Scalp Hair Regrowth Is Associated With Improvements in Health-Related Quality of Life and Psychological Symptoms in Patients With Severe Alopaeia Areata: Results From Two Randomized Controlled Trials

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BACKGROUND

Alopecia areata (AA) is a common autoimmune disorder that results in hair loss.1 Hair loss can range in severity, from loss of hair in small localized patches on the scalp, to complete loss of hair on the scalp (alopecia totalis) and/or body (alopecia universalis).2 Severe AA is frequently associated with health-related quality of life (HRQoL) impairment and psychological burden.3 However, the impact of hair regrowth on HRQoL and psychological burden has not been sufficiently investigated.

OBJECTIVE

To evaluate the association between scalp hair regrowth and improvement of HRQoL and psychological burden in patients with severe AA using pooled data from the Phase 3, randomized, placebo-controlled trials, BRAVE-AA1 (NCT03072748) and BRAVE-AA2 (NCT03893820).

METHODS

Study Design, BRAVE-AA1 and BRAVE-AA2

Key Eligibility Criteria for BRAVE-AA1 and BRAVE-AA2

Inclusion

1. Age ≥15 years to ≤80 years (males) or ≥70 years (females)
2. Severe or very severe AA
   - Hair loss encompassing ≥50% of the scalp, as measured by the Severity of Alopecia Tool (SALT)
   - Current episode of AA lasting >6 months to <8 years

Exclusion

No spontaneous improvement in the 6 months before screening
- Not primarily a "diffuse" type of AA
- No concomitant treatments for AA allowed

SALT Score

- Assesses hair loss in each quadrant of the scalp
- The SALT score is a weighted sum of the percent of hair loss in the 4 quadrants, ranging from 0 to 100

Patient Subgroups

Patients were categorized into 3 groups according to scalp hair regrowth at Week 36:
1. SALT Response (N=256): Met the primary endpoint of SALT ≤20 (≥80% scalp hair coverage)
2. Intermediate Response (N=269): Did not meet the primary endpoint but achieved ≥100% improvement from baseline in SALT score at any post-baseline visit up to Week 36 (SALT100)
3. No or Minimal Response (N=278): Did not achieve SALT100 at any post-baseline visit up to Week 36

Assessments

Skin16 adapted for AA: Assessed effects of AA on HRQoL, over 3 domains:
- Emotions, symptoms, and functioning
- Each domain score ranged from 0 to 100, with higher scores indicating greater HRQoL-related quality of life

Statistical Analyses

Data were pooled from the 3 arms (placebo, baricitinib 4 mg) of BRAVE-AA1 and BRAVE-AA2, analyzed independently of treatment allocation.

RESULTS

Demographics and Baseline Characteristics, by Hair Regrowth Response Group

Patients With a SALT ≤20 Response at Week 36 Were More Likely to Achieve Normal Anxiety and Depression Scores (HADS ≤8)

CONCLUSIONS

Patients with severe AA who achieved scalp hair regrowth at Week 36 experienced improvements in HRQoL, and symptoms of anxiety and depression when compared with those who had no or minimal regrowth.

- Higher benefit was observed in patients achieving a SALT ≤20 response
- Improvements were also observed in the intermediate response group, but generally to a lesser extent than in those with the SALT ≤20 response group
- These results support the clinical relevance of SALT ≤20, the primary endpoint for the baricitinib clinical program in severe AA
- Longer-term results may need to be assessed on the full impact of scalp hair regrowth, HRQoL, and symptoms of anxiety and depression

REFERENCES


ABBRIVATIONS

- AA = Alopecia areata
- BRAVE = Baricitinib Regrowth Evaluation
- HADS = Hospital Anxiety and Depression Scale
- HADS-A = Anxiety subscale
- HADS-D = Depression subscale
- HRQoL = Health-related quality of life
- PBO = Placebo
- SALT = Severity of Alopecia Tool
- SALT-100 = Complete scalp hair loss
- SALT ≤20 = Complete scalp hair loss

DISCLOSURES

- All authors contributed to the concept, design, and drafting of the manuscript
- Significant changes were not made after the first submission and the first round of review

For more information about potential conflicts of interest for all authors, please see the article in the reference list.