Most Baricitinib Responders Achieved Full Scalp Hair Regrowth: Findings From Adult and Paediatric BRAVE-AA Trials

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OBJECTIVE

- To evaluate complete response thresholds of Severity of Alopecia Tool (SALT) score ≤10 and ≤5 among SALT score ≤20 responders, through Week 52 in adolescent and adult populations

CONCLUSIONS

- A majority of adolescents and adults who achieved a SALT score ≤20 with baricitinib treatment also achieved full scalp hair regrowth
- Continued treatment deepens response over time

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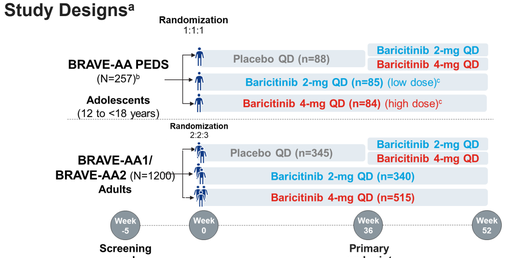
BACKGROUND

- Achievement of full scalp hair regrowth is an important outcome for patients with severe AA[1]
- A SALT score ≤20 response, which is the typical primary endpoint in clinical trials, may not reflect the completeness of regrowth experienced by patients who respond to therapy
- Baricitinib is a selective JAK inhibitor approved in adults to treat severe AA and has now been studied in 257 adolescents (ages 12 to <18 years)
  - In both adults and adolescents, clinically meaningful regrowth (80% scalp coverage) was achieved in clinical trials[2,3]

METHODS

Study Designs[a]

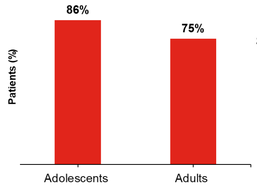


[a]Figures are not the full study design, BRAVE-AA PEDS: NCT05723198, BRAVE-AA1: NCT03570749, BRAVE-AA2: NCT03899259; [b]Pediatric population: 6 to <12 years (at least n=180) also randomized 1:1:1 but not included in this analysis; [c]Adolescents should weigh ≥30 kg; For participants weighing ≥30 kg; 4-mg QD=high dose, 2-mg QD=low dose; For participants weighing <30 kg: 2-mg QD=high dose, 1-mg QD=low dose.

SUMMARY OF KEY RESULTS

Among adolescent and adult responders[a] on baricitinib **4-mg** by **Week 36:**

Near-Complete Hair Regrowth
SALT Score ≤10



Some patients achieved a deep response *as early as* **Week 8**

100% Hair Regrowth
SALT Score 0

28% Adolescents **27%** Adults

Continued treatment increased proportions of patients with deeper response

[a]Responders defined as patients achieving SALT score ≤20 at each timepoint (n).

Key Eligibility Criteria

Criteria Common to BRAVE-AA-PEDS and BRAVE-AA1/-AA2

- SALT score ≥50 at screening and baseline
- Current episode of AA lasting >6 months to <8 years[a]
- No spontaneous improvement of AA over the past 6 months
- Not primarily a "diffuse" type of AA
- No use of concomitant treatments for AA allowed[b]

Additional Criteria for BRAVE-AA-PEDS

- Age 12 to <18 years, weighing ≥30 kg (for this analysis)
- Diagnosis of AA for ≥1 year
- History of trial and failure with ≥1 available treatment (topical or other) for AA
- History of psychological counseling related to AA
- History of psychological impact from refractory AA as reported by the investigator, parent, or participant

Additional Criteria for BRAVE-AA1/2

- Age ≥18 years to ≤60 years (males) or ≤70 years (females)[c]

[a]Participants who have severe AA for ≥8 years may be enrolled if episodes of regrowth, spontaneous or under treatment, have been observed on the affected areas over the past 8 years; [b]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 anticipated to remain on stable dose up until Week 36, and bimatoprost ophthalmic solution was allowed if on stable dose for ≥8 weeks; [c]Different upper age limits for male and female patients based on the difference in prevalence of concomitant androgenetic alopecia.

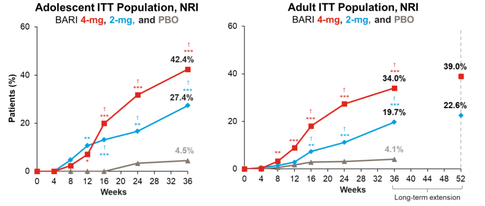
Outcomes and Statistical Analyses

- Outcomes: Proportion of baricitinib 4-mg and 2-mg responders (SALT score ≤20) who achieved SALT score ≤10 or ≤5 at each timepoint (Weeks 4, 8, 12, 16, 24, 36, and 52) from BRAVE-AA-PEDS and BRAVE-AA1/-AA2
  - The side-by-side visual of the adolescent and adult data is intended to be descriptive; due to differences in clinical trial design, cross-trial comparisons cannot be made
- As-observed analyses used all collected data

RESULTS

Patients Achieving SALT Score ≤20

BRAVE-AA-PEDs and BRAVE-AA1/AA2 Programs



†Statistically significant (p<0.05) vs. PBO after multiplicity adjustment; *p≤0.05, **p≤0.01, ***p≤0.001 vs. PBO without adjustment for multiple comparisons (Fisher exact test).
Notes: SALT score ≤20 indicates ≤20% scalp hair loss.BRAVE-AA1/-AA2 data available to Week 52.

Baseline Demographics and Clinical Characteristics

Characteristic	Adolescents (BRAVE-AA-PEDS) [n=257]	Adults (BRAVE-AA1/-AA2) [n=1200]
Age, years	14.7 (1.7)	37.5 (12.9)
Female, n (%)	127 (49.4)	728 (60.7)
Race, n (%)		
White	155 (60.3)	620 (51.8)[a]
Asian	72 (28.0)	435 (36.3)[a]
Black	19 (7.4)	98 (8.2)[a]
Multiple	7 (2.7)	19 (1.6)[a]
Duration from AA onset, years	6.4 (3.9)	12.2 (10.9)
Duration of current AA episode, years	3.2 (2.0)	3.9 (4.4)
SALT score	89.0 (16.3)	85.3 (18.0)
Severe AA (SALT score 50-94), n (%)	92 (35.8)	561 (46.8)[b]
Very severe AA (SALT score 95-100), n (%)	164 (63.8)	638 (53.2)[b]
Alopecia universalis, n (%)	138 (53.7)	531 (44.3)
Top 3 comorbidities, n (%)[c]	Allergic rhinitis: 62 (24.1) Atopic dermatitis: 58 (22.6) Asthma: 29 (11.3)	Allergic rhinitis: 287 (23.9) Atopic dermatitis: 187 (15.6) Hypertension: 117 (9.8)
Previous therapy, n (%)		
Naïve	0[d]	113 (9.4)
Topical (excluding immunotherapy)	207 (80.5)	726 (60.5)
Topical immunotherapy	55 (21.4)	321 (26.8)
Systemic agent (all)	133 (51.8)	633 (52.8)
Systemic corticosteroid	91 (35.4)	478 (39.8)
JAK inhibitor	10 (3.9)	59 (4.9)
Other systemic immunosuppressant	70 (27.2)	338 (28.2)

Duration of current episode was relatively similar between adults and adolescents

Adolescents tended to have higher baseline severity

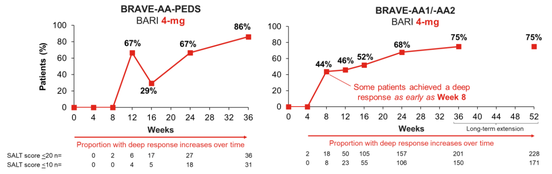
[a]N=1197 participants did not provide information on race; [b]N=1199; [c]Top 3 comorbidities listed for adolescent and adult cohorts; [d]History of trial and failure (topical or other) with ≥1 available treatment for AA was an entry criterion for BRAVE-AA-PEDS.
Data are mean (SD) unless stated otherwise.

References:
1. Craiglow B, et al. *Dermatol Ther (Heidelb)*. 2024;14:1959-1968.
2. Passeron T, et al. Oral presentation at: AAD 2025.
3. King B, et al. *N Engl J Med*. 2022;386:1687-1699.

Abbreviations: *AA=alopecia areata; BARI=baricitinib; JAK=Janus kinase; NRI=non-responder imputation; PBO=placebo; QD=once daily; SALT=Severity of Alopecia Tool; SD=standard deviation*

Near-Complete Scalp Coverage (SALT Score ≤10) Among Adolescent and Adult Responders[a]

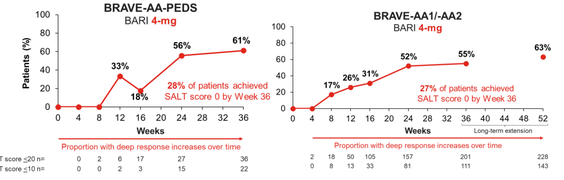
- Responders across adolescents and adults achieved a deep response



[a]Responders defined as patients achieving SALT score ≤20 at each timepoint (n).

Complete Scalp Coverage (SALT Score ≤5) Among Adolescent and Adult Responders[a]

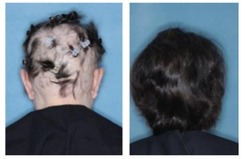
- The majority of adolescent and adult responders achieved complete response



[a]Responders defined as patients achieving SALT score ≤20 at each timepoint (n).

Clinical Examples of Patients Achieving Complete Response Among Adult Responders[b]

56-Year-Old Female, BARI 4-mg



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

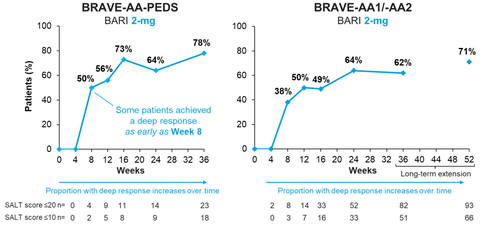
30-Year-Old Female, BARI 2-mg

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

[a]SALT score ≤5; [b]SALT score ≤20.
Note: Photographs were not taken in the BRAVE-AA-PEDS trial.

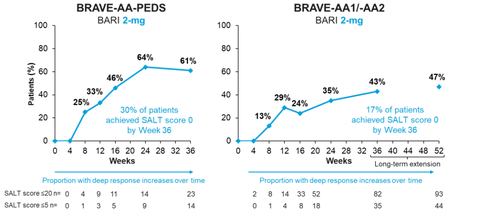
Near-Complete Scalp Coverage (SALT Score ≤10) Among Adolescent and Adult Responders[a]

- Responders across adolescents and adults achieved a deep response



Complete Scalp Coverage (SALT Score ≤5) Among Adolescent and Adult Responders[a]

- The majority of adolescent responders and nearly 50% of adult responders achieved complete response



[a]Responders defined as patients achieving SALT score ≤20 at each timepoint (n).

Disclosures: B. King has served on advisory boards and/or is a consultant and/or a clinical trial investigator and/or is on a data monitoring committee for: AbbVie, Almirall, AltruBio, AnaptysBio, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Bioniz Therapeutics, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, Equillium, Horizon Therapeutics, Incyte Corporation, Janssen, LEO Pharma, Merck, Otsuka/Visterra, Pfizer, Q32 Bio, Regeneron, Sanofi Genzyme, Sun Pharma, TWi Biotechnology, Ventyx Biosciences, and Viela Bio; has served on speakers bureaus for: AbbVie, Eli Lilly and Company, Incyte Corporation, Pfizer, Regeneron, and Sanofi Genzyme; and is a scientific advisor for: BiologicsMD; **J. Ko** has no conflicts of interest to report; **Y. Shimomura** has been an investigator for: Eli Lilly and Company; **M. Gooderham** has been an investigator, speaker, and/or advisor for: AbbVie, Akros Pharma, Alumis, Amgen, Arcutis, Aristea Therapeutics, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, Galderma, GSK, Incyte Corporation, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Merck, MoonLake Immunotherapeutics, Nimbus Therapeutics, Novartis, Pfizer, Regeneron, Reistone Biopharma, Roche, Sanofi Genzyme, Sun Pharma, UCB Pharma, and Vyne Therapeutics; **R. Chughtai** and **N. Somani** are current employees and shareholders of: Eli Lilly and Company; **S. Ogwu** is a former employee of: Eli Lilly and Company; **L. Rudnicka** has served as an invited medical lecturer for: AbbVie, Eli Lilly and Company, Janssen, LEO Pharma, L'Oreal, Novartis, and Pfizer; and served on advisory boards for: AbbVie, Eli Lilly and Company, L'Oreal, Pfizer, and Sun Pharma
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