≥50, n (%)	191 (100)
Abnormal EBA score at baseline, n (%)†	154 (80.6)
Abnormal ELA score at baseline, n (%)†	139 (72.8)
Duration of AA since diagnosis, mean (SD), years	9.8 (10.5)
Duration of current AA episode, mean (SD), years	3.3 (2.8)
Duration of significant (>50%) scalp hair loss, mean (SD), years	2.8 (2.7)
Prior pharmacological treatment for AA, n (%)	145 (75.9)
Comorbid conditions, n (%)	
Asthma	22 (11.5)
Autoimmune thyroiditis	11 (5.8)
Atopic dermatitis	31 (16.2)
Allergic rhinitis	20 (10.5)

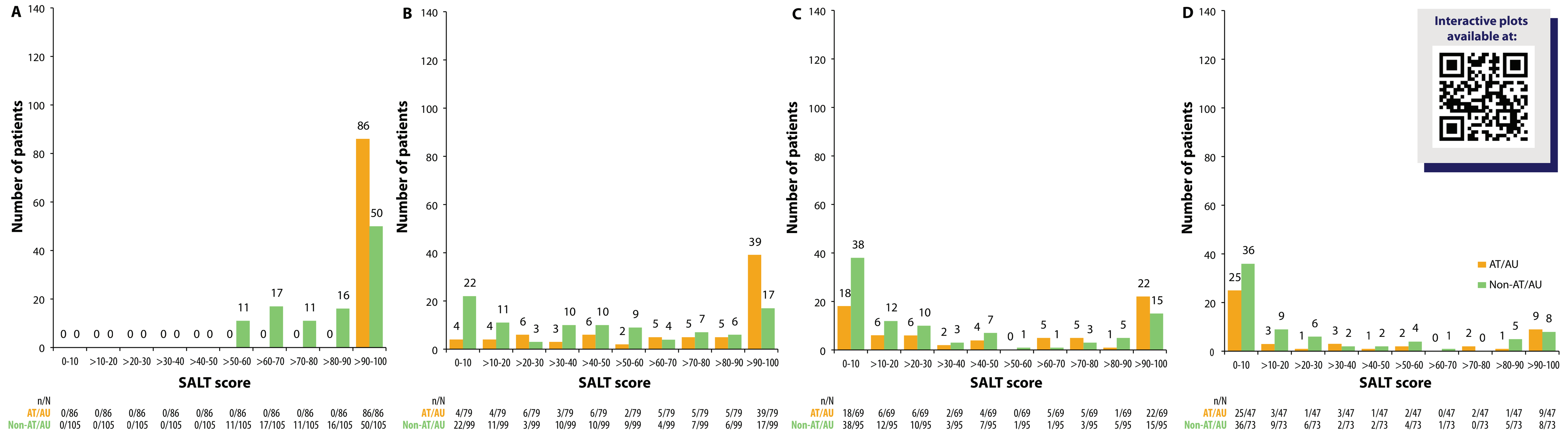
AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; BMI, body mass index; EBA, eyebrow assessment; ELA, eyelash assessment; QD, once daily; SALT, Severity of Alopecia Tool.
*Participants in the AT and AU categories had a SALT score of 100 (complete scalp hair loss) at baseline and a clinical diagnosis of AT or AU by the investigator. †An abnormal EBA or An abnormal EBA or ELA score was a score of 0 to 2 (no eyebrows/eyelashes to moderate eyebrows/eyelashes).

Figure 2. Distribution of SALT scores (as observed) at (A) baseline, (B) Month 6, (C) Month 12, and (D) Month 24 for patients receiving ritlecitinib 50 mg



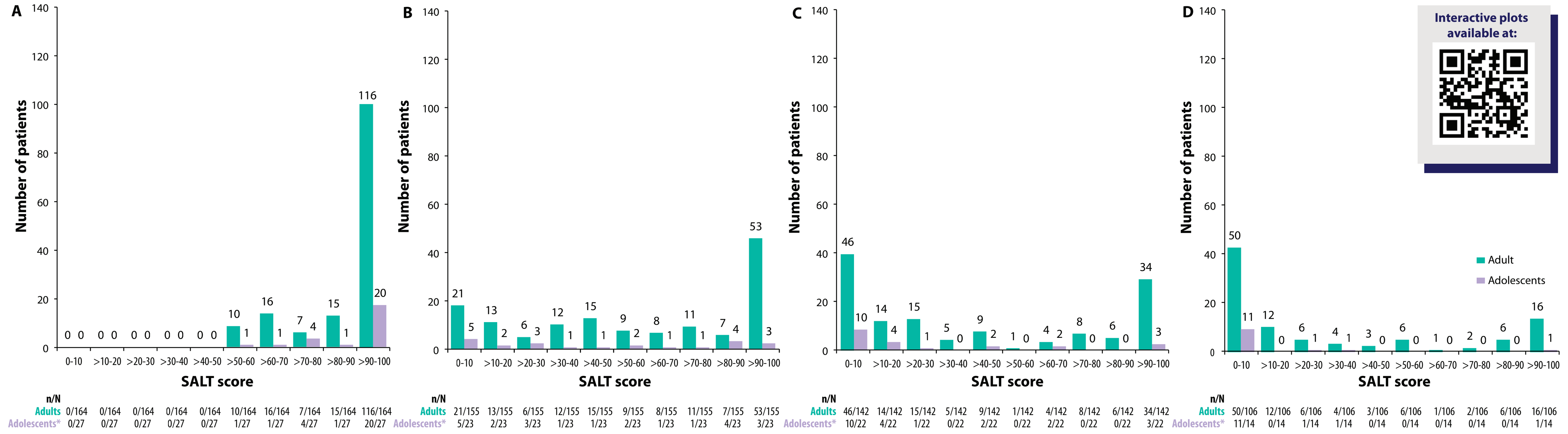
SALT, Severity of Alopecia Tool.

Figure 3. Distribution of SALT scores (as observed) at (A) baseline, (B) Month 6, (C) Month 12, and (D) Month 24 for patients receiving ritlecitinib 50 mg QD stratified by baseline non-AT/AU or AT/AU* status



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

Figure 4. Distribution of SALT scores (as observed) at (A) baseline, (B) Month 6, (C) Month 12, and (D) Month 24 for patients receiving ritlecitinib 50 mg QD stratified by adolescents and adults



SALT, Severity of Alopecia Tool.
*Patients in the adolescent category were aged 12-17 years.

CONCLUSIONS

- Over 24 months, daily treatment with ritlecitinib 50 mg resulted in fewer patients in the highest SALT score categories
- These data provide a comprehensive overview of patient response to ritlecitinib treatment and enable us to understand treatment response and time frames while on treatment with ritlecitinib
- This information can empower clinicians when counseling patients and managing treatment expectations based on patient characteristics
- This study also shows that response to treatment improves over time, which suggests that adequate time should be given when assessing treatment efficacy

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DISCLOSURES

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Z Reguiai has served as investigator, advisory board member, or speaker for AbbVie, Incyte, Lilly, Pfizer, and Sanofi. L Asfour has served as principal investigator for AbbVie, consultant for AbbVie, consultant and speaker for L'Oreal, and speaker for Pfizer; she is president of the British Hair and Nail Society and a member of Alopecia Areata Guidelines Development Group and Therapeutics & Guidelines BAD Subcommittee. D Staumont has served as an investigator and/or consultant and/or speaker for AbbVie, Almirall, Amgen, AstraZeneca, Eli Lilly, Galderma, GSK, Leo Pharma, Novartis, Pfizer, Sanofi-Regeneron, and UCB. AH Gelbard has served as principal investigator for Pfizer, investigator for Concert, investigator for Lilly, speaker for Lilly, and advisor and speaker for Pfizer. A Sechi received honoraria from Novartis, DS Laboratories, Cantabria Labs Difa Cooper, and Eli Lilly. D Wajsbrot, R Adejumo, D Woodworth, and A Lejeune are employees of Pfizer, Inc, and hold stock or stock options in Pfizer Inc.
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