# Baricitinib Provides Significant Hair Regrowth in Adolescents With Severe Alopecia Areata: 52-Week Efficacy and Safety Results From a Phase 3 Randomized, Controlled Trial



**Brittany Craiglow[1], Lisa Arkin[2], David Saceda-Corralo[3], Young Lee[4], Manabu Ohyama[5], Yves Dutronc[6], Stephanie Colvin[6], Karen Denning[6], Sylvia Su[6], Tuhina Das[6], Ulrike Blume-Peytavi[7]**

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## OBJECTIVE

- To report the 52-week efficacy and safety results for baricitinib 4-mg and 2-mg in adolescents 12 to <18 years of age with severe alopecia areata (AA)

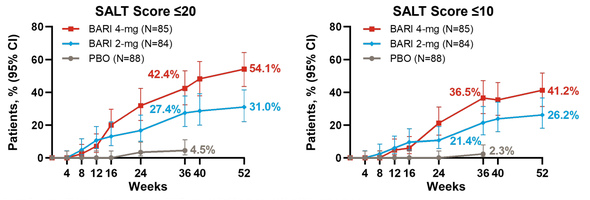
## CONCLUSIONS

- More than 50% of adolescents with severe AA treated with baricitinib 4-mg achieved successful scalp hair response by Week 52, with a response rate reaching 71% among those with baseline SALT score of 50-94
  - Successful regrowth was also observed with baricitinib 2-mg
- No new safety observation was reported, and the safety profile of baricitinib remained consistent with previous reports relating to adolescents with moderate-to-severe AD[5] and adults with severe AA[6]

**Fall Clinical Dermatology Conference (Fall CDC)**
**Las Vegas, USA; 23-26 October 2025**

## RESULTS

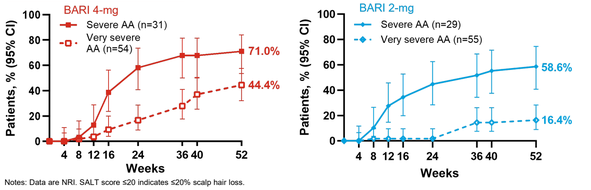
### Achievement of SALT Scores ≤20 and ≤10 to Week 52




Notes: Data are NRI for the intent-to-treat set. SALT score ≤10/≤20 indicates ≤10%/≤20% scalp hair loss.

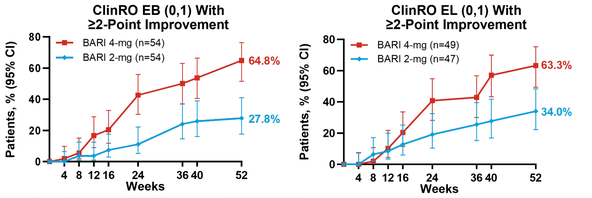
### Achievement of SALT Score ≤20 to Week 52
*Severe or Very Severe AA at Baseline*

**Severe AA:** SALT score 50-94
**Very severe AA:** SALT score 95-100




Notes: Data are NRI. SALT score ≤20 indicates ≤20% scalp hair loss.

### Eyebrow and Eyelash Regrowth at Week 52




Notes: Data are NRI. Analysis population includes participants with ClinRO EB/EL ≥2 at baseline.

### Safety Data Were Consistent With the Known Safety Profile for Baricitinib in Adolescents[5]

- No deaths, opportunistic infection, VTE, PE, or MACE were reported
- A serious infection and a malignancy (myxoid liposarcoma; reported as unrelated to study medication by the investigator) were reported in the baricitinib groups

| | PBO-Controlled Period | | | Extended BARI AA | | All BARI AA |
|---|---|---|---|---|---|---|
| | PBO (n=88) PYE=58.3 | BARI 2-mg (n=83) PYE=57.0 | BARI 4-mg (n=85) PYE=57.1 | BARI 2-mg (n=83) PYE=91.5 | BARI 4-mg (n=85) PYE=113.1 | All BARI AA (n=249) PYE=294.8 |
| **Overview of AEs** | | | | | | |
| ≥1 TEAE | 47 (53.4) [129.1] | 50 (60.2) [160.1] | 60 (70.6) [199.7] | 52 (62.7) [115.2] | 70 (82.4) [168.5] | 156 (62.7) [108.7] |
| TEAE severity[a] | | | | | | |
| Mild | 27 (30.7) [56.3] | 37 (44.6) [96.6] | 43 (50.6) [116.4] | 36 (43.4) [60.4] | 41 (48.2) [58.9] | 95 (38.2) [47.2] |
| Moderate | 18 (20.5) [36.3] | 12 (14.5) [23.3] | 15 (17.6) [28.5] | 14 (16.9) [17.2] | 26 (30.6) [27.3] | 53 (21.3) [20.5] |
| Severe | 2 (2.3) [3.5] | 1 (1.2) [1.8] | 2 (2.4) [3.6] | 2 (2.4) [2.2] | 3 (3.5) [2.7] | 8 (3.2) [2.7] |
| ≥1 serious AE | 3 (3.4) [5.2] | 2 (1.2) [1.8][b] | | 1 (1.2) [1.1] | 4 (4.7) [3.6] | 9[c] (3.6) [3.1] |
| Death | 0 | 0 | 0 | 0 | 0 | 0 |
| Temporary interruption from study treatment | 9 (10.2) [16.4] | 5 (6.0) [9.1] | 8 (9.4) [14.7] | 7 (8.4) [8.0] | 10 (11.8) [9.5] | 24 (9.6) [8.6] |
| Permanent discontinuation of study drug due to AE | 2 (2.3) [3.4] | 1 (0.6) [0.9][b] | | 1 (1.2) [1.1] | 3 (3.5) [2.7] | 5 (2.0) [1.7] |
| **Most Frequently Reported TEAEs** | | | | | | |
| TEAEs occurring at ≥5% frequency in any treatment group | | | | | | |
| Acne | 4 (4.5) [7.0] | 7 (8.4) [13.0] | 8 (9.4) [14.8] | 8 (9.6) [9.4] | 11 (12.9) [10.7] | 30 (12.0) [11.0] |
| Upper respiratory tract infection | 6 (6.8) [10.8] | 7 (8.4) [13.1] | 7 (8.2) [13.0] | 9 (10.8) [10.6] | 10 (11.8) [9.7] | 24 (9.6) [8.7] |
| Nasopharyngitis | 9 (10.2) [16.3] | 7 (8.4) [12.9] | 6 (7.1) [10.8] | 9 (10.8) [10.5] | 8 (9.4) [7.5] | 21 (8.4) [7.5] |
| Influenza | 3 (3.4) [5.2] | 10 (12.0) [19.2] | 5 (5.9) [9.0] | 10 (12.0) [12.1] | 6 (7.1) [5.6] | 21 (8.4) [7.6] |
| Headache | 5 (5.7) [8.9] | 4 (4.8) [7.2] | 7 (8.2) [13.1] | 4 (4.8) [4.5] | 10 (11.8) [9.7] | 17 (6.8) [6.1] |
| Rhinitis | 3 (3.4) [5.3] | 1 (1.2) [1.8] | 6 (7.1) [11.1] | 1 (1.2) [1.1] | 7 (8.2) [6.6] | 8 (3.2) [2.8] |
| Blood CPK increase | 2 (2.3) [3.4] | 5 events[b] | | 5 events[b] | | 5 (2.0) [1.7] |
| **Treatment-Emergent Infections** | | | | | | |
| Any treatment-emergent infection | 28 (31.8) [61.3] | 34 (41.0) [84.3] | 34 (40.0) [78.3] | 37 (44.6) [60.8] | 43 (50.6) [59.4] | 94 (37.8) [45.8] |
| Serious infection | | 1 serious infection[b] | | 1 serious infection[b] | | 1 (0.4) [0.3] |
| Opportunistic infection | 0 | 0 | 0 | 0 | 0 | 0 |
| Herpes zoster | | 1 herpes zoster[b] | | 2 herpes zoster[b] | | 2 (0.8) [0.7] |
| Herpes simplex | | 1 herpes simplex[b] | | 1 herpes simplex[b] | | 1 (0.4) [0.3] |
| Tuberculosis | 0 | 0 | 0 | 0 | 0 | 0 |
| **Led to study drug discontinuation** | | | | | | |
| Temporary interruption | 4 (4.5) [7.1] | 3 (3.6) [5.3] | 2 (2.4) [3.5] | 5 (6.0) [5.6] | 5 (5.9) [4.5] | 12 (4.8) [4.2] |
| Permanent | 0 | 0 | 0 | 0 | 0 | 0 |

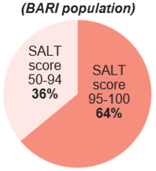
[a]Participants with multiple occurrences of the same event were counted under the highest severity; [b]This is an ongoing study and remains double-blinded after the Week 36 placebo period. Due to the low number of serious AEs and TEAEs reported, it is not possible to provide certain details to maintain the blind; [c]In the All BARI AA group: Abdominal pain upper, depression, major depression, suicide attempt, epilepsy, ligament sprain, myxoid liposarcoma, pneumonia, and upper limb fracture.
Notes: Data are presented as n (%) [IR]. IR represents 100 × (the number of participants experiencing the AE divided by the patient-years at risk). TEAE is defined as any event that occurred on or after the first dose of study drug administration or any pre-existing event that worsened in severity after dosing. Classifications of AEs are based on the MedDRA (version 27.0 Placebo-controlled period and 28.0 Extended BARI AA and All BARI AA). Data cut-off: Placebo-controlled period September 10, 2024, Extended BARI AA/All BARI AA April 15, 2025.

## SUMMARY OF KEY FINDINGS

**Participant Population**

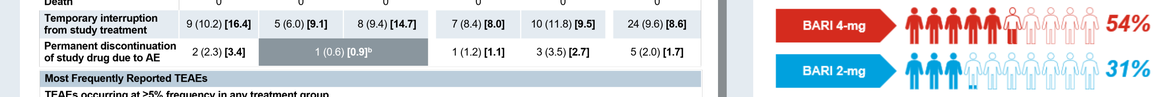
257 adolescents (12 to <18 years) with severe AA

*Baseline SALT score (BARI population)*

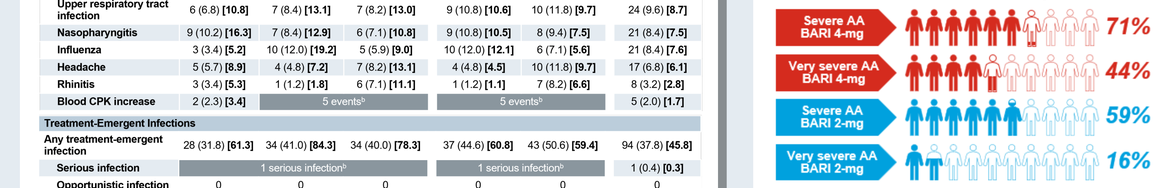



### Efficacy at Week 52 (NRI)

*Primary Endpoint: SALT Score ≤20 in All Participants*




*SALT Score ≤20 in Severe AA vs. Very Severe AA*



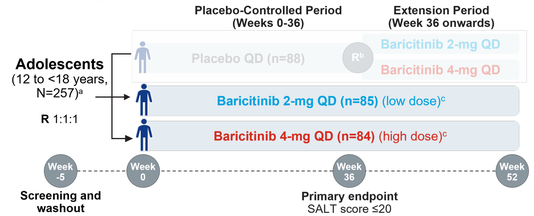

### Safety

- The most common AEs were acne, upper respiratory tract infection, nasopharyngitis, and influenza
- No VTE, PE, MACE, or opportunistic infections were reported
- No new safety signals
- Consistent with known safety profile in adolescents with moderate-to-severe AD[5] and adults with severe AA[6]

## Background

- Approximately 40% of patients with AA experience the first onset of the disease during the first 2 decades of life, with early onset often leading to extensive hair loss[1]
- Pediatric and adolescent populations are particularly susceptible to the psychosocial consequences of AA, including impaired self-esteem, stress, anxiety, and depression, highlighting the need for adapted treatments[2]
- Baricitinib, an oral, selective Janus kinase inhibitor, is approved for the treatment of severe AA in adult patients[3] and is also approved in many countries for patients ≥2 years of age with moderate-to-severe AD who are candidates for systemic therapies
- BRAVE-AA-PEDS (NCT05723198) is the largest ongoing, placebo-controlled, Phase 3 trial of pediatric participants (6 to <18 years) with severe AA
  - At 36 weeks, 42.4% and 27.4% of adolescents treated with baricitinib 4-mg and 2-mg, respectively, reached a SALT score of ≤20, compared with 4.5% with placebo[4]
  - However, longer-term data are necessary to provide a more comprehensive evaluation of the clinical response in severe AA and help physicians discuss treatment goals with their patients

### Study Design: BRAVE-AA-PEDS




[a]Figure is not the full study design, pediatric population: 6 to <12 years (at least n=180) was also randomized 1:1:1 but not included in this analysis; [b]At Week 36, non-responders (absolute SALT score >20) who were initially randomized to placebo were re-randomized in a double-blind manner to baricitinib 4-mg or baricitinib 2-mg; [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.

### Statistical Analyses

- Efficacy analyses: Adolescent (12 to <18 years of age) intent-to-treat population continuously treated with baricitinib 4-mg or 2-mg for at least 52 weeks
  - Missing data were handled by non-responder imputation, and data collected after permanent study drug discontinuation were excluded
- Safety analyses: All randomized adolescents who received ≥1 dose of study treatment
  - Extended BARI AA: Includes patients remaining on continuous treatment with baricitinib 2-mg or 4-mg from baseline to data cut-off in the Extension Period
  - All-BARI AA: Includes all patients exposed to any baricitinib dose (2-mg or 4-mg) at any time during the studies, including patients with dose or treatment change up to the data cut-off in the Extension Period

### Key Eligibility Criteria

- Age 12 to <18 years, weighing ≥30 kg
- Diagnosis of AA for ≥1 year
- Current episode of AA lasting >6 months to <8 years[a]
- SALT score ≥50 at screening and baseline
- 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
- No spontaneous improvement of AA over the past 6 months
- Not primarily a "diffuse" type of AA

[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.

## Results

### Baseline Demographics and Clinical Characteristics

| Characteristic | BARI 2-mg (n=84) | BARI 4-mg (n=85) |
|---|---|---|
| **Age, mean (SD), years** | 14.9 (1.6) | 14.6 (1.8) |
| **Female** | 39 (46.4) | 41 (48.2) |
| **Race** | | |
| **White** | 52 (61.9) | 52 (61.2) |
| **Asian** | 23 (27.4) | 23 (27.1) |
| **Black or African American** | 5 (6.0) | 8 (9.4) |
| **Other, multiple, or not reported** | 4 (4.8) | 2 (2.4) |
| **Duration of AA since onset, mean (SD), years** | 6.4 (3.9) | 6.1 (4.0) |
| **Duration of the current AA episode, mean (SD), years** | 3.2 (1.9)[a] | 3.3 (2.2) |
| **<4 years** | 54 (64.3) | 54 (63.5) |
| **≥4 years** | 29 (34.5) | 31 (36.5) |
| **SALT** | | |
| **Score, mean (SD)** | 90.4 (15.1) | 88.8 (16.6) |
| **Severe category (SALT score 50-94)** | 29 (34.5) | 31 (36.5) |
| **Very severe category (SALT score 95-100)** | 55 (65.5) | 54 (63.5) |
| **Classified as alopecia universalis** | 45 (53.6) | 50 (58.8) |
| **ClinRO EB™ score of 2 or 3** | 54 (64.3) | 54 (63.5) |
| **ClinRO EL™ score of 2 or 3** | 47 (56.0) | 49 (57.6) |

[a]n=83.
Note: Data are n (%) unless otherwise stated.

**References:** 1. Villasante Fricke AC and Miteva M. *Clin Cosmet Investig Dermatol.* 2015;8:397-403. 2. Tan IJ and Jafferany M. *J Paediatr Child Health.* 2024;60:778-782. 3. Senna M, et al. *J Eur Acad Dermatol Venereol.* 2024;38:583-593. 4. Passeron T, et al. Oral presentation at: *AAD25.* Presentation number S040. 5. Torrelo A, et al. *Br J Dermatol.* 2023;189:23-32. 6. King B, et al. *Br J Dermatol.* 2023;188:218-227.

**Abbreviations:** *AA=alopecia areata; AD=atopic dermatitis; AE=adverse event; BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; ClinRO EB=ClinRO Measure for Eyebrow Hair Loss; ClinRO EL=ClinRO Measure for Eyelash Hair Loss; CPK=creatine phosphokinase; IR=incidence rate; MACE=major adverse cardiovascular event; MedDRA=Medical Dictionary for Regulatory Activities; NRI=non-responder imputation; QD=once daily; PBO=placebo; PE=pulmonary embolism; PYE=patient-years of exposure; R=randomization; SALT=Severity of Alopecia Tool; SD=standard deviation; TEAE=treatment-emergent AE; VTE=venous thromboembolic event*

**Disclosures: B. Craiglow** has received fees and/or honoraria from: AbbVie, Arcutis, BiologicsMD, Dermavant, Eli Lilly and Company, GSK, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, Sanofi Genzyme, and Sun Pharma; **L. Arkin** has received grants or funding to the institution from: Amgen and Eli Lilly and Company; and consulting fees from: Eli Lilly and Company, Merck, Nobelpharma, Regeneron, and Sanofi; **D. Saceda-Corralo** has received honoraria and/or grants as a speaker, advisory board member, and/or investigator for: Cantabria Labs, Eli Lilly and Company, and Pfizer; **Y. Lee** has received lecture and advisory fees from: Eli Lilly and Company and ichnogene Korea; **M. Ohyama** has received lecture and advisory fees from: AbbVie, Bristol Myers Squibb Japan, Eli Lilly and Company, Kyowa Kirin, Maruho, Pfizer Japan, ROHTO Pharmaceutical, Sanofi KK, and Taisho Pharmaceutical; and has received research grants not directly related to the submitted work from: Advantest Corporation, Maruho, Shiseido, and Sun Pharma Japan; **Y. Dutronc, S. Colvin, K. Denning, S. Su,** and **T. Das** are employees and shareholders of: Eli Lilly and Company; **U. Blume-Peytavi** has served as a consultant for and/or received grants and/or honoraria from: AbbVie, Boots Healthcare, Concert Pharmaceuticals, Eli Lilly and Company, NeuroDerm, Novartis, Pfizer, Regeneron, Sanofi, and Vichy Laboratories
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# Background

- Approximately 40% of patients with alopecia areata (AA) experience the first onset of the disease during the first 2 decades of life, with early onset often leading to extensive hair loss[1]
- Pediatric and adolescent populations are particularly susceptible to the psychosocial consequences of AA, including impaired self-esteem, stress, anxiety, and depression, highlighting the need for adapted treatments[2]
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- BRAVE-AA-PEDS (NCT05723198) is the largest ongoing, placebo-controlled, Phase 3 trial of pediatric participants (6 to <18 years) with severe AA
  - At 36 weeks, 42.4% and 27.4% of adolescents treated with baricitinib 4-mg and 2-mg, respectively, reached a SALT score of ≤20, compared with 4.5% with placebo[4]
  - However, longer-term data are necessary to provide a more comprehensive evaluation of the clinical response in severe AA and help physicians discuss treatment goals with their patients.

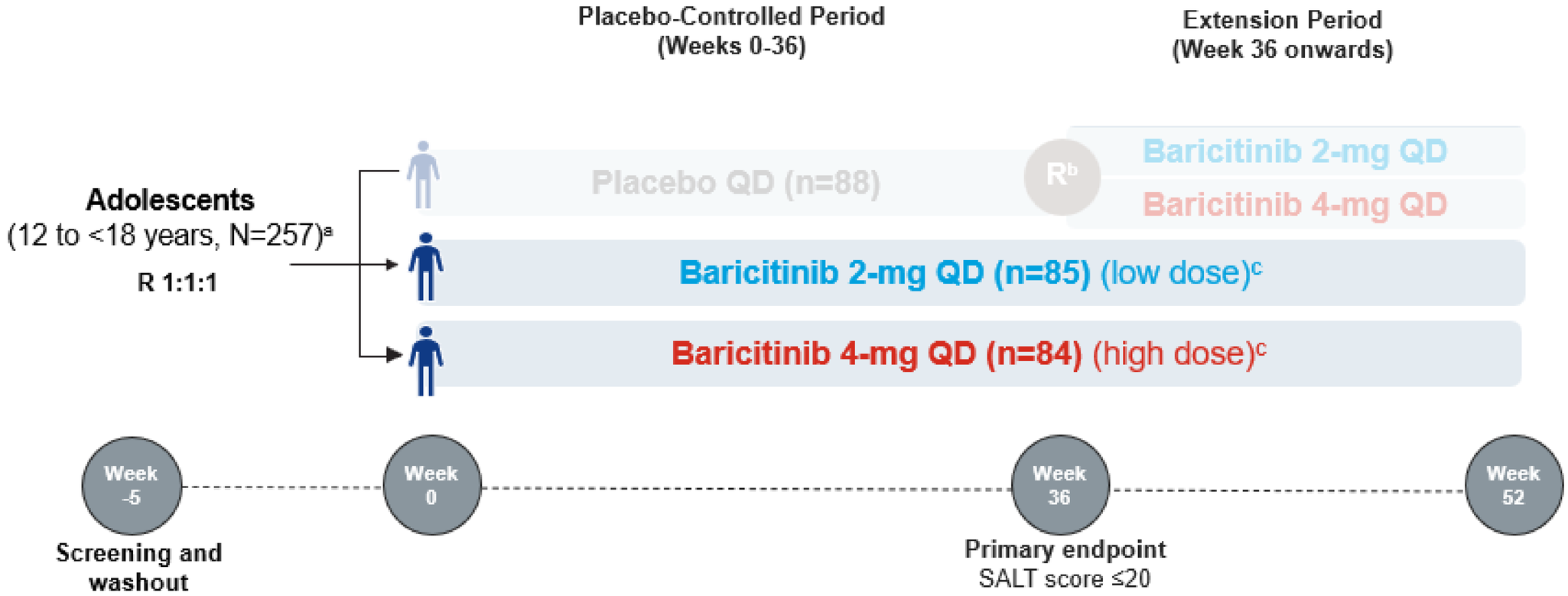
*SALT=Severity of Alopecia Tool.*

# Objective

- To report the 52-week efficacy and safety results for baricitinib 4-mg and 2-mg in adolescents 12 to <18 years of age with severe AA

*AA=alopecia areata.*

# Study Design: BRAVE-AA-PEDS

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*QD=once daily; R=randomized; SALT=Severity of Alopecia Tool.*

# Key Eligibility Criteria

- Age 12 to <18 years, weighing ≥30 kg
- Diagnosis of AA for ≥1 year
- Current episode of AA lasting >6 months to <8 years[a]
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# Statistical Analyses

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# Baseline Demographics (1/2)

| Characteristic | BARI 2-mg (n=84) | BARI 4-mg (n=85) |
|---|---|---|
| **Age, mean (SD), years** | 14.9 (1.6) | 14.6 (1.8) |
| **Female** | 39 (46.4) | 41 (48.2) |
| **Race** | | |
| **White** | 52 (61.9) | 52 (61.2) |
| **Asian** | 23 (27.4) | 23 (27.1) |
| **Black or African American** | 5 (6.0) | 8 (9.4) |
| **Other, multiple, or not reported** | 4 (4.8) | 2 (2.4) |

Note: Data are n (%) unless otherwise stated.
*BARI=baricitinib; SD=standard deviation.*

# Baseline Characteristics (2/2)

| Characteristic | BARI 2-mg (n=84) | BARI 4-mg (n=85) |
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| **Duration of AA since onset, mean (SD), years** | 6.4 (3.9) | 6.1 (4.0) |
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| **SALT** | | |
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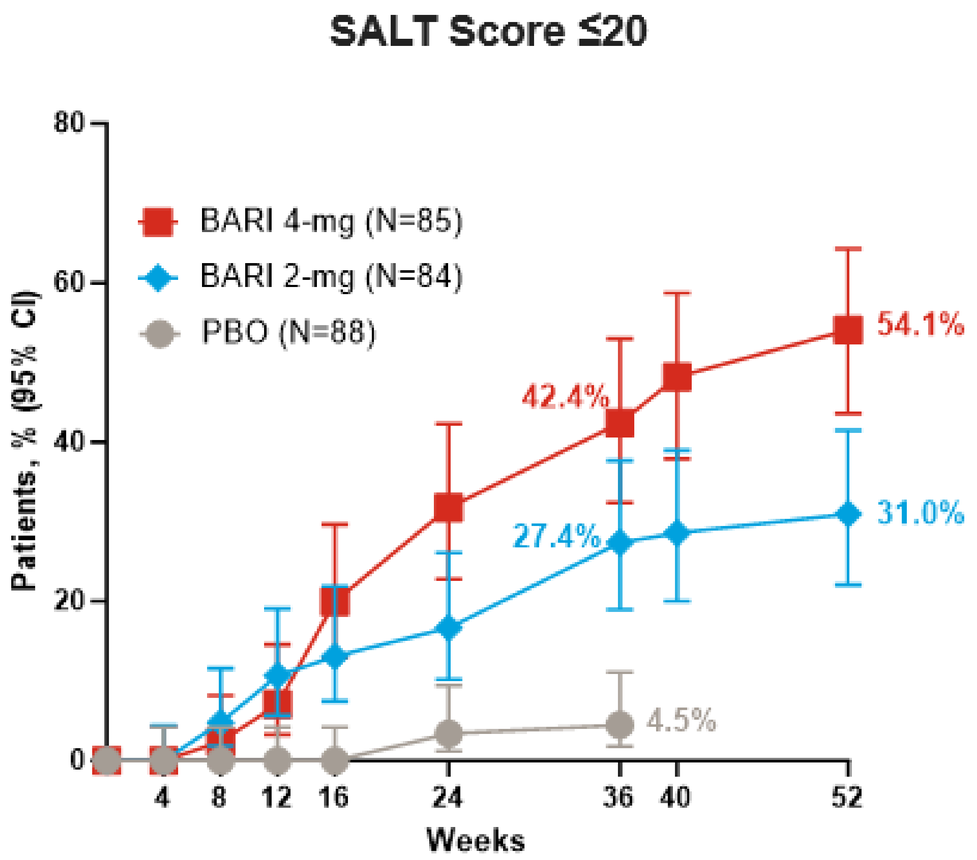
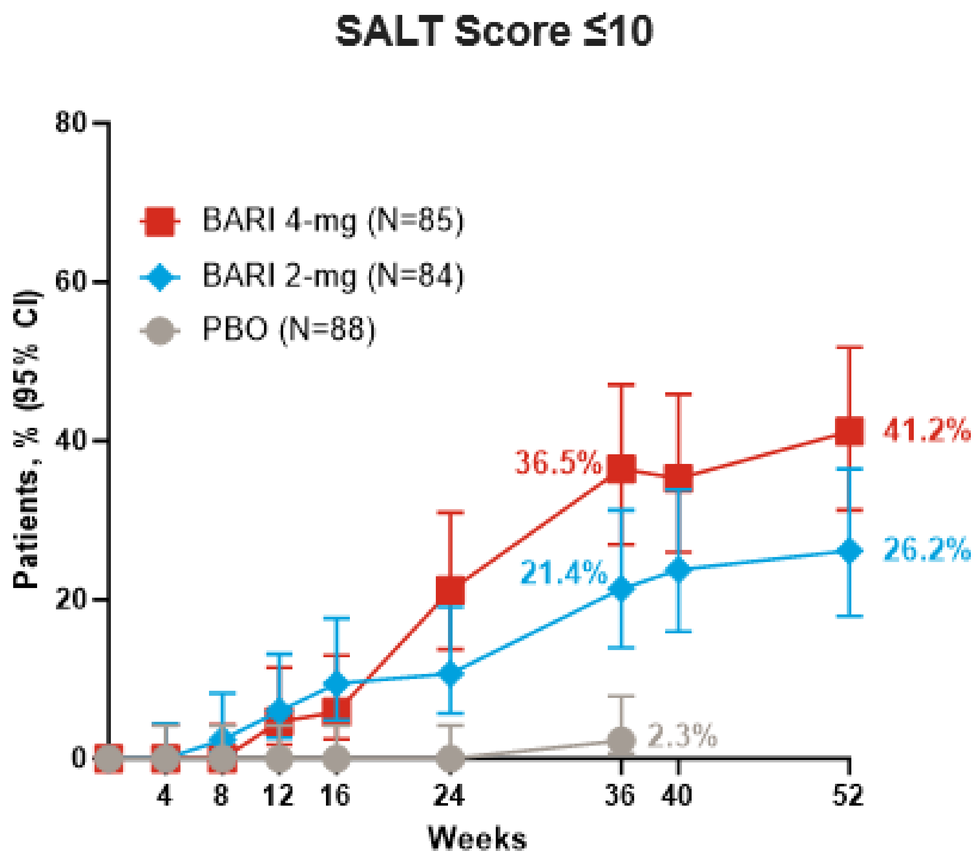
# Achievement of SALT Scores ≤20 and ≤10 to Week 52



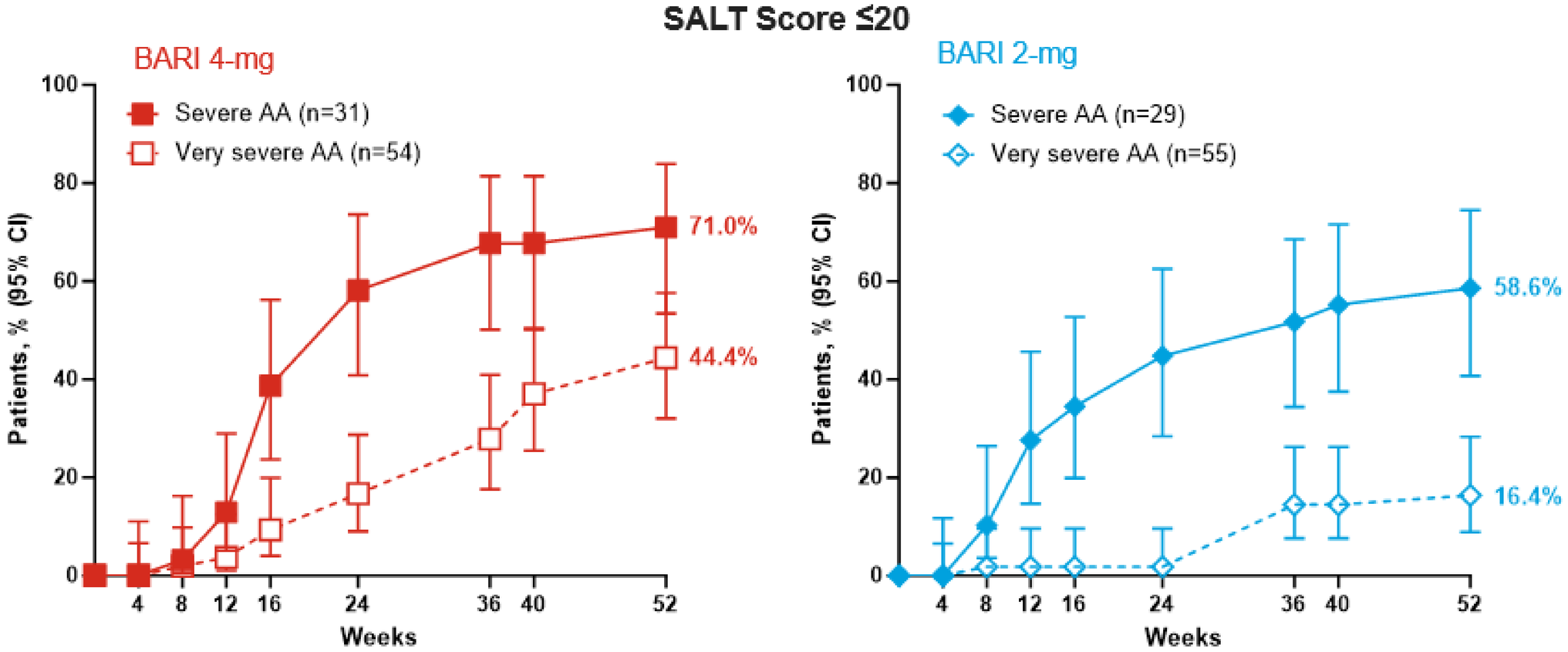




Notes: Data are NRI for the ITT set. SALT score ≤10/≤20 indicates ≤10%/≤20% scalp hair loss.

*BARI=baricitinib; CI=confidence interval; ITT=intent-to-treat; NRI=non-responder imputation; SALT=Severity of Alopecia Tool.*

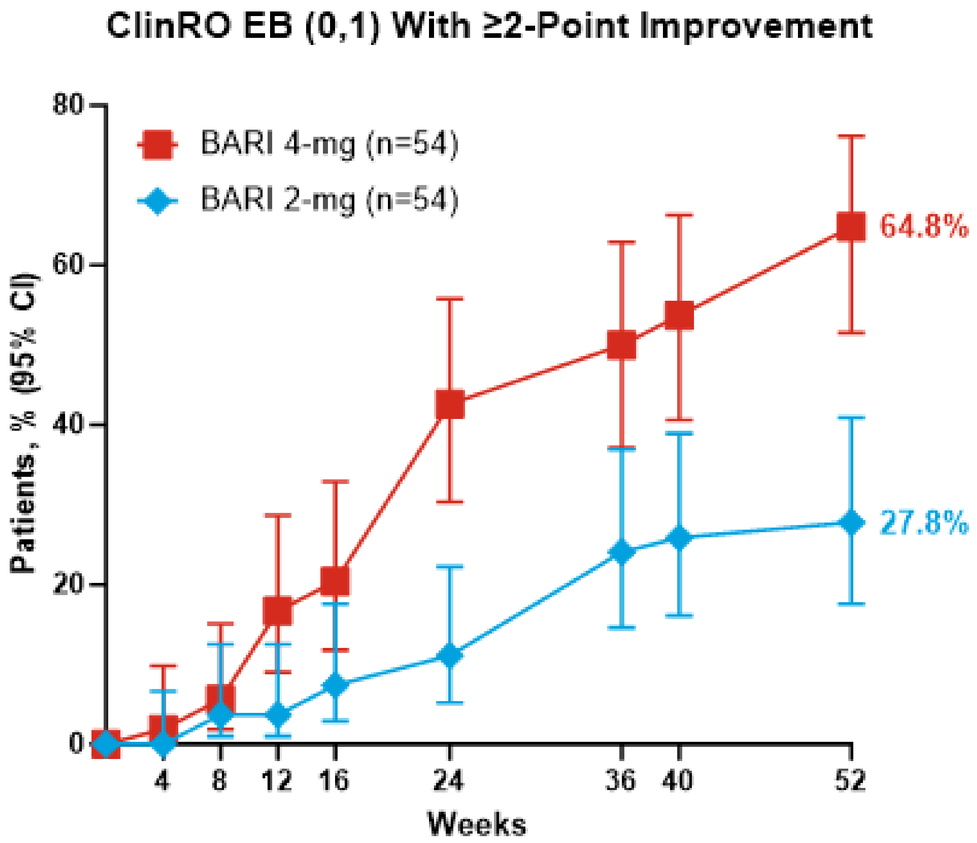
# Achievement of SALT Score ≤20 to Week 52
## *Severe or Very Severe AA at Baseline*

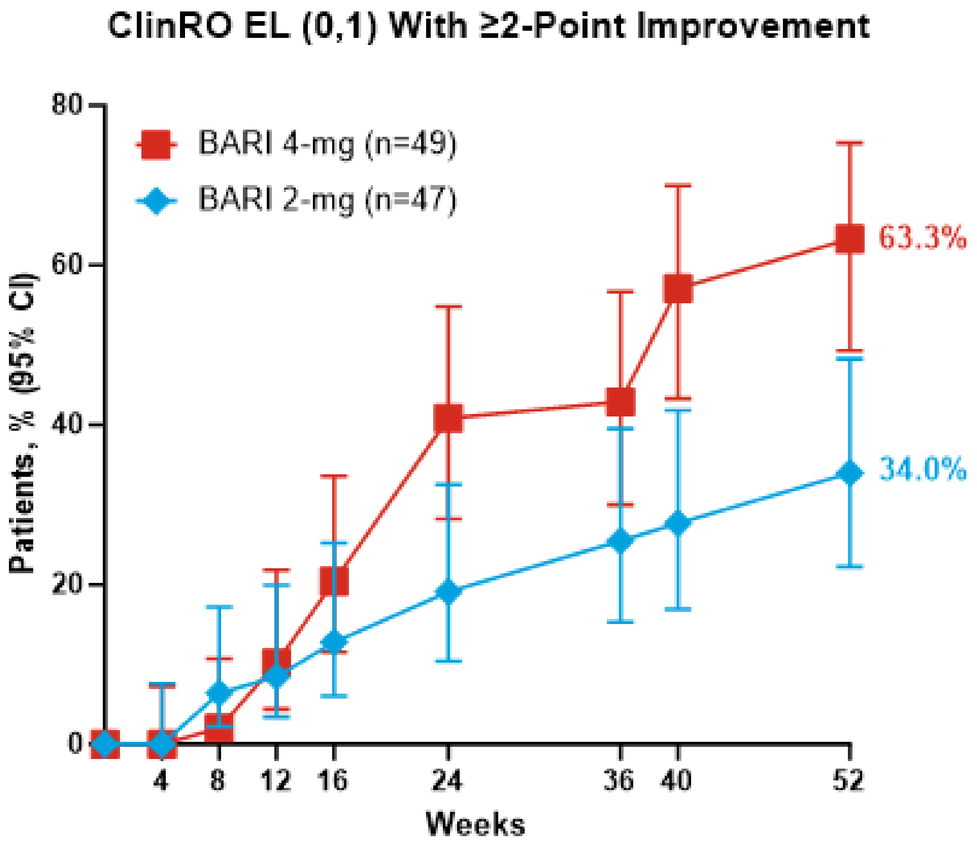
**Severe AA:** SALT score 50-94
**Very Severe AA:** SALT score 95-100




Notes: Data are NRI. SALT score ≤20 indicates ≤20% scalp hair loss.
AA=alopecia areata; *BARI=baricitinib; CI=confidence interval; NRI=non-responder imputation; SALT=Severity of Alopecia Tool.*

# Eyebrow and Eyelash Regrowth at Week 52




Notes: Data are NRI. Analysis population includes participants with ClinRO EB/EL ≥2 at baseline.

*BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; ClinRO EB=ClinRO Measure for Eyebrow Hair Loss; ClinRO EL=ClinRO Measure for Eyelash Hair Loss; NRI=non-responder imputation.*

# Safety Data Were Consistent With the Known Safety Profile for Baricitinib in Adolescents[5]

- No deaths, opportunistic infection, VTE, PE, or MACE were reported
- A serious infection and a malignancy (myxoid liposarcoma; reported as unrelated to study medication by the investigator) were reported in the baricitinib groups

*MACE=major adverse cardiovascular events; PE=pulmonary embolism; VTE=venous thromboembolic event.*

# Overview of AEs

| | PBO-Controlled Period | | | Extended BARI AA | | All BARI AA |
|---|---|---|---|---|---|---|
| | PBO (n=88) PYE=58.3 | BARI 2-mg (n=83) PYE =57.0 | BARI 4-mg (n=85) PYE=57.1 | BARI 2-mg (n=83) PYE=91.5 | BARI 4-mg (n=85) PYE=113.1 | All BARI AA (n=249) PYE=294.8 |
| **≥1 TEAE** | 47 (53.4) **[129.1]** | 50 (60.2) **[160.1]** | 60 (70.6) **[199.7]** | 52 (62.7) **[115.2]** | 70 (82.4) **[168.5]** | 156 (62.7) **[108.7]** |
| **TEAE severity[a]** | | | | | | |
| **Mild** | 27 (30.7) **[56.3]** | 37 (44.6) **[96.6]** | 43 (50.6) **[116.4]** | 36 (43.4) **[60.4]** | 41 (48.2) **[58.9]** | 95 (38.2) **[47.2]** |
| **Moderate** | 18 (20.5) **[36.3]** | 12 (14.5) **[23.3]** | 15 (17.6) **[28.5]** | 14 (16.9) **[17.2]** | 26 (30.6) **[27.3]** | 53 (21.3) **[20.5]** |
| **Severe** | 2 (2.3) **[3.5]** | 1 (1.2) **[1.8]** | 2 (2.4) **[3.6]** | 2 (2.4) **[2.2]** | 3 (3.5) **[2.7]** | 8 (3.2) **[2.7]** |
| **≥1 serious AE** | 3 (3.4) **[5.2]** | **2 (1.2) [1.8][b]** | | 1 (1.2) **[1.1]** | 4 (4.7) **[3.6]** | 9[c] (3.6) **[3.1]** |
| **Death** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Temporary interruption from study treatment** | 9 (10.2) **[16.4]** | 5 (6.0) **[9.1]** | 8 (9.4) **[14.7]** | 7 (8.4) **[8.0]** | 10 (11.8) **[9.5]** | 24 (9.6) **[8.6]** |
| **Permanent discontinuation of study drug due to AE** | 2 (2.3) **[3.4]** | **1 (0.6) [0.9][b]** | | 1 (1.2) **[1.1]** | 3 (3.5) **[2.7]** | 5 (2.0) **[1.7]** |

[a]Participants with multiple occurrences of the same event were counted under the highest severity; [b]This is an ongoing study and remains double-blinded after the Week 36 placebo period. Due to the low number of serious AEs and TEAEs reported, it is not possible to provide certain details to maintain the blind; [c]In the All BARI AA group: Abdominal pain upper, depression, major depression, suicide attempt, epilepsy, ligament sprain, myxoid liposarcoma, pneumonia, and upper limb fracture.

Notes: Data are presented as n (%) **[IR]**. IR represents 100 × (the number of participants experiencing the AE divided by the patient-years at risk). TEAE is defined as any event that occurred on or after the first dose of study drug administration or any pre-existing event that worsened in severity after dosing. Classifications of AEs are based on the MedDRA (version 27.0 Placebo-controlled period and 28.0 Extended BARI AA and All BARI AA). Data cut off: Placebo-controlled period September 10, 2024, Extended BARI AA/All BARI AA April 15, 2025.

*AE=adverse event; BARI=baricitinib; IR=incidence rate; MedDRA=Medical Dictionary for Regulatory Activities; PBO=placebo; PYE=patient-years of exposure; TEAE=treatment-emergent AE.*

# Most Frequently Reported TEAEs

| | PBO-Controlled Period | | | Extended BARI AA | | All BARI AA |
|---|---|---|---|---|---|---|
| | PBO (n=88) PYE=58.3 | BARI 2-mg (n=83) PYE =57.0 | BARI 4-mg (n=85) PYE=57.1 | BARI 2-mg (n=83) PYE=91.5 | BARI 4-mg (n=85) PYE=113.1 | All BARI AA (n=249) PYE=294.8 |
| **TEAEs occurring at ≥5% frequency in any treatment group** | | | | | | |
| **Acne** | 4 (4.5) **[7.0]** | 7 (8.4) **[13.0]** | 8 (9.4) **[14.8]** | 8 (9.6) **[9.4]** | 11 (12.9) **[10.7]** | 30 (12.0) **[11.0]** |
| **Upper respiratory tract infection** | 6 (6.8) **[10.8]** | 7 (8.4) **[13.1]** | 7 (8.2) **[13.0]** | 9 (10.8) **[10.6]** | 10 (11.8) **[9.7]** | 24 (9.6) **[8.7]** |
| **Nasopharyngitis** | 9 (10.2) **[16.3]** | 7 (8.4) **[12.9]** | 6 (7.1) **[10.8]** | 9 (10.8) **[10.5]** | 8 (9.4) **[7.5]** | 21 (8.4) **[7.5]** |
| **Influenza** | 3 (3.4) **[5.2]** | 10 (12.0) **[19.2]** | 5 (5.9) **[9.0]** | 10 (12.0) **[12.1]** | 6 (7.1) **[5.6]** | 21 (8.4) **[7.6]** |
| **Headache** | 5 (5.7) **[8.9]** | 4 (4.8) **[7.2]** | 7 (8.2) **[13.1]** | 4 (4.8) **[4.5]** | 10 (11.8) **[9.7]** | 17 (6.8) **[6.1]** |
| **Rhinitis** | 3 (3.4) **[5.3]** | 1 (1.2) **[1.8]** | 6 (7.1) **[11.1]** | 1 (1.2) **[1.1]** | 7 (8.2) **[6.6]** | 8 (3.2) **[2.8]** |
| **Blood CPK increase** | 2 (2.3) **[3.4]** | 5 events[a] | | 5 events[a] | | 5 (2.0) **[1.7]** |

[a]This is an ongoing study and remains double-blinded after the Week 36 placebo period. Due to the low number of serious AEs and TEAEs reported, it is not possible to provide certain details to maintain the blind.

Notes: Data are presented as n (%) **[IR]**. IR represents 100 × (the number of participants experiencing the AE divided by the patient-years at risk). TEAE is defined as any event that occurred on or after the first dose of study drug administration or any pre-existing event that worsened in severity after dosing. Classifications of AEs are based on the MedDRA (version 27.0 placebo-controlled period and 28.0 Extended BARI AA and All BARI AA). Data cut off: placebo-controlled period September 10, 2024, Extended BARI AA/All BARI AA April 15, 2025.

*AE=adverse event; BARI=baricitinib; CPK=creatine phosphokinase; IR=incidence rate; MedDRA=Medical Dictionary for Regulatory Activities; PBO=placebo; PYE=patient-years of exposure; TEAE=treatment-emergent AE.*

# Treament-Emergent Infections

| | PBO-Controlled Period | | | Extended BARI AA | | All BARI AA |
|---|---|---|---|---|---|---|
| | PBO (n=88) PYE=58.3 | BARI 2-mg (n=83) PYE =57.0 | BARI 4-mg (n=85) PYE=57.1 | BARI 2-mg (n=83) PYE=91.5 | BARI 4-mg (n=85) PYE=113.1 | All BARI AA (n=249) PYE=294.8 |
| **Any treatment-emergent infection** | 28 (31.8) **[61.3]** | 34 (41.0) **[84.3]** | 34 (40.0) **[78.3]** | 37 (44.6) **[60.8]** | 43 (50.6) **[59.4]** | 94 (37.8) **[45.8]** |
| **Serious infection** | 1 serious infection[a] | | | 1 serious infection[a] | | 1 (0.4) **[0.3]** |
| **Opportunistic infection** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Herpes zoster** | 1 herpes zoster[a] | | | 2 herpes zoster[a] | | 2 (0.8) **[0.7]** |
| **Herpes simplex** | 1 herpes simple[a] | | | 1 herpes simplex[a] | | 1 (0.4) **[0.3]** |
| **Tuberculosis** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Led to study drug discontinuation** | | | | | | |
| **Temporary interruption** | 4 (4.5) **[7.1]** | 3 (3.6) **[5.3]** | 2 (2.4) **[3.5]** | 5 (6.0) **[5.6]** | 5 (5.9) **[4.5]** | 12 (4.8) **[4.2]** |
| **Permanent** | 0 | 0 | 0 | 0 | 0 | 0 |

[a]This is an ongoing study and remains double-blinded after the Week 36 placebo period. Due to the low number of serious AEs and TEAEs reported, it is not possible to provide certain details to maintain the blind.

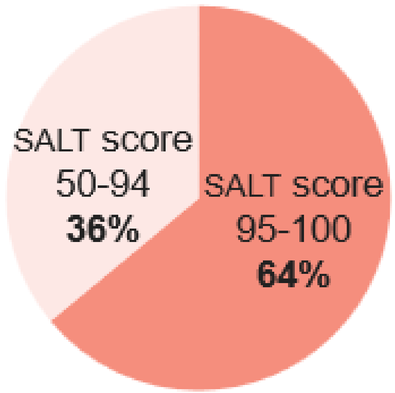
Notes: Data are presented as n (%) **[IR]**. IR represents 100 × (the number of participants experiencing the AE divided by the patient-years at risk). TEAE is defined as any event that occurred on or after the first dose of study drug administration or any pre-existing event that worsened in severity after dosing. Classifications of AEs are based on the MedDRA (version 27.0 placebo-controlled period and 28.0 Extended BARI AA and All BARI AA). Data cut-off: placebo-controlled period September 10, 2024, Extended BARI AA/All BARI AA April 15, 2025. *AE=adverse event; BARI=baricitinib; IR=incidence rate; MedDRA=Medical Dictionary for Regulatory Activities; PBO=placebo; PYE=patient-years of exposure; TEAE=treatment-emergent AE.*

# Summary of Key Findings

## Participant Population

257 adolescents (12 to <18 years) with severe AA

*Baseline SALT score (baricitinib population)*




## Efficacy at Week 52 (NRI)

*Primary Endpoint: SALT Score ≤20 in All Participants*



*SALT Score ≤20 in Severe AA vs. Very Severe AA*





## Safety

- The most common AEs were acne, upper respiratory tract infection, nasopharyngitis, and influenza
- No VTE, PE, MACE, or opportunistic infections were reported
- No new safety signals
- Consistent with known safety profile in adolescents with moderate-to-severe AD[5] and adults with severe AA[6]

*AA=alopecia areata; AD=atopic dermatitis; BARI=baricitinib; MACE=major adverse cardiovascular event; NRI=non-responder imputation; PE=pulmonary embolism SALT=Severity of Alopecia Tool; VTE=venous thromboembolic event.*

# CONCLUSIONS

- More than 50% of adolescents with severe AA treated with baricitinib 4-mg achieved successful scalp hair response by Week 52, with a response rate reaching 71% among those with baseline SALT score of 50-94
  - Successful regrowth was also observed with baricitinib 2-mg
- No new safety observation was reported, and the safety profile of baricitinib remained consistent with previous reports relating to adolescents with moderate-to-severe AD[5] and adults with severe AA[6]

*AA=alopecia areata; AD=atopic dermatitis; SALT=Severity of Alopecia Tool.*

# References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6. King B, et al. *Br J Dermatol.* 2023*;188*:218-227.

# Abbreviations

*AA=alopecia areata; AD=atopic dermatitis; AE=adverse event; BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; CPK=creatine phosphokinase; IR=incidence rate; MACE=major adverse cardiovascular event; MedDRA=Medical Dictionary for Regulatory Activities; NRI=non-responder imputation; QD=once daily; PBO=placebo; PE=pulmonary embolism; PYE=person-years of exposure; R=randomized; SALT=Severity of Alopecia Tool; SD=standard deviation; TEAE=treatment-emergent AE; VTE=venous thromboembolic event*

# Disclosures

**B. Craiglow** has received fees and/or honoraria from: AbbVie, Arcutis, BiologicsMD, Dermavant, Eli Lilly and Company, GSK, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, Sanofi Genzyme, and Sun Pharma; **L. Arkin** has received grants or funding to the institution from: Amgen and Eli Lilly and Company; and consulting fees from: Eli Lilly and Company, Merck, Nobelpharma, Regeneron, and Sanofi; **D. Saceda-Corralo** has received honoraria and/or grants as a speaker, advisory board member, and/or investigator for: Cantabria Labs, Eli Lilly and Company, and Pfizer; **Y. Lee** has received lecture and advisory fees from: Eli Lilly and Company and ichrogene Korea; **M. Ohyama** has received lecture and advisory fees from: AbbVie, Bristol Myers Squibb Japan, Eli Lilly and Company, Kyowa Kirin, Maruho, Pfizer Japan, ROHTO Pharmaceutical, Sanofi KK, and Taisho Pharmaceutical; and has received research grants not directly related to the submitted work from: Advantest Corporation, Maruho, Shiseido, and Sun Pharma Japan; **Y. Dutronc**, **S. Colvin**, **K. Denning**, **S. Su**, and **T. Das** are employees and shareholders of: Ei Lilly and Company; **U. Blume-Peytavi** has served as a consultant for and/or received grants and/or honoraria from: AbbVie, Boots Healthcare, Concert Pharmaceuticals, Eli Lilly and Company, NeuroDerm, Novartis, Pfizer, Regeneron, Sanofi, and Vichy Laboratories

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