# Impact of Severity and Disease Course on Baricitinib Treatment Response in Adolescent Patients With Severe AA From the BRAVE-AA-PEDS Trial

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## OBJECTIVE

- To assess the impact of alopecia areata (AA) severity and disease course on the achievement of clinically meaningful scalp hair regrowth (SALT score ≤20) by Week 52 in adolescents with severe AA treated with baricitinib in the BRAVE-AA-PEDS Phase 3 trial

## CONCLUSIONS

- The highest response rates were observed for participants with baseline SALT score 50-94 (severe AA) and those with disease duration of ≤2 years
- A trend for better response rate among participants with shorter duration of current episode was also observed as previously described in the adult population
- Conversely, onset before 5 years and very severe AA at baseline (SALT score 95-100) were associated with less favorable AA prognosis
- Although subgroups were defined based on disease duration, severity, and current episode duration, it is important to note that these parameters are likely interrelated. For instance, defining a subgroup by shorter episode duration may inherently select for participants with shorter time since diagnosis. Similarly, participants with earlier onset of AA may also tend to experience more severe disease
- Sample size was limited in some subgroups; therefore, these preliminary data should be confirmed in a larger cohort
- Altogether, these results show the importance of early treatment after diagnosis and before disease has progressed to maximize the likelihood of positive treatment outcomes


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

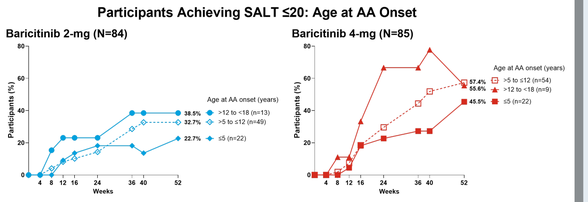

## RESULTS

### Baseline Demographics and Characteristics

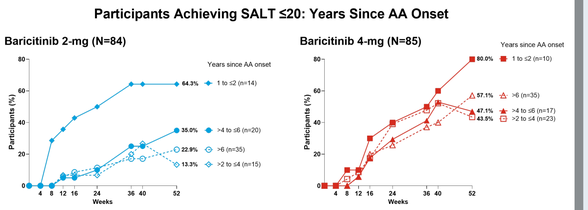
| Characteristic | BARI 2-mg (N=84) | BARI 4-mg (N=85) |
|---|---|---|
| **Age, years, mean (SD)** | 14.9 (1.6) | 14.6 (1.8) |
| **Female** | 39 (46.4) | 41 (48.2) |
| **Race** | | |
| **White** | 52 (61.9) | 52 (61.2) |
| **Asian** | 23 (27.4) | 23 (27.1) |
| **Black or African American** | 5 (6.0) | 8 (9.4) |
| **Other, multiple, or not reported** | 4 (4.8) | 2 (2.4) |
| **Duration of AA since onset, years, mean (SD)** | 6.4 (3.9) | 6.1 (4.0) |
| **Duration of the current AA episode, years, mean (SD)** | 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 Measure for Eyebrow Hair Loss™ (scores of 2 and 3)[b]** | 54 (64.3) | 54 (63.5) |
| **ClinRO Measure for Eyelash Hair Loss™ (scores of 2 and 3)[b]** | 47 (56.0) | 49 (57.6) |

[a]n=83; [b]ClinRO score of 2 represents significant gaps and/or uneven distribution; ClinRO score of 3 represents no notable eyebrow or eyelash.
Note: Data are n (%) unless otherwise stated.

### Earlier Onset of AA (≤5 Years of Age) Associated With Poorer Prognosis and Slower Response Rates to Baricitinib in Adolescents

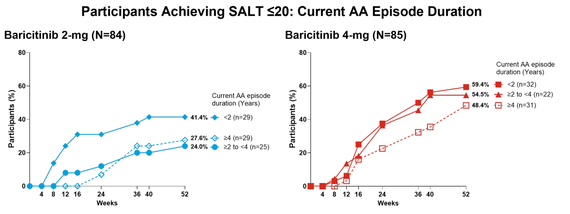



### Disease Duration ≤2 Years Associated With the Highest Response Rates to Baricitinib in Adolescents

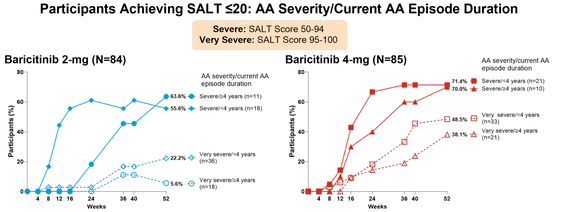



Notes: Data are NRI. SALT score ≤20 indicates ≤20% scalp hair loss. Percentage of response is calculated by n/Ns*100. Primary censoring rule excludes data collected after permanent study drug discontinuation or during temporary interruptions due to prohibited medication.

### AA Episode Duration Impacted Speed and Magnitude of Response to Baricitinib in Adolescents




### Lower AA Disease Severity Associated With Better Response Rates Irrespective of Duration of Current Episode

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## Background

- BRAVE-AA-PEDS is the largest ongoing, placebo-controlled, Phase 3 trial of pediatric participants with severe AA
- Baricitinib has demonstrated efficacy for the treatment of severe AA in adolescents enrolled in BRAVE-AA-PEDS and is undergoing further investigation including in children aged 6-11 years[1,2]
- Baseline factors such as disease severity and duration of current AA episode influence timing and magnitude of response to JAK inhibitors, including baricitinib, in adults with severe AA[3,4]

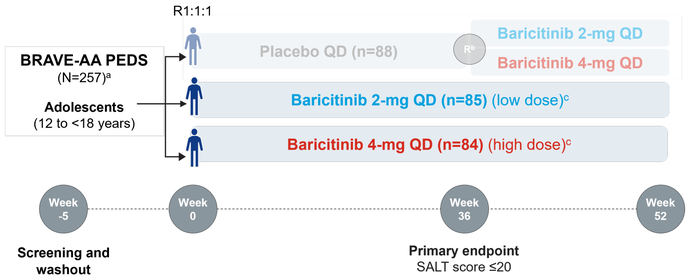
## Methods

### Key Eligibility Criteria

- Aged 12 to <18 years with 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 with severe AA for ≥8 years may be enrolled if episodes of regrowth, spontaneous or under treatment, have been observed on affected areas over the past 8 years.

## Study Design




[a]Figure is not the full study design, BRAVE-AA PEDS: NCT05723198; pediatric population: 6 to <12 years (at least n=180) also randomized 1:1:1 but not included in this analysis; [b]At Week 36, nonresponders (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.

### Assessments and Statistical Analyses

- The patient population consisted of adolescent participants (12 to <18 years of age) treated with baricitinib 4-mg or 2-mg
  - Response to baricitinib was assessed in participants with:
    - Age of AA onset: ≤5, >5 to ≤12, and >12 to <18 years of age
    - Disease duration: 1 to ≤2, >2 to ≤4, >4 to ≤6, and >6 years
    - Current AA episode duration: <2 years, ≥2 to <4, and ≥4 years
    - Baseline AA disease severity combined with current AA episode duration: (1) SALT 50-94 and <4 years' episode duration; (2) SALT 50-94 and ≥4 years' episode duration; (3) SALT 95-100 and <4 years' episode duration; (4) SALT 95-100 and ≥4 years' episode duration
- Outcomes are reported as the proportion of baricitinib responders (SALT score ≤20) in each group
- Missing data were handled by NRI and data collected after permanent study drug discontinuation or during temporary interruptions were excluded


**References**

1. Passeron T, et al. Oral presentation at: *AAD 2025*.
2. https://clinicaltrials.gov/study/NCT05723198. September 2025.
3. King B, et al. *J Eur Acad Dermatol Venereol*. 2025;39:1163-1173.
4. Taylor S, et al. *Dermatol Ther (Heidelb)*. 2023;13:3181-3191.


**Abbreviations**

*AA=alopecia areata; BARI=baricitinib; ClinRO=clinician-reported outcome; JAK=Janus kinase; n=number of participants in the specified category; NRI=non-responder imputation; Ns=number of participants in each subgroup; PBO=placebo; QD=once daily; R=randomization; SALT=Severity of Alopecia Tool; SD=standard deviation*

**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 Pharmaceuticals; **B. Piraccini** has received honoraria from or been a consultant for: Almirall, Eli Lilly and Company, ISDIN, Pfizer, and Vichy Laboratoires; **J. Soung** has received honoraria and/or grants as a speaker, advisory board member, and/or investigator for: AbbVie, Amgen, Boehringer Ingelheim, Cassiopeia Pharmaceuticals, Celgene, Dermira, Eli Lilly and Company, Galderma, GSK, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, Novan, Novartis, Pfizer, Regeneron, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant Pharmaceuticals; **M. Ohyama** receives lecture and advisory fees from: AbbVie, Bristol Myers Squibb Japan, Eli Lilly and Company, Kyowa Kirin, Maruho, Pfizer Japan, ROHTO Pharmaceutical, Sanofi, Taisho Pharmaceutical; and research grants not directly related with the submitted work from: Advantest, Maruho, Shiseido, and Sun Pharma Japan; **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; **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; **A. Sontag**, **Y. Dutronc**, **H. Pandey**, and **K. Singh** are current employees and shareholders of: Eli Lilly and Company; **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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# Background and Objective

## Background

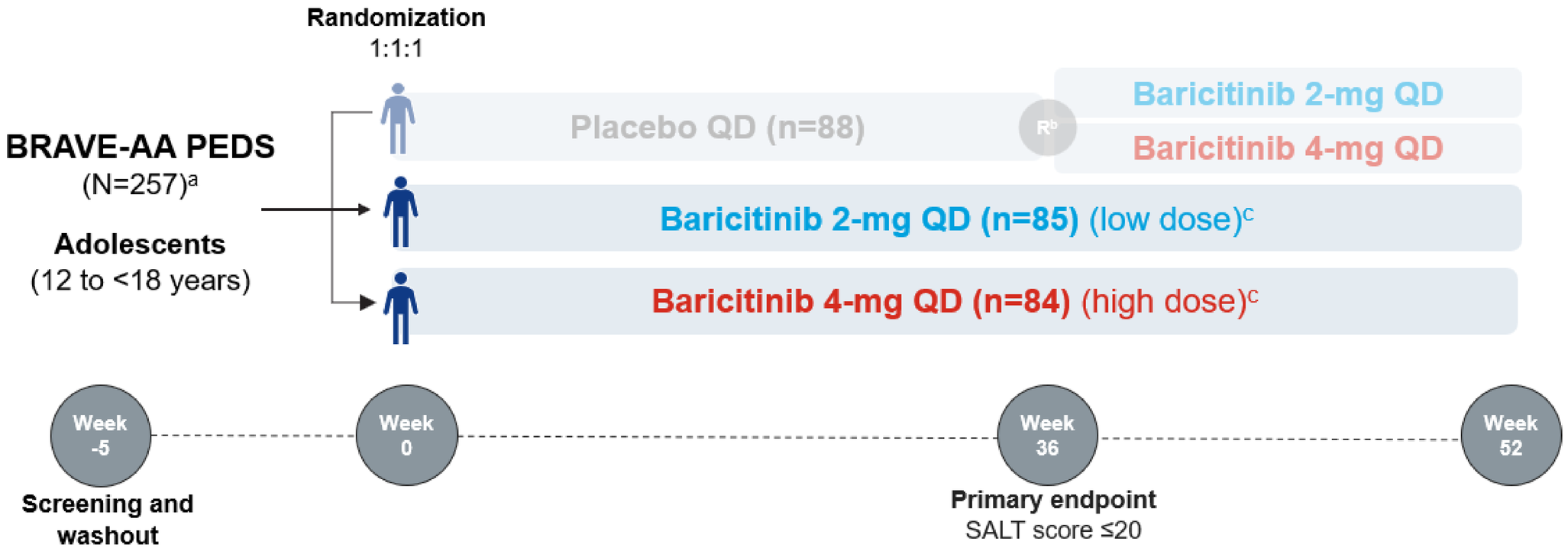
- BRAVE-AA-PEDS (NCT05723198) is the largest ongoing, placebo-controlled, Phase 3 trial of pediatric participants (6 to <18 years) with severe AA
- Baricitinib has demonstrated efficacy for the treatment of severe alopecia areata (AA) in adolescents enrolled in BRAVE-AA-PEDS and is undergoing further investigation including in children aged 6-11 years[1,2]
- Baseline factors such as disease severity and duration of current AA episode influence timing and magnitude of response to JAK inhibitors, including baricitinib, in adults with severe AA[3,4]

## Objective

- To assess the impact of AA severity and disease course on the achievement of clinically meaningful scalp hair regrowth (SALT score ≤20) by Week 52 in adolescents with severe AA treated with baricitinib in the BRAVE-AA-PEDS Phase 3 trial

*AA=alopecia areata; JAK=Janus kinase; SALT=Severity of Alopecia Tool.*

# Study Design

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# Assessments and Statistical Analyses

- The patient population consisted of adolescent participants (12 to <18 years of age) treated with baricitinib 4-mg or 2-mg
  - Response to baricitinib was assessed in participants with:
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    - Disease duration: 1 to ≤2, >2 to ≤4, >4 to ≤6, and >6 years
    - Current AA episode duration: <2 years, ≥2 to <4, and ≥4 years
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# Baseline Demographics (1/2)

| Characteristic | BARI 2-mg (N=84) | BARI 4-mg (N=85) |
|---|---|---|
| **Age, years, mean (SD)** | 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) |
|---|---|---|
| Duration of AA since onset, years, mean (SD) | 6.4 (3.9) | 6.1 (4.0) |
| Duration of the current AA episode, years, mean (SD) | 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) |
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Note: Data are n (%) unless otherwise stated.
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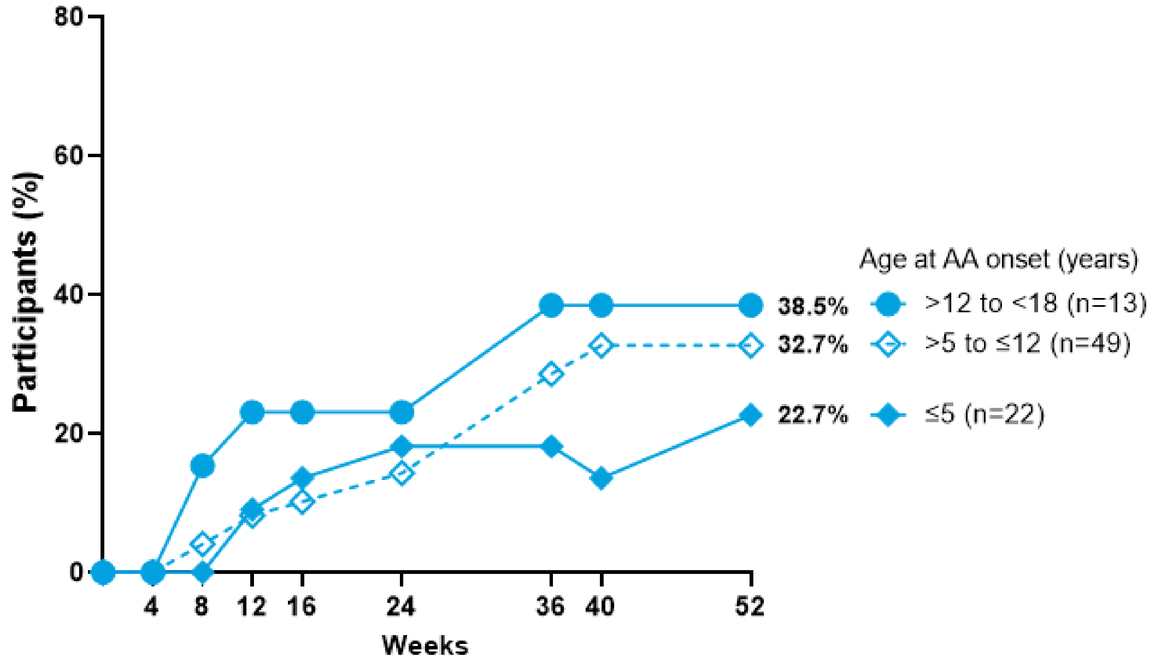
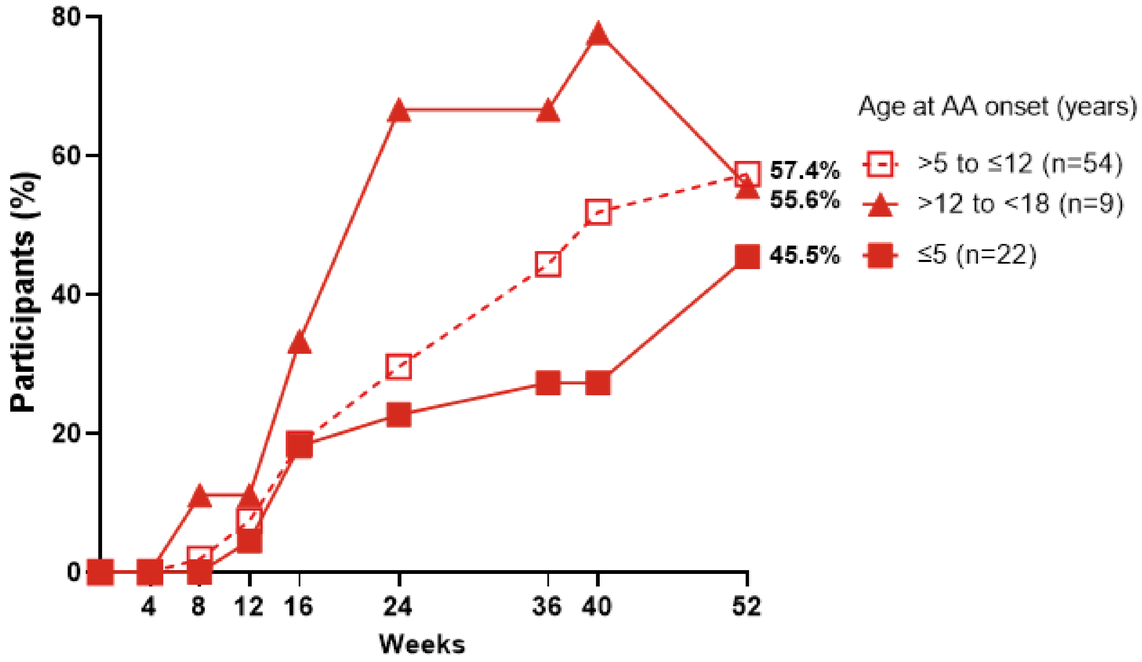
# Earlier Onset of AA (≤5 Years of Age) Associated With Poorer Prognosis and Slower Response Rates to Baricitinib in Adolescents

## Participants Achieving SALT ≤20: Age at AA Onset

### Baricitinib 2-mg (N=84)




### Baricitinib 4-mg (N=85)




Notes: Data are NRI. SALT score ≤20 indicates ≤20% scalp hair loss. Percentage of response is calculated by n/Ns*100. Primary censoring rule excludes data collected after permanent study drug discontinuation or during temporary interruptions due to prohibited medication.

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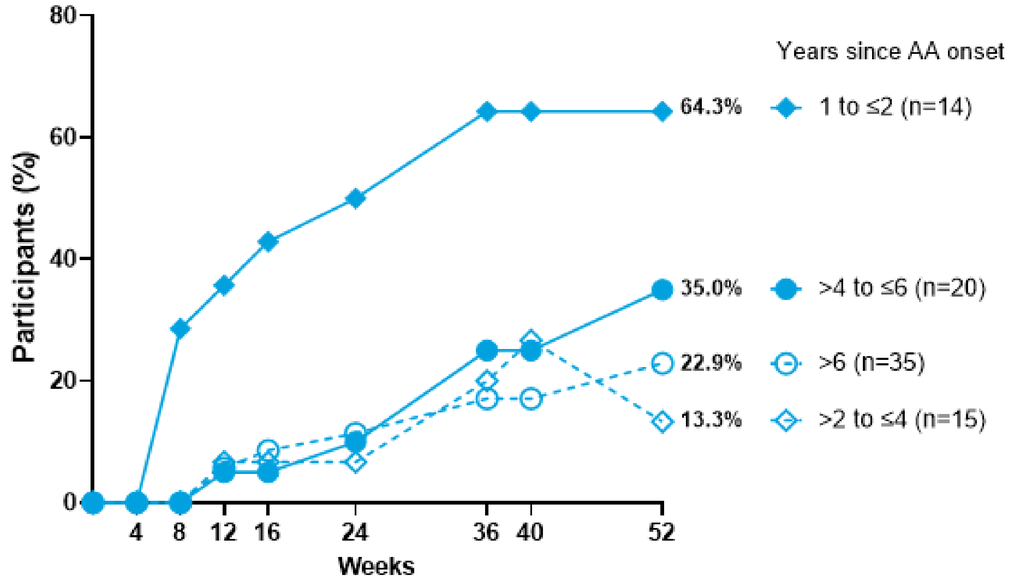
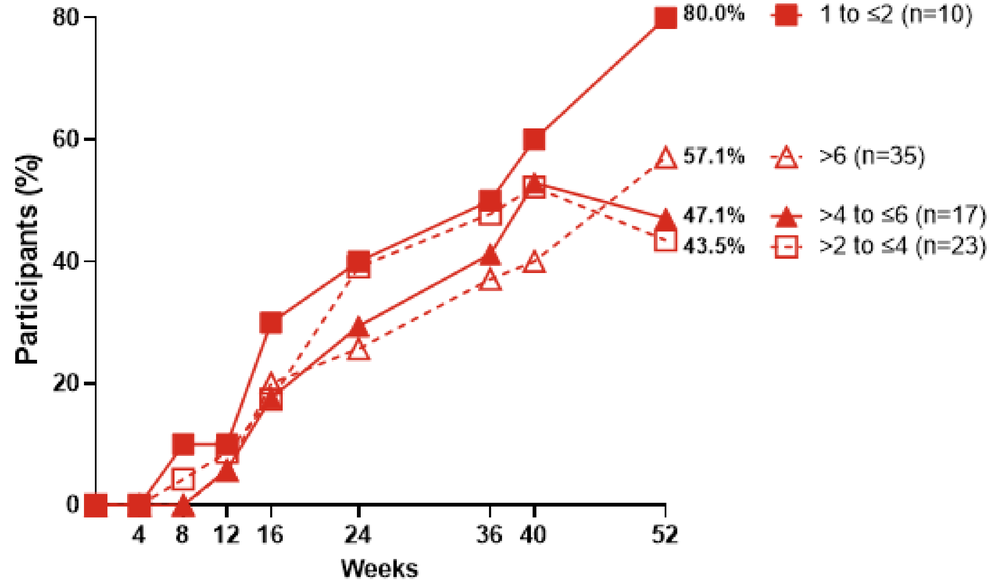
# Disease Duration ≤2 Years Associated With the Highest Response Rates to Baricitinib in Adolescents

## Participants Achieving SALT ≤20: Years Since AA Onset

### Baricitinib 2-mg (N=84)




### Baricitinib 4-mg (N=85)

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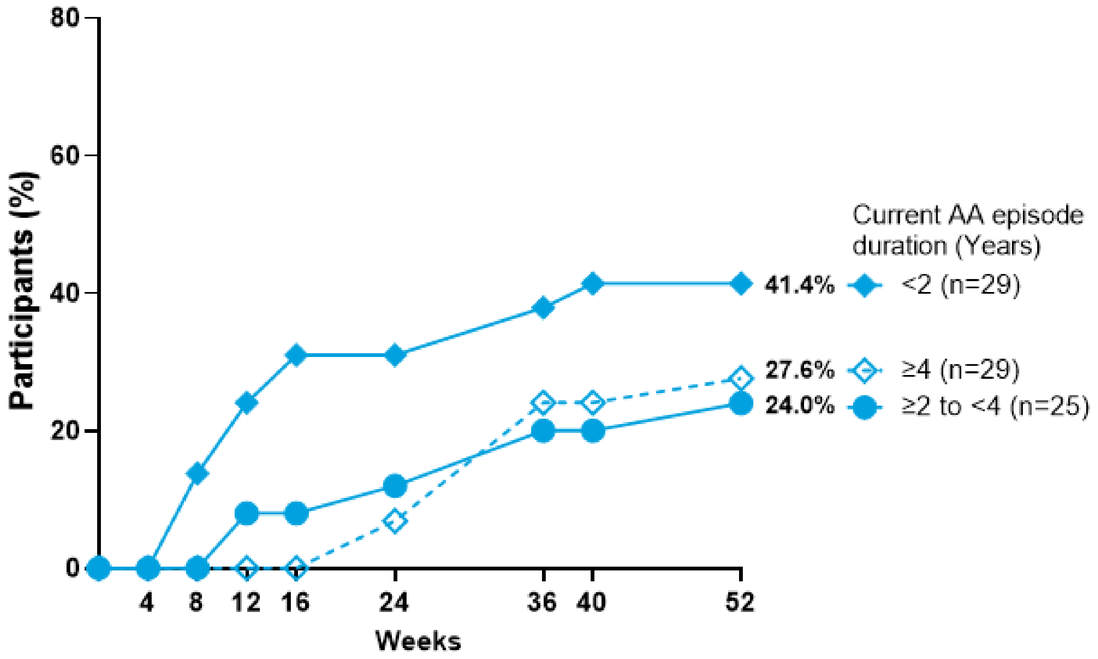
# AA Episode Duration Impacted Speed and Magnitude of Response to Baricitinib in Adolescents

## Participants Achieving SALT ≤20: Current AA Episode Duration

### Baricitinib 2-mg (N=84)

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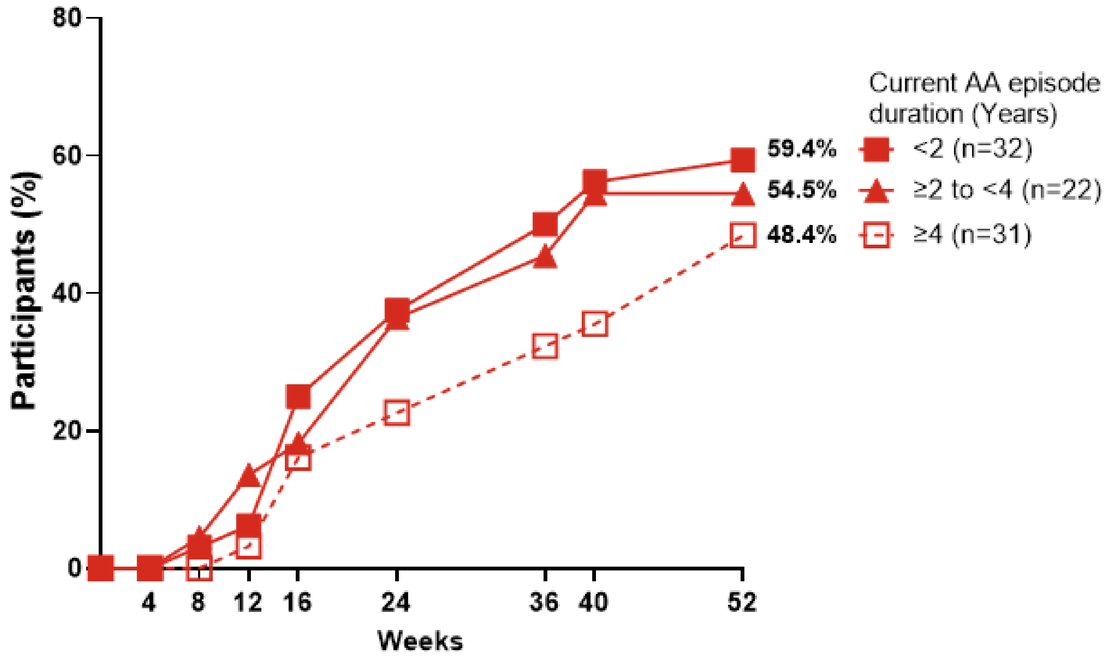


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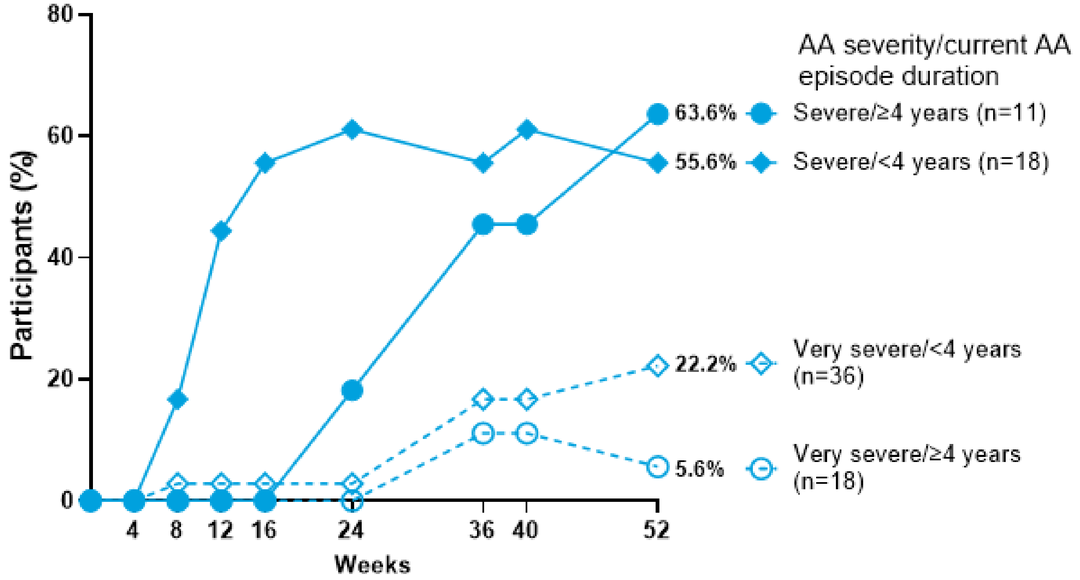
# Lower AA Disease Severity Associated With Better Response Rates Irrespective of Duration of Current Episode

## Participants Achieving SALT ≤20: AA Severity/Current AA Episode Duration

**Severe:** SALT Score 50-94
**Very Severe:** SALT Score 95-100

### Baricitinib 2-mg (N=84)

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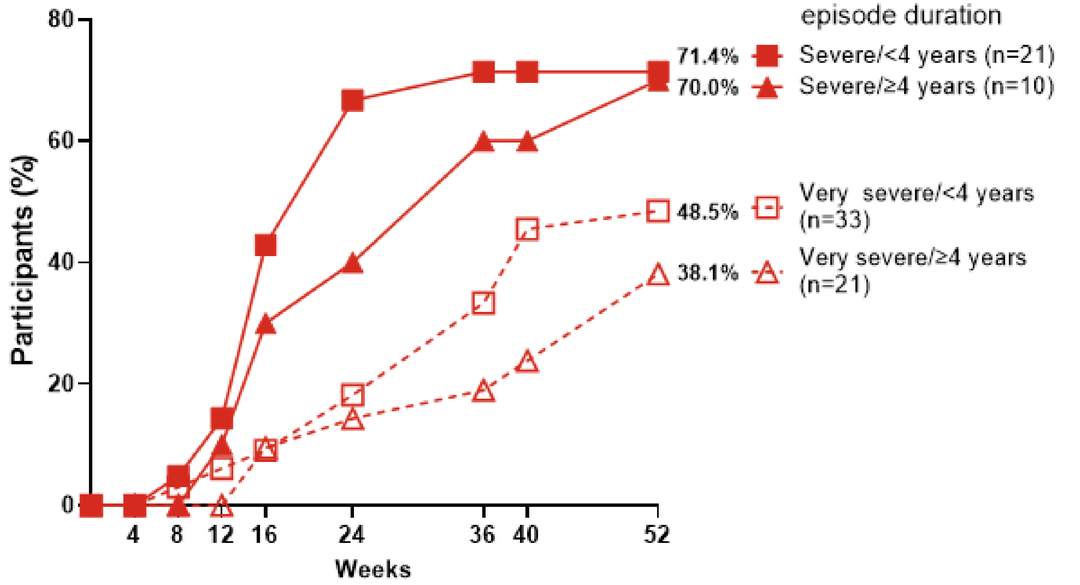


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# Conclusions

- The highest response rates were observed for participants with baseline SALT score 50-94 (severe AA) and those with disease duration of ≤2 years
- A trend for better response rate among participants with shorter duration of current episode was also observed as previously described in the adult population
- Conversely, onset before 5 years and very severe AA at baseline (SALT score 95-100) were associated with less favorable AA prognosis
- Although subgroups were defined based on disease duration, severity, and current episode duration, it is important to note that these parameters are likely interrelated. For instance, defining a subgroup by shorter episode duration may inherently select for participants with shorter time since diagnosis. Similarly, participants with earlier onset of AA may also tend to experience more severe disease
- Sample size was limited in some subgroups; therefore, these preliminary data should be confirmed in a larger cohort
- Altogether, these results show the importance of early treatment after diagnosis and before disease has progressed to maximize the likelihood of positive treatment outcomes

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# Abbreviations

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4. Taylor S, et al. *Dermatol Ther (Heidelb)*. 2023;13:3181-3191.

# 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 Pharmaceuticals; **B. Piraccini** has received honoraria from or been a consultant for: Almirall, Eli Lilly and Company, ISDIN, Pfizer, and Vichy Laboratoires; **J. Soung** has received honoraria and/or grants as a speaker, advisory board member, and/or investigator for: AbbVie, Amgen, Boehringer Ingelheim, Cassiopeia Pharmaceuticals, Celgene, Dermira, Eli Lilly and Company, Galderma, GSK, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, Novan, Novartis, Pfizer, Regeneron, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant Pharmaceuticals; **M. Ohyama** receives lecture and advisory fees from: AbbVie, Bristol Myers Squibb Japan, Eli Lilly and Company, Kyowa Kirin, Maruho, Pfizer Japan, ROHTO Pharmaceutical, Sanofi, Taisho Pharmaceutical; and research grants not directly related with the submitted work from: Advantest, Maruho, Shiseido, and Sun Pharma Japan; **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; **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; **A. Sontag, Y. Dutronc, H. Pandey**, and **K. Singh** are current employees and shareholders of: Eli Lilly and Company; **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
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