

Baricitinib Treatment Increases Eyebrow and Eyelash Regrowth Up to 52 Weeks



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OBJECTIVE

- To evaluate efficacy of baricitinib in eyebrow and eyelash regrowth from baseline through 52 weeks in BRAVE-AA1 and BRAVE-AA2 trials

CONCLUSIONS

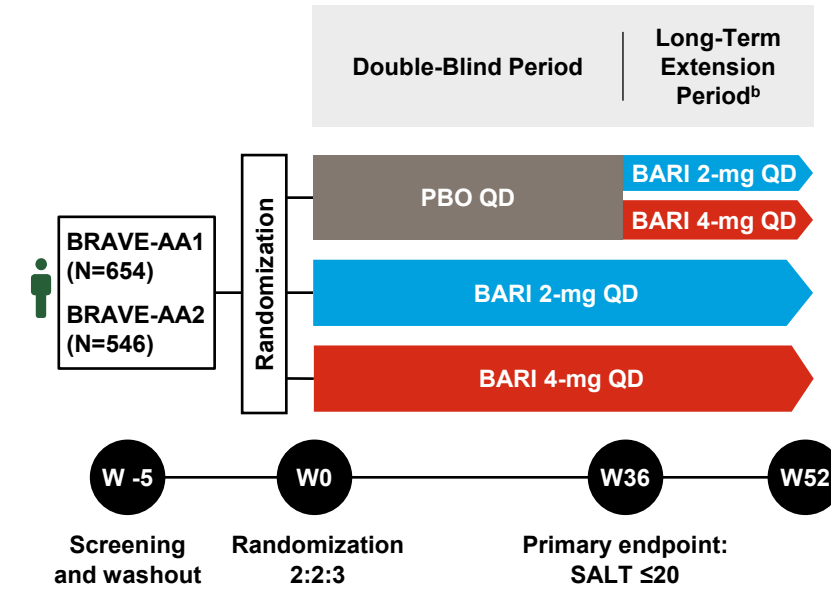
- The proportion of patients experiencing regrowth of eyebrow and eyelash on baricitinib vs. PBO was statistically significant as early as:
 - Week 4 for eyebrow and Week 8 for eyelash among patients on baricitinib 4-mg
 - Week 8 for eyebrow and eyelash among patients on baricitinib 2-mg
- In the baricitinib 4-mg group, approximately 60% of patients had improvements in eyebrow and eyelash regrowth at Week 36, and this continued to increase to approximately 70% by Week 52
- While baricitinib has demonstrated significant efficacy in regrowth of scalp hair, these data demonstrate the holistic efficacy of baricitinib also in regrowing eyebrows and eyelashes
- These data across multiple timepoints can help inform healthcare practitioners about expectations for eyebrow and eyelash regrowth with baricitinib treatment up to 1 year

BACKGROUND

- AA is an autoimmune disease characterized by unpredictable hair loss that can range from a single bald patch to total scalp or body hair loss, including the scalp, eyebrows, and eyelashes^{1,2}
- Baricitinib is an oral JAK inhibitor that has demonstrated efficacy in patients with severe AA in 2 Phase 2/3 randomized, double-blind, placebo-controlled trials, BRAVE-AA1 (NCT03570749) and BRAVE-AA2 (NCT03899259),³ and is approved for scalp hair, eyebrow, and eyelash regrowth in patients with severe AA in the USA, Europe, and Japan
- Eyebrow and eyelash hair loss has been associated with physical and psychological distress to patients^{4,5}
 - Absence of eyelashes is associated with ocular irritation⁶
 - Eyebrows play an important role in emotional expression, communication, and identity⁷

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 Patients randomized to BARI (4-mg or 2-mg QD) at baseline retained their treatment allocation through Week 52, whereas PBO non-responders were rescued at Week 36

Key Eligibility Criteria: BRAVE-AA1 and BRAVE-AA2 Inclusion

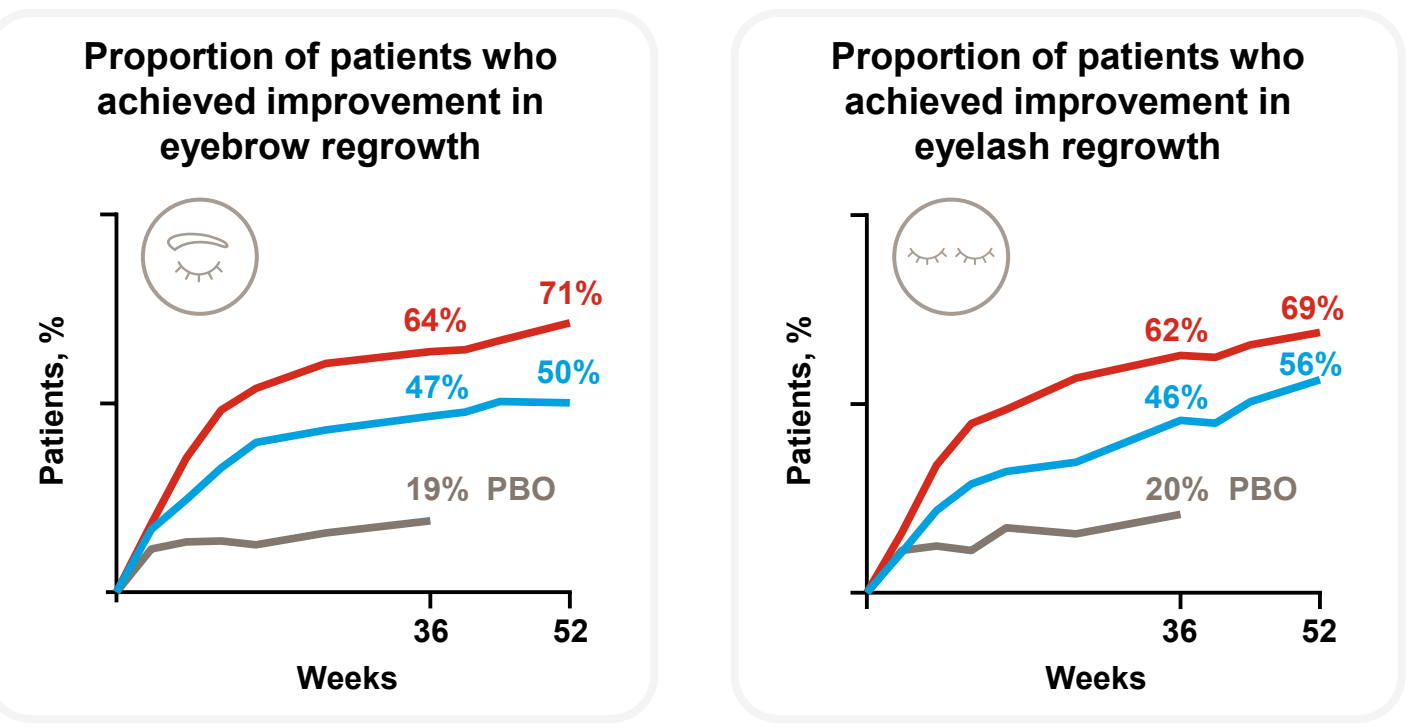
- Age ≥18 years to ≤60 years (males) or ≤70 years (females)^a
- Severe or very severe AA
 - Hair loss involving ≥50% of the scalp, as measured by SALT score
- Current episode of AA lasting >6 months to <8 years^b
- No spontaneous improvement in the 6 months before screening

Exclusion

- Primarily "diffuse" type of AA
- Concomitant treatments for AA^c

^a Different upper age limits have been included for male and female patients based on the difference in 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 Not permitted: Topical corticosteroids within 1 week before randomization; topical JAK inhibitor, diphenylcyclopropenone, or other topical immunotherapies within 4 weeks before randomization; systemic corticosteroids, immunosuppressants, intra-lesional or intra-articular corticosteroid injections, or oral JAK inhibitor within 8 weeks before randomization; monoclonal antibody <5 half-lives before randomization; probenecid at the time of randomization. Oral/topical minoxidil or finasteride was permitted if on stable dose for 12 months, and bimatoprost ophthalmic solution was allowed if on stable dose for 8 weeks

SUMMARY OF KEY FINDINGS



- The proportion of patients reporting eyebrow and eyelash regrowth continued to increase through 52 weeks with BARI 4-mg and 2-mg
- Higher response rates were observed with the 4-mg dose vs. the 2-mg dose on all timepoints

METHODS

ClinRO Measures for Eyebrow and Eyelash Hair Loss^{TM,6}

- ClinRO Measure for Eyebrow Hair Loss^a**
 - Score 0: Full coverage and no areas of hair loss
 - Score 1: Minimal gaps and even distribution
 - Score 2: Significant gaps or uneven distribution
 - Score 3: No notable eyebrow hair
- ClinRO Measure for Eyelash Hair Loss^b**
 - Score 0: Continuous line along the eyelids on both eyes
 - Score 1: Minimal gaps and even distribution along the eyelids on both eyes
 - Score 2: Significant gaps or uneven distribution along the eyelids
 - Score 3: No notable eyelashes

Example Photo Guides^c

The photo guides show two rows of eyes. The top row shows eyebrow hair loss with scores 1, 2, and 3. The bottom row shows eyelash hair loss with scores 1 and 2.

- A 1-point improvement in ClinRO eyebrow and eyelash indicates early appreciable improvement in eyebrow and eyelash regrowth

^a Clinician should examine both eyebrows from 2 feet away; ^b Clinician should examine the upper and lower eyelashes of both eyes; ^c The ClinRO measure is supported by photoguides, which are subject to copyright owned by Eli Lilly and Company. Permission to use is granted under Creative Commons Attribution-No Derivatives 4.0 International License (<https://creativecommons.org/licenses/by-nc/4.0/>)

Statistical Analyses

- Pooled Week 36 efficacy population and pooled Week 52 efficacy population (among patients with ClinRO measure for eyebrow or eyelash hair loss ≥1 at baseline)
- Censoring excluded data collected after permanent discontinuation
- Response confidence intervals were constructed using the Wilson method, without continuity correction
- Logistic regression analysis with treatment group, study, geographic region, duration of current episode at baseline (<4 years vs. ≥4 years), and baseline ClinRO measure for eyebrow or eyelash hair loss as factors was used with NRI up to Week 36 data
- Descriptive statistic summary was used for Week 40 to Week 52 data

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Abbreviations: AA=alopecia areata; BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; ITT=intent-to-treat; JAK=Janus kinase; NRI=non-responder imputation; PBO=placebo; QD=once daily; SALT=Severity of Alopecia Tool; SD=standard deviation; W=Week

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