RITLECITINIB

FAST FACTS

EXPLORE

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FAST FACTS

- Comparison of ritlecitinib's **efficacy** in patients with **different extents of hair loss** (including AT and AU)
- Comparison of the efficacy of ritlecitinib between patients with **longer or shorter AA episode durations**
- Most common **side effects** with ritlecitinib in the pivotal Phase IIb/III trial
- Association between **early eyebrow/ eyelash regrowth and subsequent scalp hair regrowth**
- Key drivers behind **physicians' therapy choices** in AA
- Consequences of **withdrawal** and **retreatment** with ritlecitinib
- **Laboratory parameters** following treatment with ritlecitinib
- Efficacy of ritlecitinib in **adolescent patients**
- **Long-term efficacy** of ritlecitinib
- **Long-term safety** of ritlecitinib
- What we know about ritlecitinib and **herpes zoster and opportunistic infections**
- Impact of hair **regrowth** on the **Patient Global Impression of Change** (PGI-C) **response**
- Impact of hair **regrowth** on **psychological** and **productivity measures**

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis.

COMPARISON OF RITLECITINIB'S EFFICACY IN PATIENTS WITH DIFFERENT EXTENTS OF HAIR LOSS (INCLUDING AT AND AU)

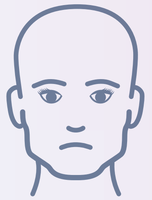
In the ALLEGRO Phase IIb/III clinical trial, ritlecitinib demonstrated efficacy in AA patients[a] with more than 50% SCALP hair loss[1,2]

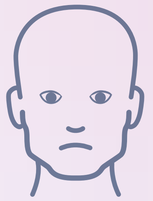
A *post hoc* analysis demonstrated clinical efficacy with ritlecitinib across all AA subgroups, including more extensive forms of AA (AT and AU)[1]

In the pivotal trial the primary endpoint was SALT score ≤20 at Week 24:[2]

- **Ritlecitinib 50 mg QD**
  23% achieved SALT score ≤20
- **Ritlecitinib 30 mg QD**
  14% achieved SALT score ≤20

% OF PATIENTS ACHIEVING SALT SCORE ≤20[1]





	WEEK	NON-AT/ NON-AU	AT	AU
RITLECITINIB 50 mg QD (n=130)	24	36.2	7.4	9.1
	48	52.9	22.2	40.9
RITLECITINIB 30 mg QD (n=132)	24	20.6	7.7	8.0
	48	45.3	19.2	11.5

[a]Aged 12 years older with more than 50% hair loss.

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; QD, once daily; SALT, Severity of Alopecia Tool.

1. Zhang X, et al. Poster #P0486 and Abstract #1511. Presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.
2. King B, et al. *Lancet*. 2023 [In Press, doi: 10.1016/S0140-6736(23)00222-2].

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COMPARISON OF RITLECITINIB'S EFFICACY IN PATIENTS WITH DIFFERENT EXTENTS OF HAIR LOSS (INCLUDING AT AND AU)

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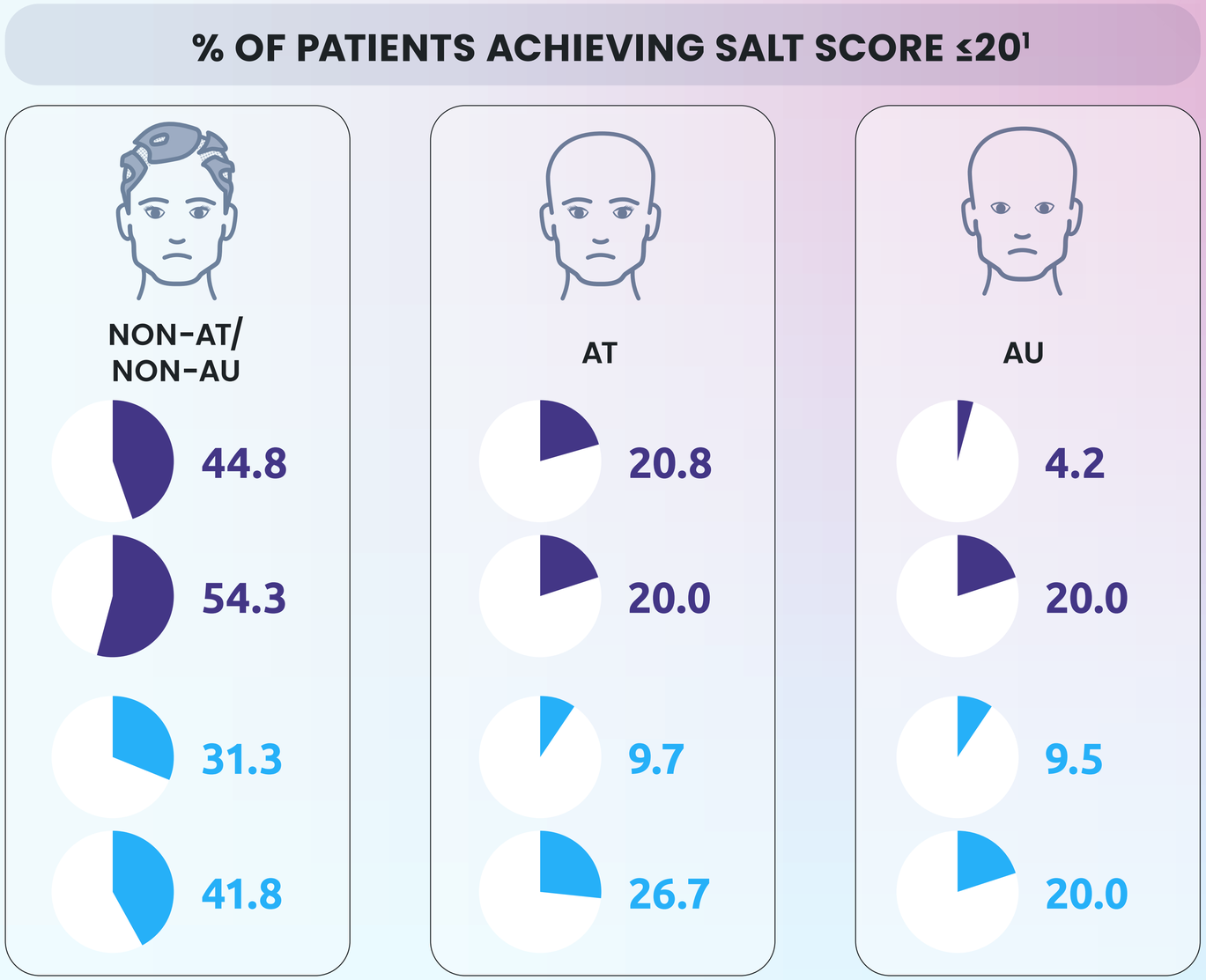
A *post hoc* analysis demonstrated clinical efficacy with ritlecitinib across all AA subgroups, including more extensive forms of AA (AT and AU)[1]

In the pivotal trial the primary endpoint was SALT score ≤20 at Week 24:[2]

- **Ritlecitinib 200/50 mg QD**
  31% achieved SALT score ≤20
- **Ritlecitinib 200/30 mg QD**
  22% achieved SALT score ≤20



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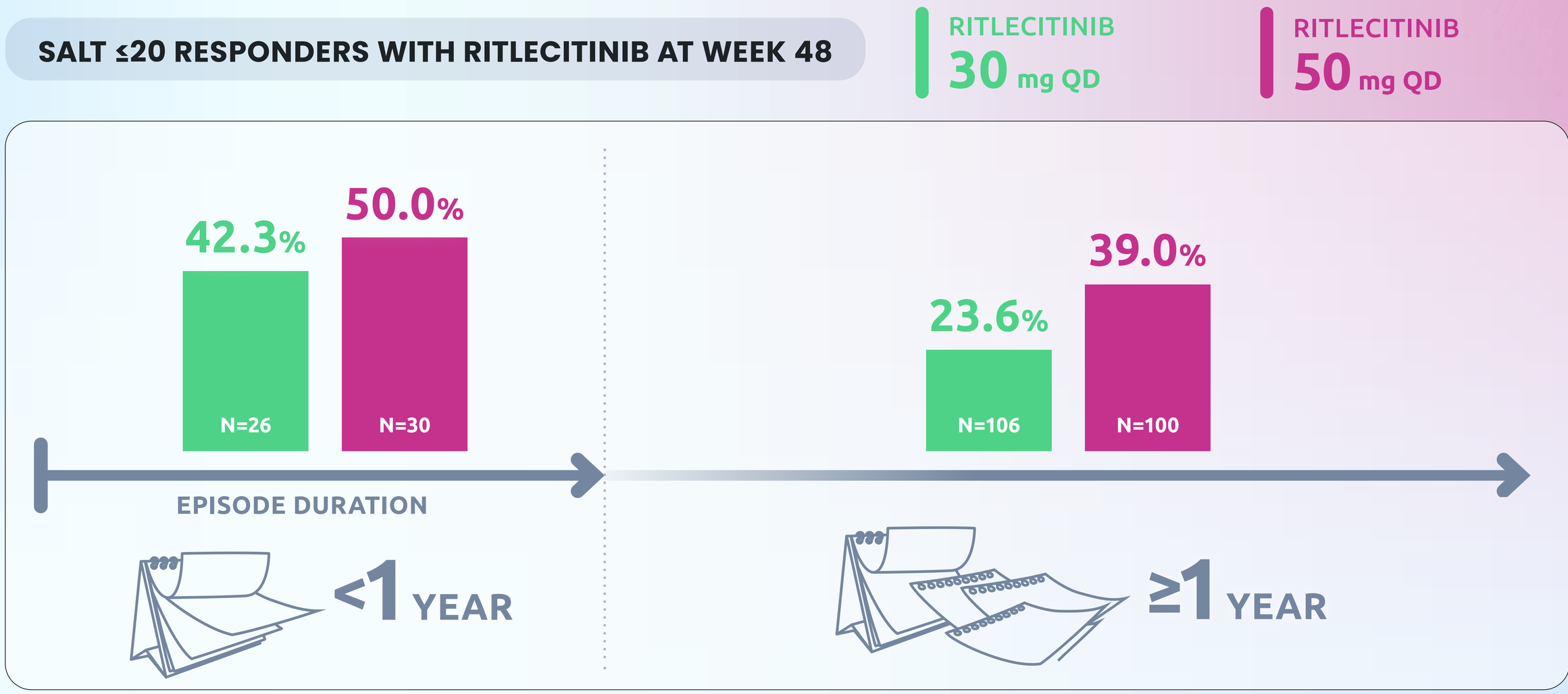
In a *post hoc* analysis of the ALLEGRO Phase IIb/III clinical trial,[a] ritlecitinib was shown to be efficacious in AA regardless of episode duration, however earlier treatment appeared to result in better outcomes

SALT ≤20 RESPONDERS WITH RITLECITINIB AT WEEK 48



[a]*Post hoc* analysis of the ALLEGRO Phase IIb/III trial to analyze the impact of disease and episode duration on response to ritlecitinib up to Week 48. At baseline, mean (range) duration of disease since initial diagnosis was 10.06 (0.04–60.11) years and duration of current AA episode was 3.35 (0.02–9.97) years; most patients had disease and episode duration ≥1 year; mean current AA episode 50 mg: 3.2 (2.67), 30 mg 3.6 (2.82). Patients had a current AA episode duration of 6 months to 10 years. Baseline SALT score mean (SD) was: ritlecitinib 50 mg, 90.3 (14.7); ritlecitinib 30 mg, 90.0 (15.1). Proportions of patients with AT/AU was 46.2% in those treated with 50 mg ritlecitinib and 46.2% in those treated with 30 mg ritlecitinib.

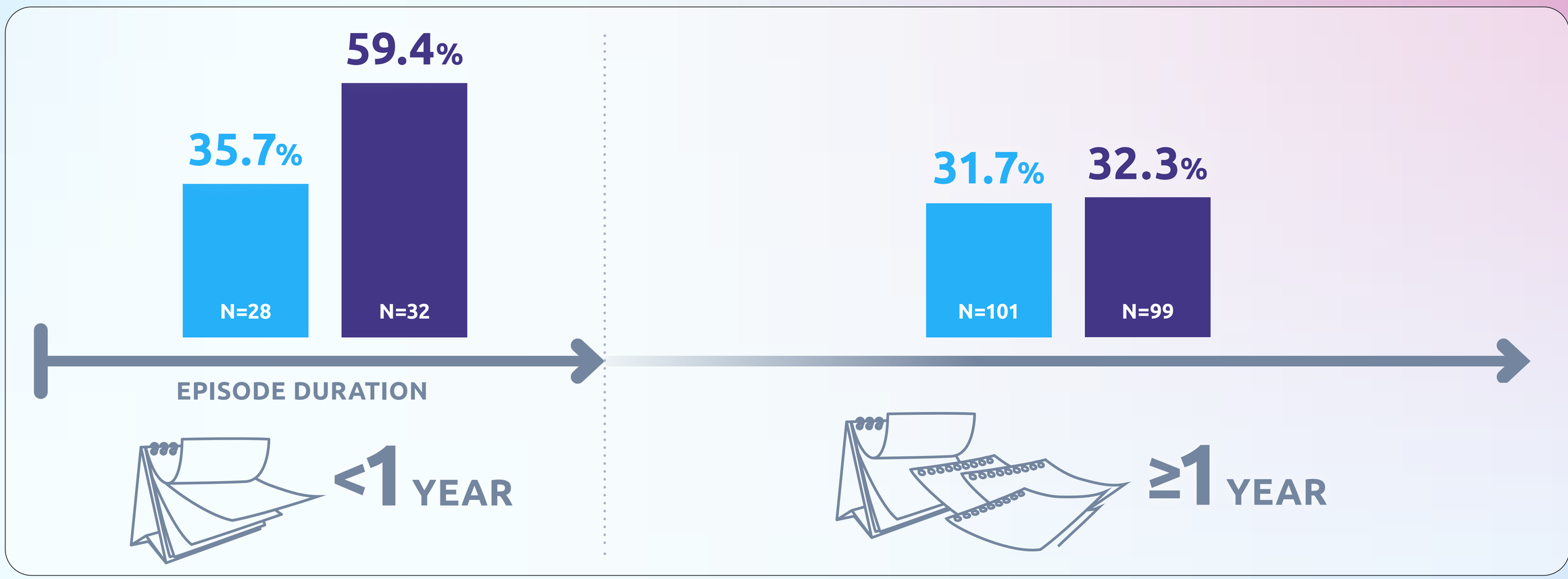
AA, alopecia areata; QD, once daily.

King B, et al. Poster #P0485. Presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

COMPARISON OF THE EFFICACY OF RITLECITINIB BETWEEN PATIENTS WITH LONGER OR SHORTER AA EPISODE DURATIONS

In a *post hoc* analysis of the ALLEGRO Phase IIb/III clinical trial,[a] ritlecitinib was shown to be efficacious in AA regardless of episode duration, however earlier treatment appeared to result in better outcomes

SALT ≤20 RESPONDERS WITH RITLECITINIB AT WEEK 48



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King B, et al. Poster #P0485. Presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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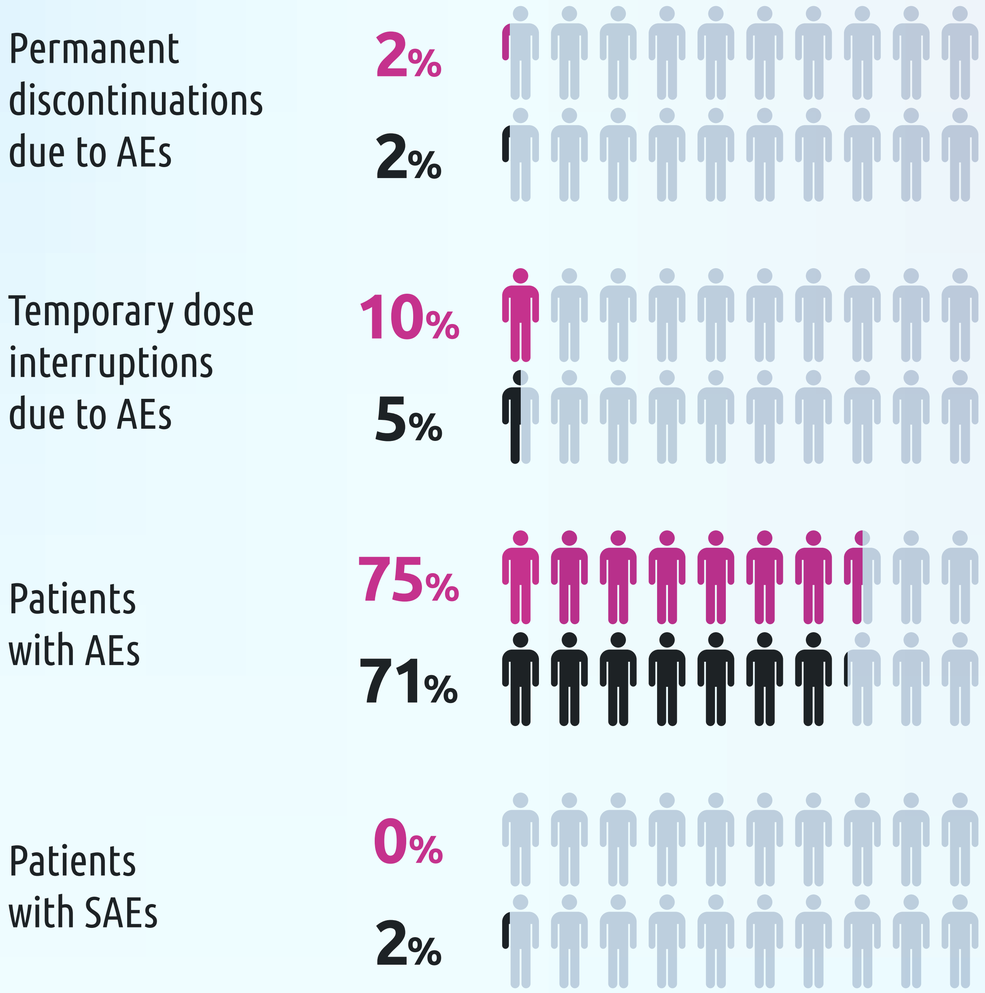
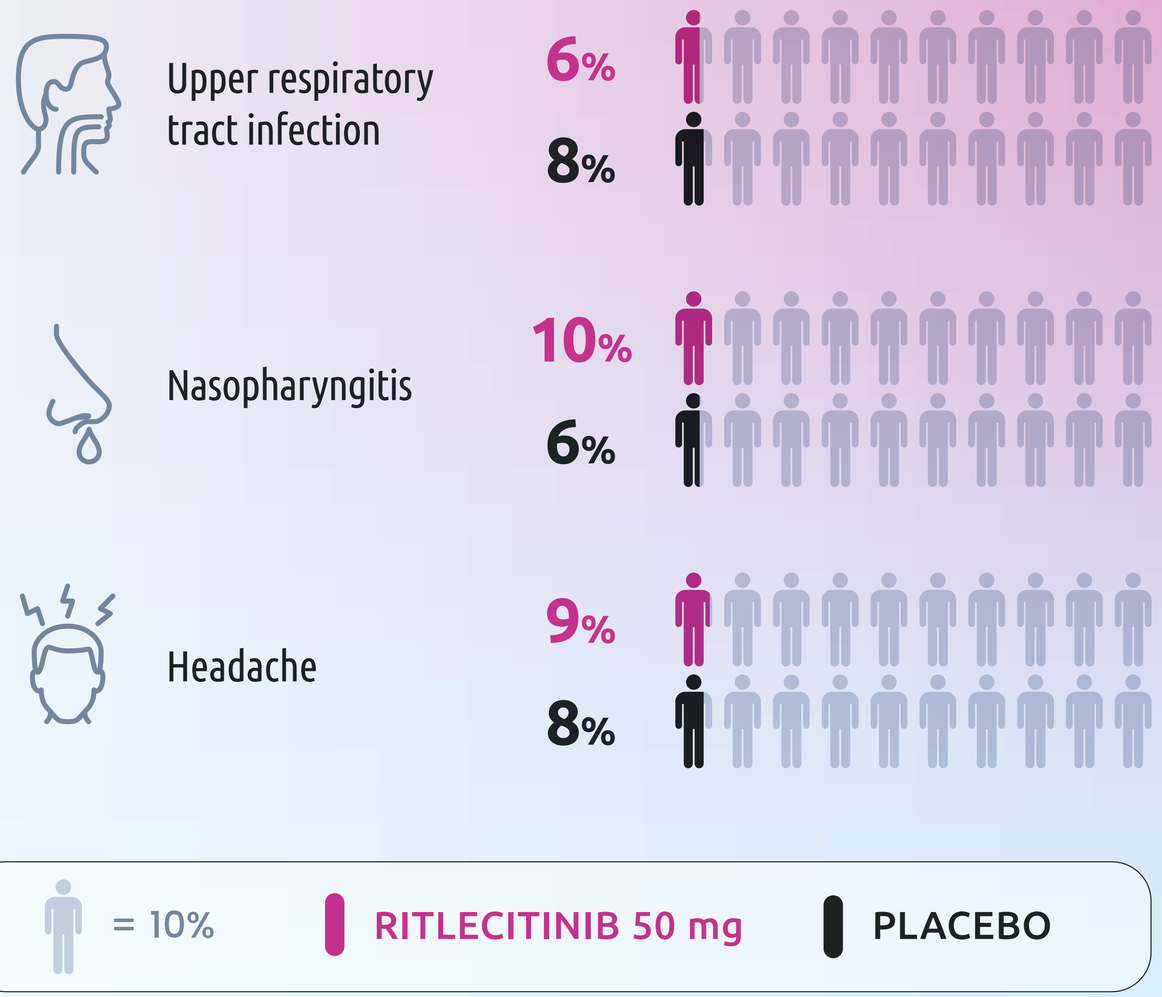
MOST COMMON SIDE EFFECTS WITH RITLECITINIB IN THE PIVOTAL PHASE IIB/III TRIAL

In an analysis of patients aged ≥12 years, with a diagnosis of AA with SALT score ≥50, the most common adverse events associated with ritlecitinib 50 mg were upper respiratory tract infection, nasopharyngitis, and headache

SUMMARY OF AEs UP TO WEEK 24 vs. PLACEBO



AEs OCCURRING IN ≥10% OF PATIENTS vs. PLACEBO[a]



[a]Individual AEs (by preferred term) occurring in ≥10% of patients in treatment group during the indicated period.

AA, alopecia areata; AE, adverse event; SAE, severe adverse event; SALT, Severity of Alopecia Tool.

King B, et al. *Lancet*. 2023 [In Press, doi: 10.1016/S0140-6736(23)00222-2].

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LABORATORY PARAMETERS FOLLOWING TREATMENT WITH RITLECITINIB

The interim results of a long-term, open-label Phase III trial of ritlecitinib in AA[a] demonstrated no clinically relevant median changes from baseline in hematological parameters, and no patients met discontinuation criteria for neutrophils, lymphocytes, platelets, AST, ALT, or CK

ANEMIA

<8.0 G/dL:

0.2%

LIPID LEVELS

0.0%

No clinically relevant changes over time

LABORATORY TEST ABNORMALITIES

1.8%

AST >3x ULN

2.3%

ALT >3x ULN

13.5%

CK >2x ULN

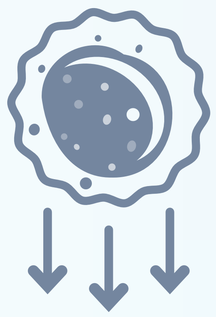
NEUTROPHIL COUNT DECREASED[b]

CTCAE

Grade 3: **0.9%**

Grade 4: **0.0%**

LYMPHOCYTE COUNT DECREASED[c]



CTCAE

Grade 3: **1.6%**

Grade 4: **0.0%**

[a]Interim results from *de novo* participants treated with ritlecitinib 200/50 mg QD (safety analysis set; N=447) from ALLEGRO-LT (NCT04006457), an ongoing Phase III study investigating the long-term safety and efficacy of ritlecitinib in patients with AA. [b]CTCAE Grade 3: <1000–500 cells/mm^3, Grade 4: <500 cells/mm^3. [c]CTCAE Grade 3: <500–200 cells/mm^3, Grade 4: <200 cells/mm^3.

AA, alopecia areata; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CK, creatine kinase; CTCAE, Common Terminology Criteria for Adverse Events; Hb, hemoglobin; QD, once daily; ULN, upper limit of normal.

Sinclair R, et al. Oral presentation at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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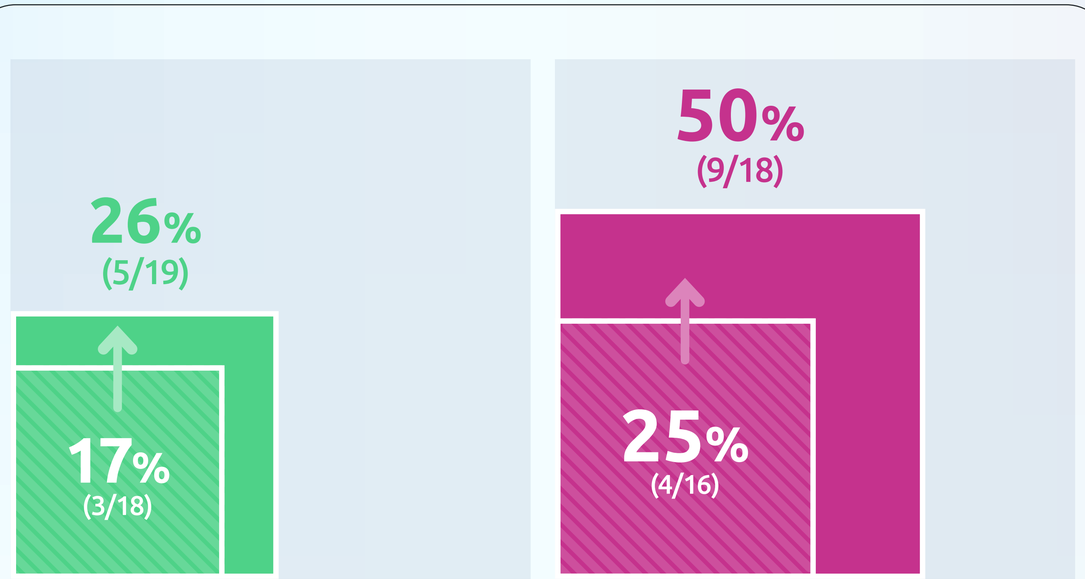
In a *post hoc* analysis of the ALLEGRO Phase IIb/III clinical trial,[a] ritlecitinib was shown to be efficacious in adolescents aged 12–17 years with extensive AA

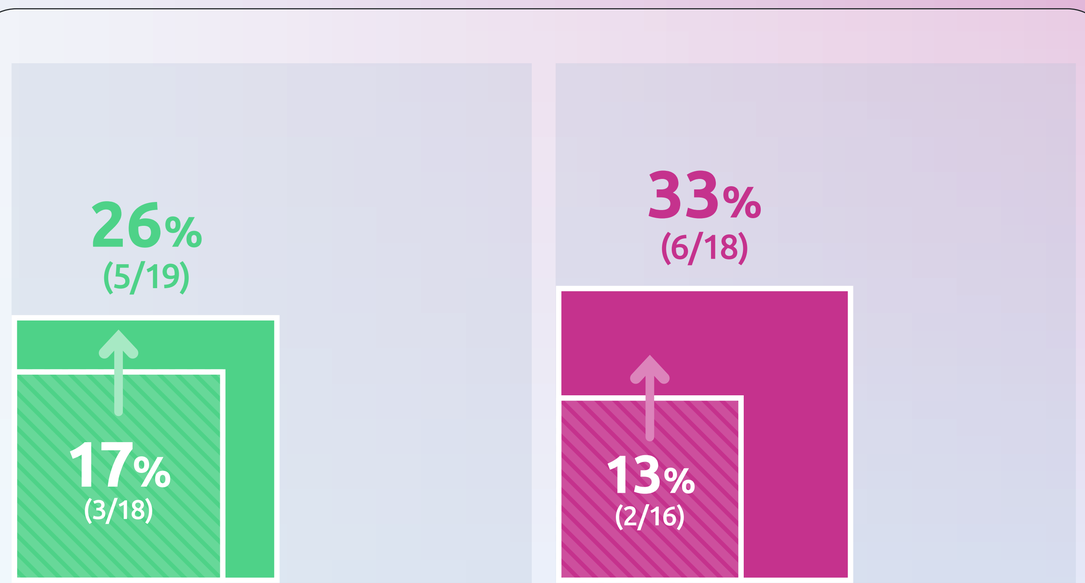
RITLECITINIB **30** mg QD — WEEK 24 — WEEK 48

RITLECITINIB **50** mg QD — WEEK 24 — WEEK 48

% PATIENTS ACHIEVING SALT ≤20



% PATIENTS ACHIEVING SALT ≤10



No patients in the placebo groups achieved SALT ≤20 or SALT ≤10 at Week 24

[a]A *post hoc* analysis of ALLEGRO IIb/III that assessed efficacy and safety of ritlecitinib up to 48 weeks in patients aged ≥12 years with a diagnosis of AA and ≥50% scalp hair loss (including patients with AT and AU) and a current AA episode duration of 6 months to 10 years. The *post hoc* analysis focused on the adolescent population aged 12–17 years. Number of patients with valid data in the ritlecitinib 30 mg QD and 50 mg QD groups, respectively: Week 24, n=18 and n=16; Week 48, n=19 and n=18.

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis; QD, once daily; SALT, Severity of Alopecia Tool.

Hordinsky M, et al. Poster presented at the 47th Annual Meeting of the Society for Pediatric Dermatology; July 7–10, 2022; Indianapolis, IN, USA.

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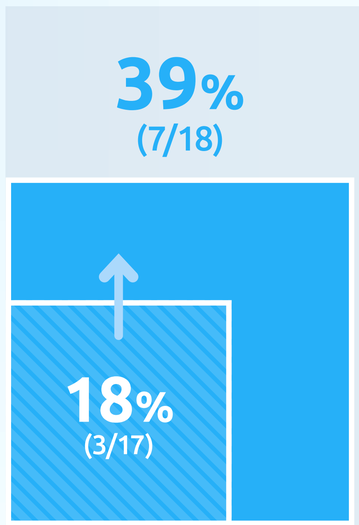
EFFICACY OF RITLECITINIB IN ADOLESCENT PATIENTS

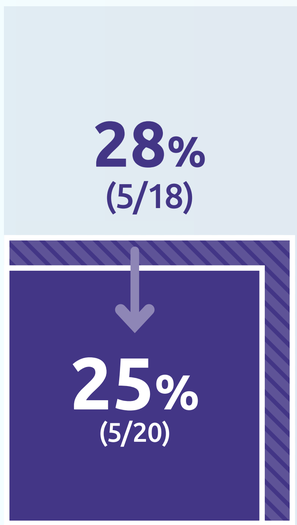
In a *post hoc* analysis of the ALLEGRO Phase IIb/III clinical trial,[a] ritlecitinib was shown to be efficacious in adolescents aged 12–17 years with extensive AA

RITLECITINIB **200/30 mg QD** — WEEK 24 — WEEK 48

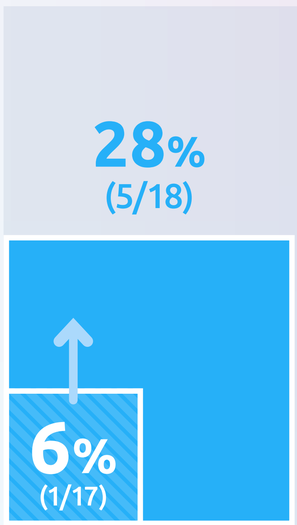
RITLECITINIB **200/50 mg QD** — WEEK 24 — WEEK 48

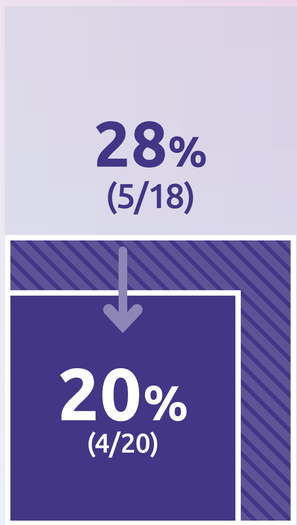
% PATIENTS ACHIEVING SALT ≤20





% PATIENTS ACHIEVING SALT ≤10





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Hordinsky M, et al. Poster presented at the 47th Annual Meeting of the Society for Pediatric Dermatology; July 7–10, 2022; Indianapolis, IN, USA.

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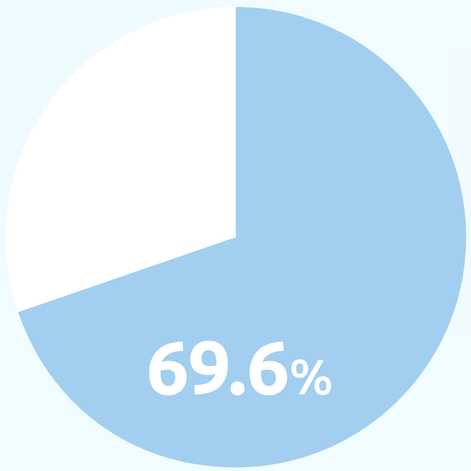
Data from an interim analysis at Month 24 of a long-term, open-label Phase III trial of ritlecitinib in AA[a] reveal SALT score and PGI-C responses similar to those achieved in the pivotal ALLEGRO Phase IIb/III clinical trial

RESPONSES WITH RITLECITINIB 200/50 MG QD AT MONTH 24 IN THE *DE NOVO* POPULATION OF ALLEGRO-LT (N=447)[a,b]

% of patients achieving scalp hair regrowth as defined by

SALT ≤20[c]

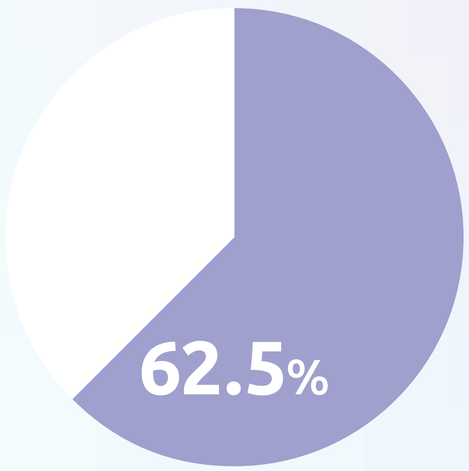
n/N=39/56



% of patients achieving scalp hair regrowth as defined by

SALT ≤10[c]

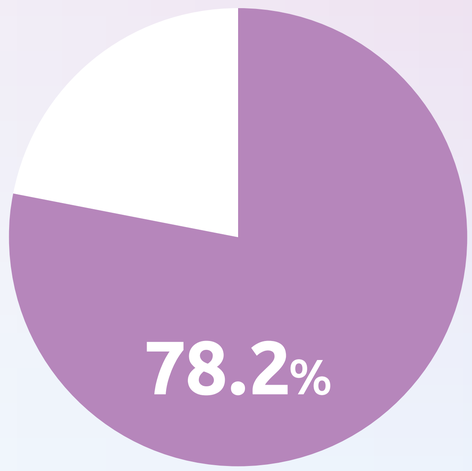
n/N=35/36



% of patients reporting a moderate or great improvement in their disease as measured by

PGI-C response[d]

n/N=43/55



Percentages are based on the number of patients with observed data.

[a]ALLEGRO-LT is an open-label, multicenter, long-term study that enrolled patients into two arms: (1) roll-over patients who had received study intervention in either the ALLEGRO Phase IIa study (NCT02974868) or Phase IIb/III study (NCT03732807), and (2) *de novo* patients who had not received treatment in either study. Interim results for the *de novo* cohort are reported here. [b]Patients received an initial 4-week, open-label loading dose of ritlecitinib 200 mg QD, followed by ritlecitinib 50 mg QD. [c]Achievement of SALT score ≤20 (≤20% scalp without hair) or SALT score ≤10 (≤10% scalp without hair). [d]The PGI-C is a patient-reported outcome measure that quantifies the patient's global impression of the change in their disease. A PGI-C response was defined as patients who reported their AA as "moderately improved" or "greatly improved".

AA, alopecia areata; PGI-C, Patient Global Impression of Change; QD, once daily; SALT, Severity of Alopecia Tool.

Sinclair R, et al. Abstract 3454 presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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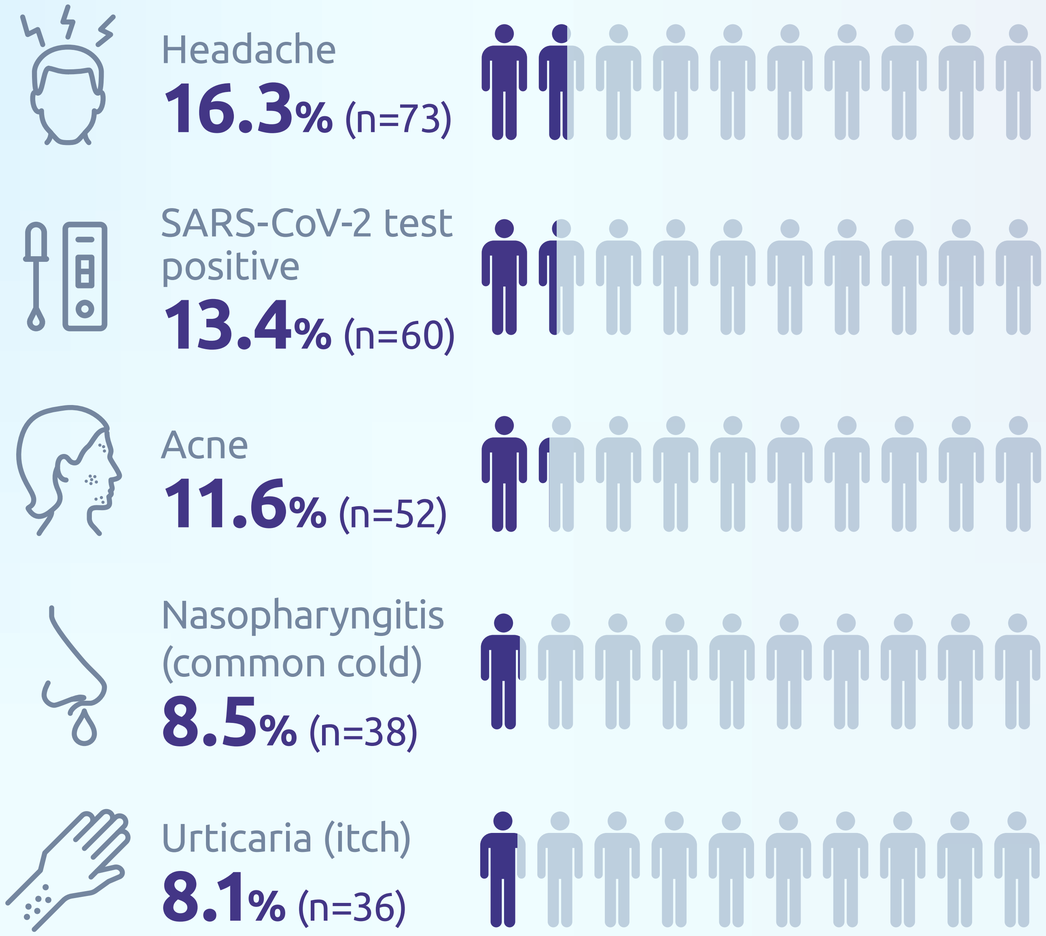
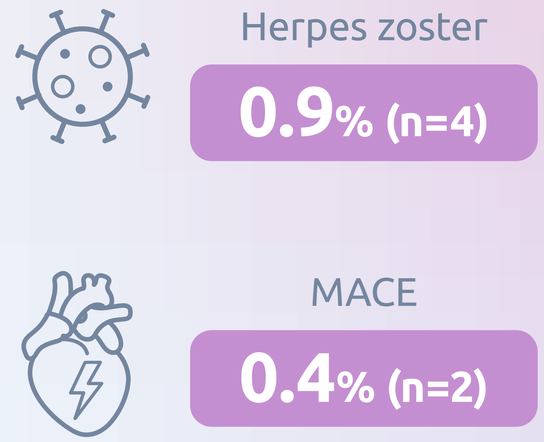
In an interim analysis of a long-term, open-label Phase III trial of ritlecitinib in AA,[a] ritlecitinib was generally well tolerated with most AEs being mild to moderate in severity

TOP FIVE MOST COMMON TEAEs

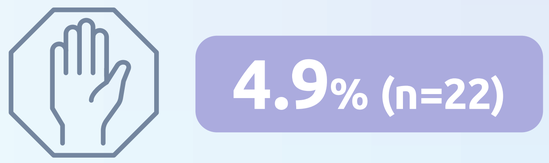
= 10%



AEs OF SPECIAL INTEREST



DISCONTINUATIONS DUE TO AEs



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AA, alopecia areata; AE, adverse event; MACE, major adverse cardiovascular events; QD, once daily; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; TEAE, treatment-emergent AE.

Sinclair R, et al. Abstract 3454 presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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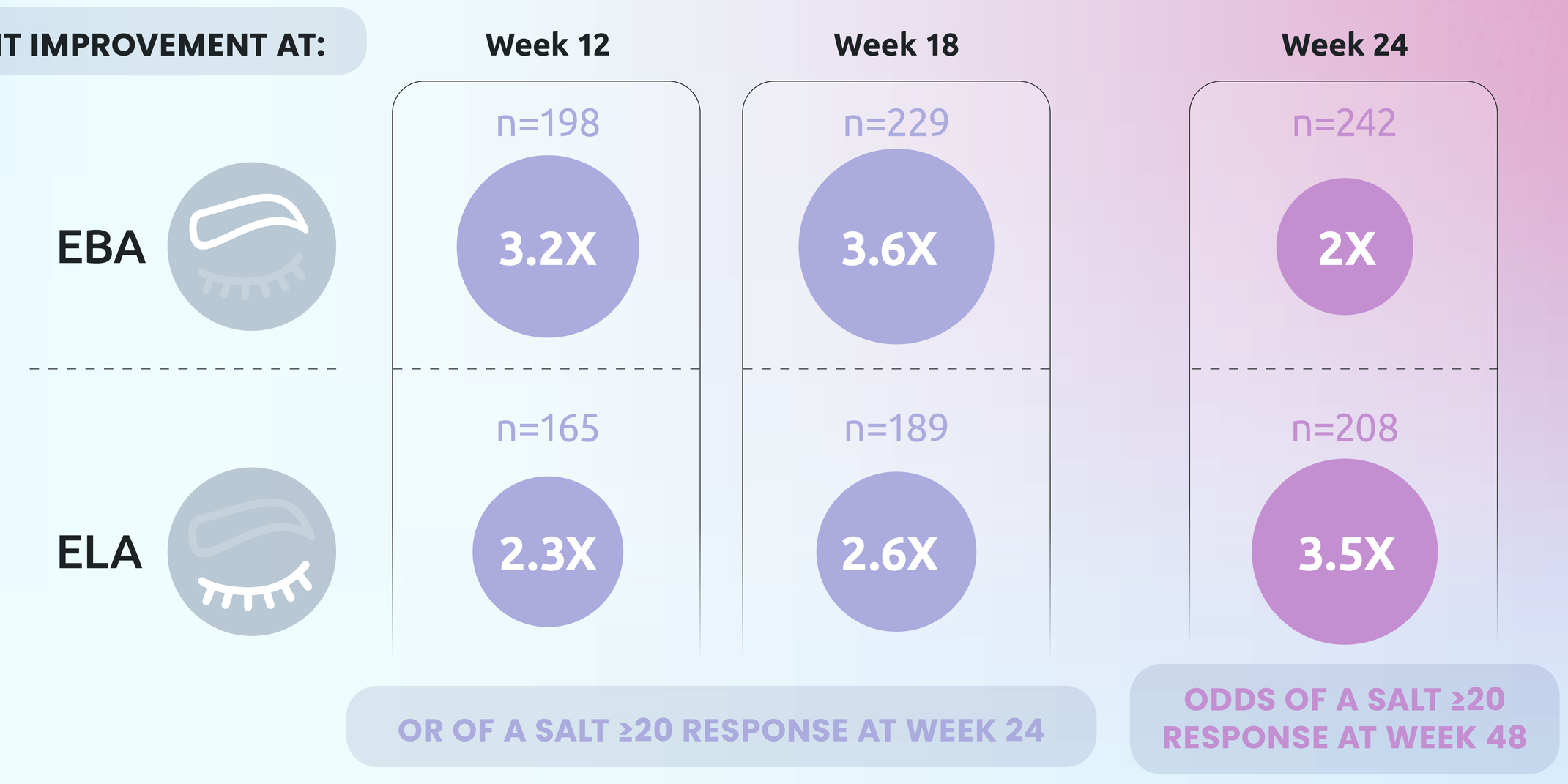
Data from a *post hoc* analysis of the ALLEGRO Phase IIb/III clinical trial[a] suggest that early ≥1-point improvements in EBA/ELA with ritlecitinib are associated with a higher likelihood of subsequent scalp hair regrowth



[a]A *post hoc* analysis of ALLEGRO IIb/III was conducted to investigate whether ≥1-point eyebrow and eyelash improvements were associated with scalp hair regrowth. The analysis included patients (n=442) who were initially randomized to receive ritlecitinib 200/50, 200/30, 50, or 30 mg and had baseline EBA or ELA of 0 to 2 (no to moderate eyebrows/eyelashes). Using ≥1-point improvements in EBA and ELA as 2 of 14 demographic and alopecia-related covariates evaluated, multivariable logistic and linear regressions using a stepwise method were used to evaluate the outcomes of SALT ≤20.

AA, alopecia areata; EBA, eyebrow assessment; ELA, eyelash assessment; OR, odds ratio; SALT, Severity of Alopecia Tool.

Holmes S, et al. Abstract 501 presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September, 2022; Milan, Italy.

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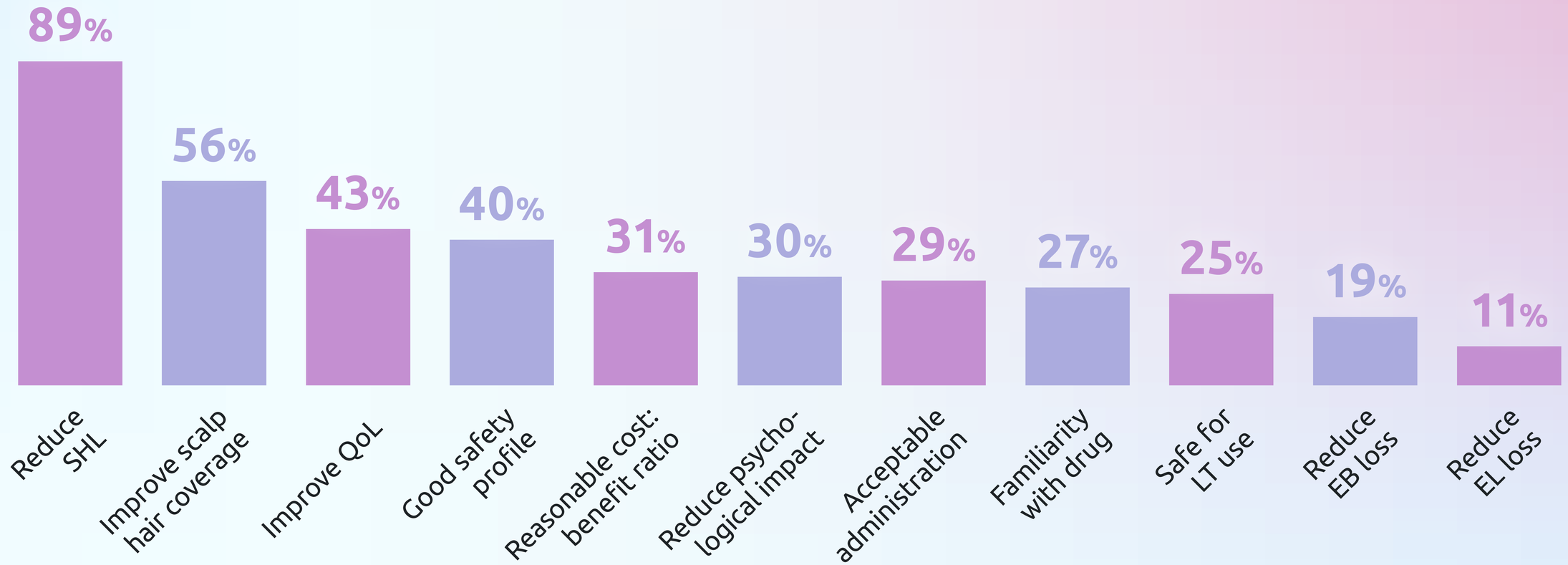
KEY DRIVERS BEHIND PHYSICIANS' THERAPY CHOICES IN AA

According to a survey of dermatologists, the key drivers for them choosing an AA treatment include reducing scalp hair loss, improving scalp hair coverage, improving patient quality of life, and having a favorable safety profile

PHYSICIANS' REASONS FOR CHOOSING TREATMENTS FOR THEIR PATIENTS[a,b]



[a]Results from a real-world study using data from the 2021 Adelphi AA Disease Specific Programme, a survey of dermatologists and their adult AA patients in France, Germany, Italy, Spain, and the United Kingdom. The analysis included 1,720 patients with AA. [b]Results displayed for all patients regardless of level of SHL.

AA, alopecia areata; EB, eyebrow; EL, eyelash; LT, long term; QoL, quality of life; SHL, scalp hair loss.

Anderson P, et al. Poster 1075 presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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In the SBE period of the ALLEGRO IIa study, after ritlecitinib withdrawal, patients with AA who had previously achieved $SALT_{30}$[a,b] experienced improved SALT scores during retreatment but not all patients regained this initial hair regrowth response[c]

22 PATIENTS IN THE RITLECITINIB GROUP ACHIEVED $SALT_{30}$ AT WEEK 24 OF THE DBP OF THE ALLEGRO IIa TRIAL AND HAD THEIR TREATMENT WITHDRAWN

OF THESE, 14 (64%) PATIENTS MET THE RETREATMENT CRITERION (loss of >30% of hair regrown during the DBP)

OF THESE, 8 PATIENTS (57%) ACHIEVED $SALT_{30}$ AT WEEK 24 OF THE SBE

[a]$SALT_{30}$ at Week 24 was an efficacy endpoint of the double-blind Phase IIa ALLEGRO clinical trial. [b]Patients who achieved $SALT_{30}$ at Week 24 of the DBP of the ALLEGRO Phase IIa study were eligible to enter a SBE period in which treatment was withdrawn until >30% of the hair regrown during the DBP was lost. Treatment was with the same dosing regimen as in the DBP (200 mg of ritlecitinib once daily for four weeks, followed by 50 mg of ritlecitinib once daily for 20 weeks) then reinitiated for 24 weeks to assess hair regrowth after withdrawal. [c]The study was not statistically powered to confirm that the efficacy of retreatment following withdrawal was decreased as compared to initial response in the DBP.

AA, alopecia areata; DBP, double-blind period; SALT, Severity of Alopecia Tool; $SALT_{30}$, ≥30% improvement in SALT score, or ≥30% hair regrowth compared with baseline; SBE, single-blind extension.

Peeva E, et al. *J Am Acad Dermatol.* 2022;87(2):390–3.

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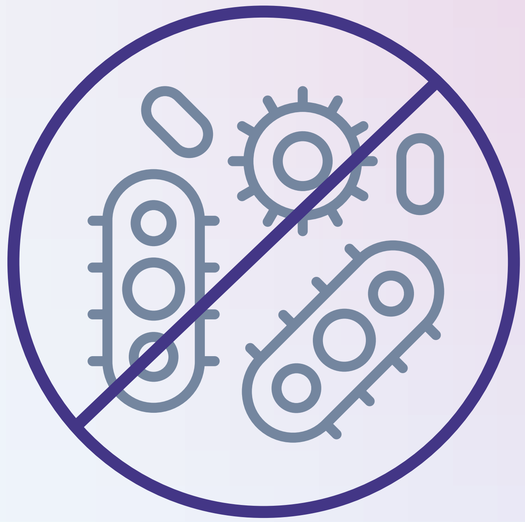
At Month 24 of an interim analysis of a long-term, open-label Phase III trial of ritlecitinib in AA,[a] all events of herpes zoster were mild or moderate, none were disseminated, and no opportunistic infections occurred[a]

4/447 **(0.9%)**
of patients treated with ritlecitinib had herpes zoster infections

0 disseminated

0 serious



0 opportunistic infections

[a]Interim results from *de novo* participants treated with ritlecitinib 200/50 mg QD (safety analysis set; N=447) from ALLEGRO-LT (NCT04006457), an ongoing Phase III study investigating the long-term safety and efficacy of ritlecitinib in patients with AA.

AA, alopecia areata; QD, once daily.

Sinclair R, et al. Abstract 3454 and oral presentation presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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IMPACT OF HAIR REGROWTH ON THE PATIENT GLOBAL IMPRESSION OF CHANGE (PGI-C) RESPONSE

In the ALLEGRO Phase IIb/III trial in AA, patients who experienced hair regrowth as defined by SALT ≤20 response at Week 24 were more likely [than SALT >20 non-responders] to report improvements in their disease as defined by PGI-C[a]

% OF PATIENTS WHO REPORTED 'MODERATE' OR 'GREAT' IMPROVEMENTS IN THEIR DISEASE AT WEEK 24 AS MEASURED BY THE PGI-C RESPONSE:

SALT ≤20 (responders) at Week 24

97.4%
(111/114)[b]

SALT >20 (non-responders) at Week 24

26.9%
(144/535)[b]

[a]*Post hoc* analysis of the ALLEGRO randomized, double-blind, placebo-controlled, dose-ranging Phase IIb/III study. [b]This is from the ALLEGRO Phase IIb/III study design diagram where it is (n) with N=718.
AA, alopecia areata; PGI-C, Patient Global Impression of Change; SALT, Severity of Alopecia Tool.
Law EH, et al. Poster #P1062 [and supplemental data] presented at the 31st Congress of the European Academy of Dermatology and Venereology (EADV). 7–10 September 2022; Milan, Italy.

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IMPACT OF HAIR REGROWTH ON PSYCHOLOGICAL AND PRODUCTIVITY MEASURES

In a *post hoc* analysis of the ALLEGRO Phase IIb/III trial in AA, patients who achieved a SALT ≤20 response were more likely to report improvements in mental health, psychosocial, and emotional aspects of HRQoL, and in work productivity[a]

AT WEEK 24, COMPARED WITH NON-RESPONDERS, SALT ≤20 RESPONDERS….

…showed greater mean improvement in change from baseline in **SF-36 mental component summary scores**
(2.3 [95% CI: 0.5, 4.0] vs. -0.3 [95% CI: -0.9, 0.4])

Social functioning	**General mental health**
Role emotional	**Vitality**

…showed greater mean improvement in HADS Anxiety score
(-1.1 [95% CI: -1.7, -0.5] vs. -0.5 [95% CI: -0.8, -0.3])

…reported greater mean improvements from baseline in the WPAI-AA in:

- **Overall Work Impairment**
  -5.00 (-10.50 to 0.50) vs. -1.20 (-3.20 to 0.90)
- **Presenteeism**
  -5.60 (-11.10 to -0.10) vs. -1.30 (-3.40 to 0.80)
- **Activity Impairment**
  -8.40 (-13.10 to -3.70) vs. -4.00 (-6.30 to -1.80)

…had larger mean changes from baseline for the **4 Hair Loss items and the Emotional Symptoms items of the AAPPO**

Hair Loss items

1. SCALP **-2.2** vs. **-0.6**
2. EYEBROWS **-1.4** vs. **-0.6**
3. EYELASHES **-1.0** vs. **-0.4**
4. BODY **-0.9** vs. **-0.4**

Emotional Symptoms domain

5. SELF-CONSCIOUS **-1.2** vs. **-0.6**
6. EMBARRASSED **-1.2** vs. **-0.5**
7. SAD **-1.2** vs. **-0.4**
8. FRUSTRATED **-1.1** vs. **-0.3**

[a]*Post hoc* analysis of the ALLEGRO randomized, double-blind, placebo-controlled, dose-ranging Phase IIb/III study. N=718; Dosing (4 weeks loading/30 weeks maintenance/24 weeks extension): 200 mg/50 mg/50 mg (n=132); 200 mg/30 mg/30 mg (n=130); 50 mg/50 mg/50 mg (n=130); 30 mg/30 mg/30 mg (n=132); 10 mg/10 mg/10 mg (n=63); PBO/PBO/(ext: 200 mg/50 mg) (n=65); PBO/PBO/50 mg (n=66).

AA, alopecia areata; AAPPO, Alopecia Areata Patient Priority Outcomes; CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; HRQoL, health-related quality of life; SALT, Severity of Alopecia Tool; SF-36, 36-Item Short Form Health Survey; WPAI-AA, Work Productivity Activity Index–Alopecia Areata.

Law EH, et al. Poster #P1062 presented at the 31st EADV Congress; 7–10 September 2022; Milan, Italy.

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