Baricitinib Achieved Complete/Near Complete Scalp Coverage in SALT Score ≤20 Responders: 52-Week Findings From BRAVE-AA Trials

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OBJECTIVE

- To evaluate the proportion of patients achieving SALT score ≤10 or ≤5 among patients who achieved a SALT score ≤20 after treatment with baricitinib 4-mg or 2-mg at Weeks 4, 8, 12, 16, 24, 36, and 52

CONCLUSIONS

- A significant proportion of patients who achieve SALT score ≤20 with baricitinib treatment also achieve complete or nearly complete scalp coverage
- Patients achieving a deep response can be seen as early as Week 8, and the proportions continue to increase over time with ongoing therapy

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BACKGROUND

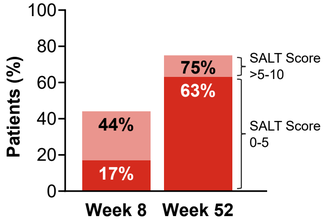
- Baricitinib is an approved systemic therapy (Janus kinase inhibitor) for the treatment of severe alopecia areata (AA), and in 2 Phase 3 trials (BRAVE-AA1 [NCT03570749] and BRAVE-AA2 [NCT03899259]), a significant proportion of patients receiving baricitinib achieved a SALT score ≤20 and maintained it through 152 weeks[1]
- Achievement of a SALT score ≤20 (20% or less hair loss) is the typically used endpoint across clinical trial programs for severe AA to allow for a degree of incomplete scalp coverage that may result from concomitant androgenetic or other alopecia unrelated to AA
- Many patients treated with baricitinib who achieve a SALT score ≤20 also achieve complete or near-complete scalp coverage, but these data have not been previously reported

SUMMARY OF KEY RESULTS

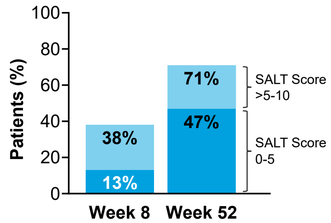
Complete or Near Complete Scalp Coverage[a] is Seen in a Significant Proportion of SALT Score ≤20 Responders

- A high proportion of patients achieved complete or nearly complete scalp coverage[a] *at early and 1-year time points*
- Among responders (SALT score ≤20), patients with 95%+ scalp hair coverage (SALT score 0-5) *increases over time*

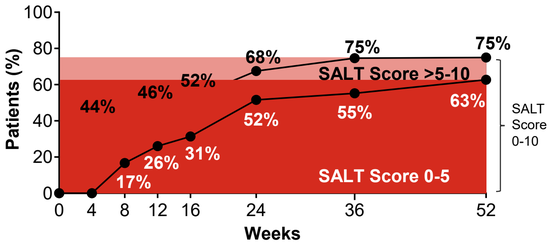
Response Rates With BARI 4-mg



Response Rates With BARI 2-mg



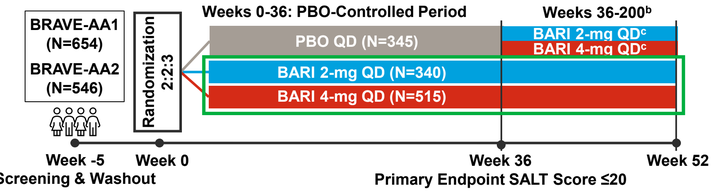
Response Rates With BARI 4-mg



[a]SALT score ≤10 or ≤5.

Methods

Study Design: BRAVE-AA1 and BRAVE-AA2[a]



[a]Figure is not the full study design; only the first year of both trials is shown; [b]LTE period lasted from Week 36 to Week 104. Eligible patients remained in the trials until Week 200 (Bridging Extension); [c]Non-responders rerandomized.

Key Eligibility Criteria: BRAVE-AA1 and BRAVE-AA2

- Male (≥18 to ≤60 years) or female (≥18 to ≤70 years)[a]
- Hair loss involving ≥50% of the scalp, assessed with SALT score
- Current episode of AA >6 months to <8 years[b]
- No spontaneous improvement in the 6 months before screening
- Not primarily a "diffuse" type of AA
- No concomitant treatments for AA allowed[c]

[a]Different upper age limits were included for male and female patients based on differences in the prevalence of concomitant androgenetic alopecia; [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; [c]Oral/topical minoxidil or finasteride was allowed if on stable dose for ≥12 months and bimatoprost ophthalmic solution was allowed if on stable dose for ≥8 weeks.

Assessments and Statistical Analyses

- Patients from pooled BRAVE-AA1 and AA2 Phase 3 trials treated with baricitinib 4-mg and 2-mg were evaluated for achievement of SALT score ≤10 or ≤5 from among those patients who achieved SALT score ≤20 at Weeks 4, 8, 12, 16, 24, 36, and 52
- Baseline demographics were evaluated to assess potential differences between patients with different levels of response
- As-observed analyses used all collected data

SALT Score

- The SALT score is a weighted sum of the percentage of hair loss in the 4 quadrants of the scalp (left side, right side, top, and back), ranging from 0 (no hair loss) to 100 (complete hair loss)[2]
- SALT score interpretation
  - SALT score 0=no hair loss
  - SALT score 100=complete hair loss
  - SALT score ≤20=20% or less hair loss (80% scalp coverage)

Results

Baseline Demographics and Patient Characteristics

	SALT Score ≤20 Responders (N=321)[a]	SALT Score ≤10 (N=237)	SALT Score ≤5 (N=187)	Overall ITT Population (N=843)
Age, years	37.0 (12.6)	36.8 (13.0)	37.2 (13.5)	37.1 (12.9)
Female, n (%)	221 (68.8)	164 (69.2)	125 (66.8)	522 (61.9)
Duration of AA since onset, years	10.2 (10.1)	9.6 (10.1)	8.8 (9.3)	12.0 (10.8)
Duration of current AA episode, years	3.0 (3.2)	2.7 (3.2)	2.6 (2.7)	3.7 (3.8)
Absolute SALT score	79.3 (19.0)	78.7 (18.7)	78.0 (18.7)	85.9 (17.9)
SALT score category, n (%)				
Severe AA (SALT score 50-94)	209 (65.1)	162 (68.4)	130 (69.5)	385 (45.7)
Very severe AA (SALT score 95-100)[b]	112 (34.9)	75 (31.6)	57 (30.5)	458 (54.3)
Atopic background, n (%)	131 (40.8)	97 (40.9)	79 (42.2)	315 (37.4)

Patients achieving SALT score ≤10 or ≤5 tended to have:

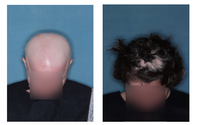
- Shorter duration of current episode compared with the overall population
- Lower proportion with very severe baseline disease compared with the overall population

[a]BARI 4-mg–treated and 2-mg–treated patients with SALT score ≤20 at Week 52; [b]Consistent with alopecia totalis.
Note: Data are mean (SD) unless stated otherwise.

Clinical Examples

SALT Score ≤10

39-Year-Old Female, BARI 2-mg



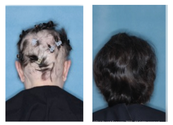
Baseline, SALT Score 95 | Week 52, SALT Score 10

SALT Score ≤5

30-Year-Old Female, BARI 2-mg

Baseline, SALT Score 50 | Week 52, SALT Score 3

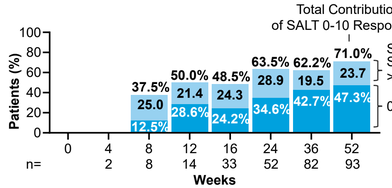
56-Year-Old Female, BARI 4-mg



Baseline, SALT Score 53 | Week 52, SALT Score 0

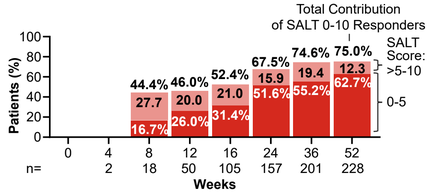
How Many Patients Who Respond[a] to Baricitinib 2-mg Achieve Complete or Near Complete Scalp Coverage?

Proportion of Patients Achieving SALT Score ≤10 or ≤5[b]



How Many Patients Who Respond[a] to Baricitinib 4-mg Achieve Complete or Near Complete Scalp Coverage?

Proportion of Patients Achieving SALT Score ≤10 or ≤5[b]



[a]Response defined as patients achieving SALT score ≤20 at each given timepoint; [b]Proportion of patients achieving SALT score ≤10 or ≤5 is calculated from among patients who achieved SALT score ≤20 at each time point.

References: 1. Senna M, et al. Poster presented at: *AAD 2024*. Poster 49690. 2. Olsen EA, et al. *J Am Acad Dermatol*. 2004;51:440-447.

Abbreviations: *AA=alopecia areata; BARI=baricitinib; LTE=long-term extension; N=number of patients in the analysis population; n=number of patients achieving SALT score ≤20 at each timepoint; PBO=placebo; QD=once daily; SALT=Severity of Alopecia Tool; SD=standard deviation*

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