Distribution of SALT scores by therapeutic response in patients with severe alopecia after 52 weeks of baricitinib therapy

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OBJECTIVE

- To report the distribution of SALT scores across the spectrum of therapeutic response in patients with severe alopecia areata (AA) who were treated with baricitinib in the BRAVE-AA1 and BRAVE-AA2 clinical trials.

BACKGROUND

- Baricitinib is an oral selective JAK inhibitor that has demonstrated efficacy versus placebo to regrow scalp hair, eyebrows, and eyelashes in patients with severe AA in the phase 3 trials BRAVE-AA1 and -AA2.[1,2]
- The safety profile across indications including rheumatoid arthritis, atopic dermatitis, and AA, is well-characterized.[3]
- Clinical trial response criteria were defined as achievement of SALT score ≤20 (80% scalp coverage) by weeks 36 and 52. However, the distribution of absolute SALT scores across patients who do not meet this response threshold have not been described.
- The treatment benefit and distribution of SALT scores at Week 52 across the spectrum of responders are reported here.

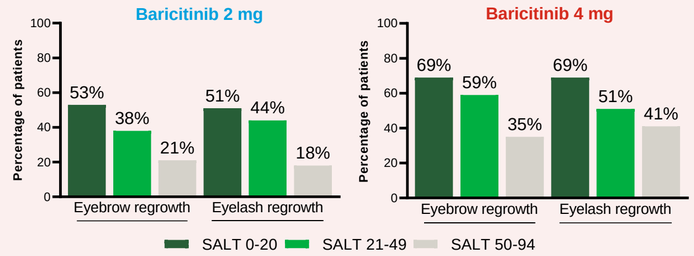
KEY FINDINGS

Over half of patients achieved improved* SALT scores at Week 52 regardless of baseline severity

Baseline SALT score	SALT 50-94 (N=245) (Non-AT)	SALT 95-100 (N=263) (Consistent with AT)
2 mg	67% Improved (95/142)	54% Improved (102/189)
4 mg	80% Improved (195/245)	67% Improved (175/263)

*Improvement from baseline SALT category; patients with severe disease (SALT 50-94) at baseline achieving SALT 0-49 or patients with very severe disease (SALT 95-100) at baseline achieving SALT 0-94

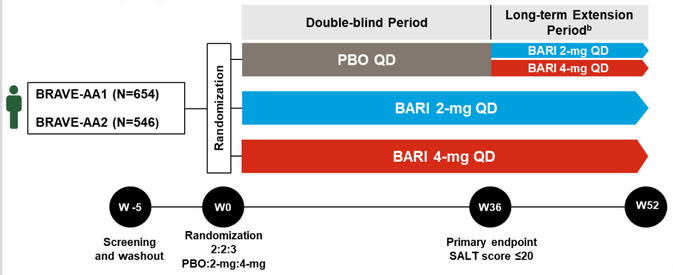
Meaningful regrowth of eyebrows and eyelashes was observed at Week 52 regardless of scalp regrowth (ITT population)



CONCLUSIONS

- While a significant proportion of patients treated with baricitinib 2 mg and 4 mg achieved clinically meaningful response goal of SALT ≤20 (80% scalp coverage), a substantial proportion of additional patients demonstrated movement towards improvement.
- Proportion of patients improved from baseline SALT category was higher among those with lower baseline severity.
- Patients across the treatment spectrum demonstrated clinically meaningful regrowth of eyebrows and eyelashes.
- These data provide a broader view of the continuum of patient responses observed among baricitinib-treated patients with severe AA.

METHODS



Key Eligibility Criteria

- Male or female ≥18 years old; ≤60 years for males and ≤70 years for females[a]
- Hair loss involving ≥50% of the scalp, as measured by SALT
- Current episode of AA >6 months to <8 years[b]
- No spontaneous improvement in the 6 months prior to screening

[a]Upper age limits were based on sex differences in the prevalence and severity of androgenetic alopecia and were included to limit the potential impact on AA assessment; [b]Patients who had AA for ≥8 years could be enrolled if episodes of regrowth, spontaneous or under treatment, had been observed on the affected areas over the past 8 years

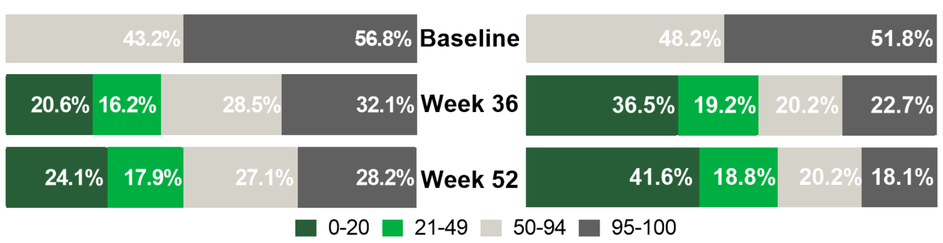
Statistical Analysis

- Data were pooled from patients randomized at baseline to baricitinib 2 mg or baricitinib 4 mg (intention-to-treat [ITT] population)
- Outcomes were assessed in patients with SALT≤20, SALT 21-49, SALT 50-94 (non-alopecia totalis [AT]), and SALT 95-100 (consistent with AT) at Week 52
  - Median and interquartile range (IQR) of SALT scores
  - Proportions of patients achieving Clinician-Reported Outcomes for Eyebrow (ClinRO EB) Hair Loss scores of 0 or 1 with ≥2-point improvement from baseline
  - Proportions of patients achieving Clinician-Reported Outcomes for Eyelash (ClinRO EL) Hair Loss scores of 0 or 1 with ≥2-point improvement from baseline
- Missing data were imputed with non-responder imputation (categorical outcomes) and last observation carried forward (continuous outcomes)
- Primary censoring rule excluded data collected after permanent study drug discontinuation or data collected at remote visits due to the COVID-19 pandemic

RESULTS

Distribution of SALT scores over time with treatment (ITT population)

A)

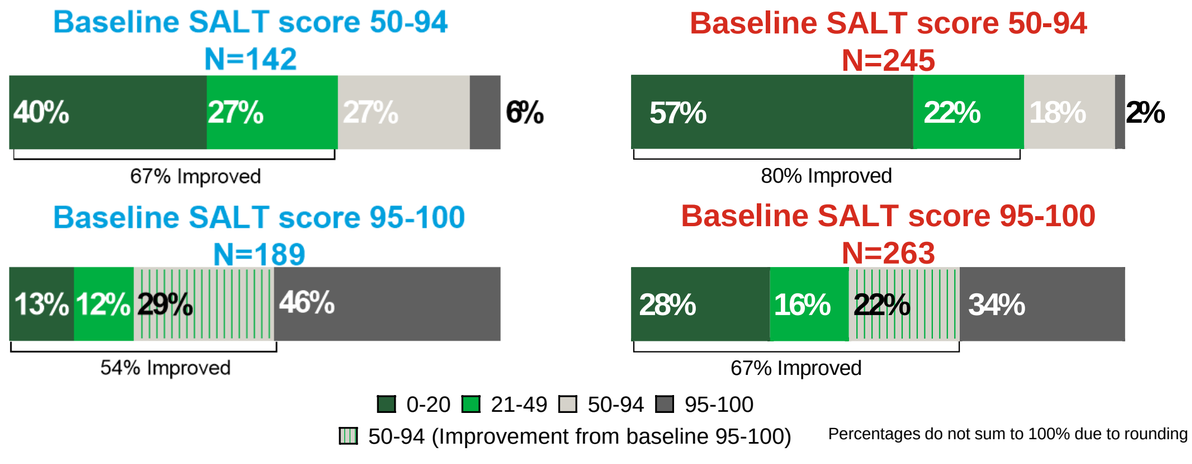


B)

Median SALT score								
0-20	21-49	50-94	95-100		0-20	21-49	50-94	95-100
-	-	66	100	Baseline	-	-	69	100
9	37	71	100	Week 36	4.5	33	72.5	100
7	34	72	100	Week 52	3	31	69.5	100

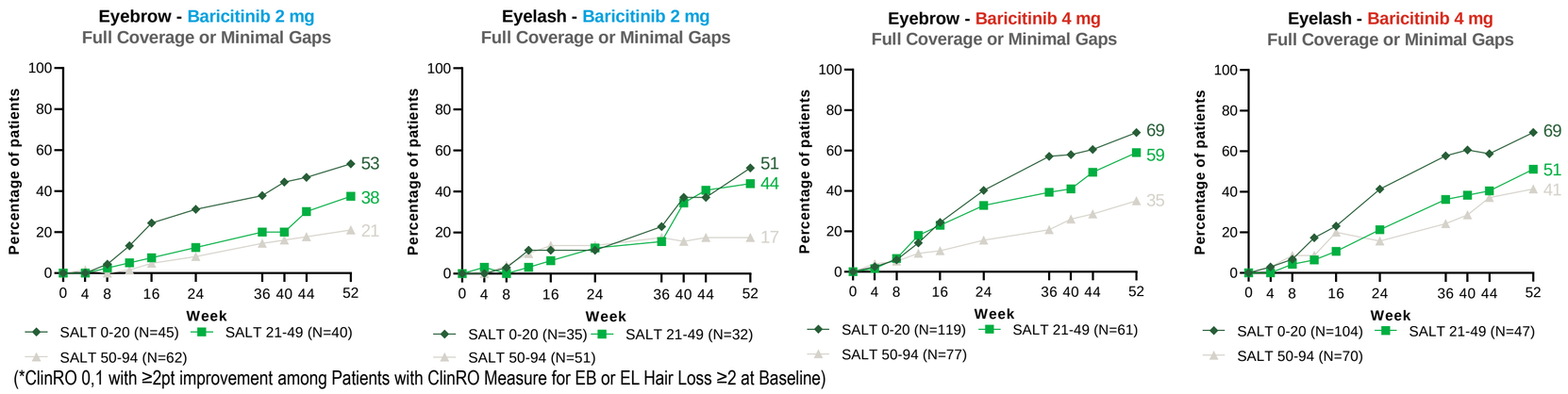
A) Horizontal bars demonstrate proportion of patients with baseline SALT scores across the ITT population and the redistribution of these proportions within each SALT score category over 36 and 52 weeks of treatment with baricitinib 2 mg and 4 mg.
B) Table shows median SALT scores achieved by patients within each SALT score category at baseline, Week 36, and Week 52 for baricitinib 2mg and 4mg. For example, median SALT score achieved by 4mg SALT score 0-20 responders at Week 52 was absolute SALT score 3.

Proportion of patients achieving each SALT score subcategory at Week 52 by baseline disease severity



Percentages do not sum to 100% due to rounding

Proportion of patients achieving Eyebrow/Eyelash regrowth* by dose and by scalp response



(*ClinRO 0,1 with ≥2pt improvement among Patients with ClinRO Measure for EB or EL Hair Loss ≥2 at Baseline)

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References

1. King B, et al. *J Am Acad Dermatol.* 2021;85:847-853.
2. King B, et al. *N Engl J Med.* 2022;386:1687-1699.
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Abbreviations: AA=alopecia areata; AT=alopecia totalis; BARI=baricitinib; ClinRO EB=Clinician-Reported Outcomes for Eyebrow; ClinRO EL=Clinician-Reported Outcomes for Eyelash; ITT=intention-to-treat; IQR=interquartile range; JAK=Janus kinase; SALT=Severity of Alopecia Tool

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