Baricitinib Provides Higher Efficacy in Adolescents Relative to Adults With Alopecia Areata Despite More Severe Disease at Baseline: 36-Week Outcomes From BRAVE-AA Trials

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OBJECTIVE

- To assess baseline characteristics and Week 36 efficacy and safety outcomes in trials of baricitinib for severe alopecia areata (AA) in adolescent (BRAVE-AA-PEDS) and adult (integrated BRAVE-AA1/-AA2) participants

CONCLUSIONS

- The adolescent and adult cohorts with severe AA share important characteristics
  - Both cohorts showed a high prevalence of comorbid atopic conditions, but elevated IgE levels were even more common in adolescents
  - Both cohorts presented with high prevalence of eyebrow and eyelash involvement; however, the adolescent population had about 10% higher prevalence of very severe AA compared with the adult population
- Despite the higher baseline disease severity, the efficacy of baricitinib in adolescents seems higher than in adults with response rates of SALT score ≤20 at Week 36 comparable to those observed at Week 52 in adults; response rates for eyebrow and eyelash growth were also numerically higher for adolescents as compared with adults
  - This may be related to a shorter duration of disease highlighting the benefit of early intervention to maximize likelihood of treatment response
- Baricitinib safety profile was similar for adolescents and adults

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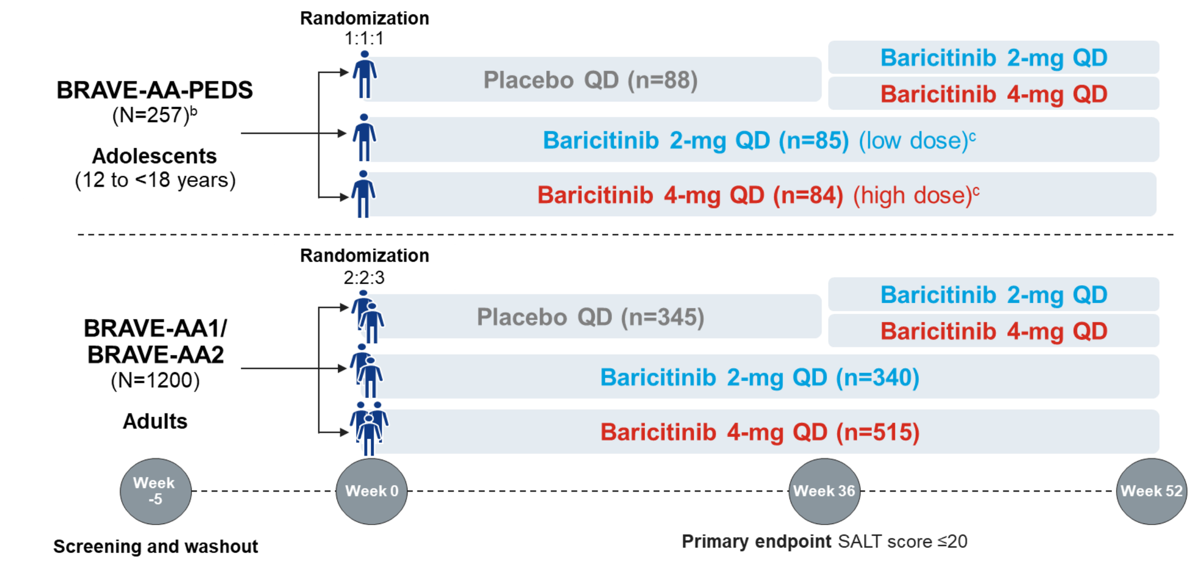
BACKGROUND

- Approximately 40% of patients with AA experience the first onset of the disease by age 20[1]
- Baricitinib, an oral, selective, reversible JAK inhibitor, is an effective treatment for severe AA in adults[2]
- There is limited knowledge on the differences in clinical presentations and characteristics between adolescents and adults and how these may impact treatment response

PARALLEL STUDY designs[a]


Randomization
1:1:1
BRAVE-AA-PEDS
(N=257)[b]
Adolescents
(12 to <18 years)
Placebo QD (n=88)
Baricitinib 2-mg QD
Baricitinib 4-mg QD
Baricitinib 2-mg QD (n=85) (low dose)[c]
Baricitinib 4-mg QD (n=84) (high dose)[c]
Randomization
2:2:3
BRAVE-AA1/
BRAVE-AA2
(N=1200)
Adults
Placebo QD (n=345)
Baricitinib 2-mg QD (n=340)
Baricitinib 4-mg QD (n=515)
Week -5
Week 0
Week 36
Week 52
Screening and washout
Primary endpoint SALT score ≤20

[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.

Key Eligibility CriteriaCriteria Common to BRAVE-AA-PEDS and BRAVE-AA1/-AA2

- SALT score ≥50 at screening and baseline
- Current episode of AA lasting >6months 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/-AA2

- 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.

METHODS

Study Population and Statistical Analysis

- Efficacy analysis
  - BRAVE-AA-PEDS: Intent-to-treat population, NRI
  - BRAVE-AA1/-AA2: Pooled Week 36/52 efficacy population, NRI
  - These trials were powered to test statistical significance of the superiority of baricitinib doses over placebo
    - The comparison between the adolescent and adult data is purely descriptive and cross-trial comparisons cannot be made
- Safety analysis
  - Safety populations comprised participants who received 1 dose of investigational product and were not reported as lost to follow-up at the first post-baseline visit

RESULTS

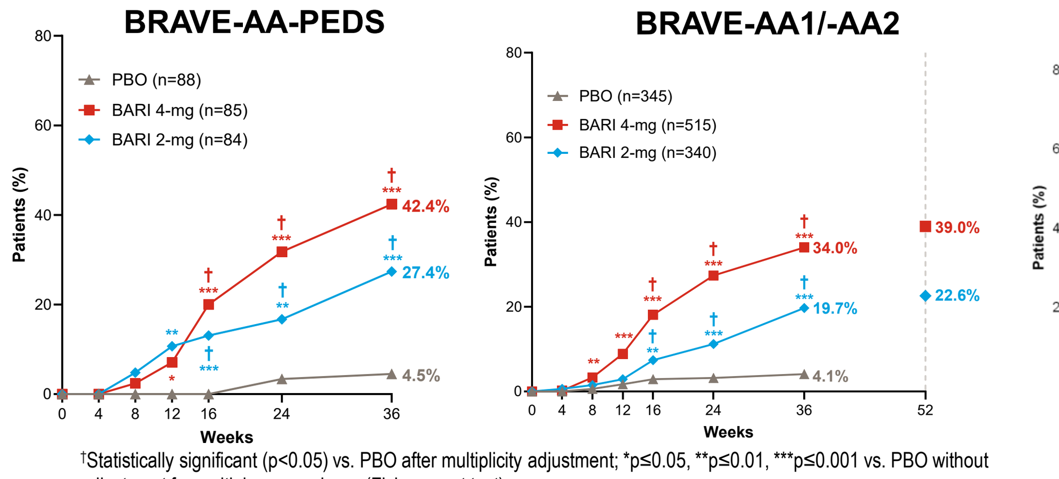
Baseline Demographics

Characteristic	Adolescents (BRAVE-AA-PEDS) [n=257]	Adults (BRAVE-AA1/-AA2) [n=1200]
Age, years	14.7 (1.7)	37.5 (12.9)
Age at AA onset, years	7.9 (3.9)	25.3 (14.7)
Female, n (%)	127 (49.4)	728 (60.7)
Race, n (%)[a]		
White	155 (60.3)	620 (51.8)
Asian	72 (28.0)	435 (36.3)
Black	19 (7.4)	98 (8.2)
Multiple	7 (2.7)	19 (1.6)
Geographical region, n (%)		
North America	76 (29.6)	548 (45.7)
Asia	67 (26.1)	394 (32.8)
Europe	109 (42.4)	0
Rest of the world	5 (1.9)	258 (21.5)
Weight, kg	59.2 (16.3)	74.1 (17.2)
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)
<4 years, n (%)	169 (65.8)	782 (65.4)[b]
≥4 years, n (%)	86 (33.5)	413 (34.6)[b]
SALT score	89.0 (16.3)	85.3 (18.0)
Severe AA (SALT score 50-94), n (%)	92 (35.8)	561 (46.8)[c]
Very severe AA (SALT score 95-100), n (%)	164 (63.8)	638 (53.2)[c]
Alopecia universalis, n (%)	138 (53.7)	531 (44.3)
Alopecia ophiasis, n (%)	23 (8.9)	109 (9.1)
ClinRO Measure for Eyebrow Hair Loss™ score of 2 or 3, n (%)	168 (65.4)	825 (69.3)[d]
ClinRO Measure for Eyelash Hair Loss™ score of 2 or 3, n (%)	146 (56.8)	693 (58.2)[d]
Top 3 comorbidities, n (%)[e]	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)
IgE ≥200 (IU/mL), n (%)	129 (50.2)	300 (26.0)
Previous therapy, n (%)		
Naïve	0[f]	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)

[a]N=1197, 3 participants did not provide information on race; [b]N=1195; [c]N=1199; [d]N=1191; [e]Top 3 comorbidities listed for adolescent and adult cohorts; [f]History of trial and failure (topical or other) with 1 available treatment for AA was an entry criterion for BRAVE-AA-PEDS.
Note: Data are mean (SD) unless stated otherwise.

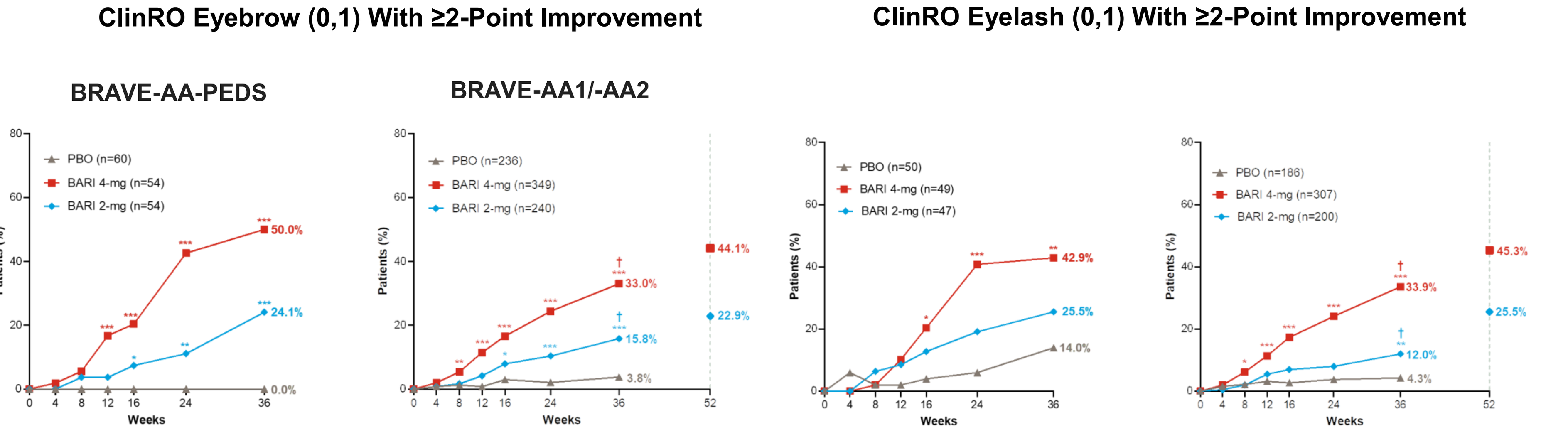
- A higher proportion of adolescents had very severe AA at baseline compared with adults

Primary Outcome: Proportion of Patients With SALT Score ≤20 Through Week 36, Extending to Week 52 for the Adult Population



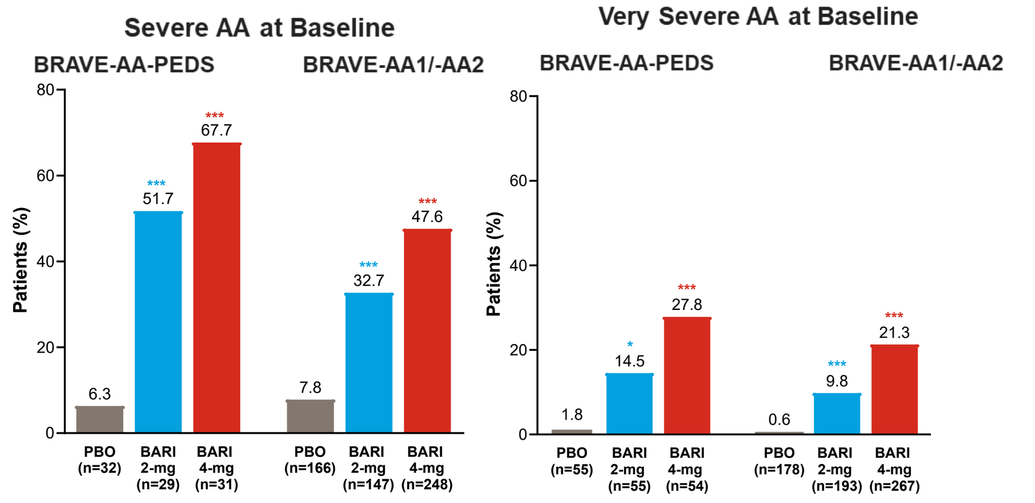
[†]Statistically significant (p<0.05) vs. PBO after multiplicity adjustment; *p≤0.05, **p≤0.01, ***p≤0.001 vs. PBO without adjustment for multiple comparisons (Fisher exact test).
Notes: Data are NRI. SALT score ≤20 indicates ≤20% scalp hair loss. BRAVE-AA1/-AA2 data available to Week 52.

Regrowth of Eyebrows and Eyelashes Through Week 36, Extending to Week 52 for the Adult Population



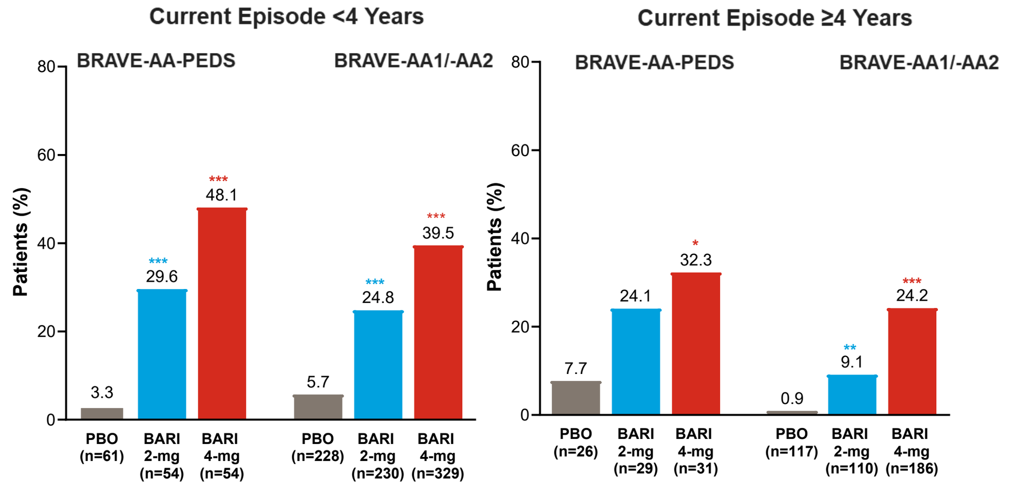
[†]Statistically significant (p<0.05) vs. PBO after multiplicity adjustment; *p≤0.05, **p≤0.01, ***p≤0.001 vs. PBO without adjustment for multiple comparisons (Fisher exact test).
Notes: Data are NRI. Analysis population includes participants with ClinRO Eyebrow and Eyelash ≥2 at baseline.

Proportion of Patients With SALT Score ≤20 at Week 36 by AA Severity at Baseline


Severe AA at Baseline
Very Severe AA at Baseline
BRAVE-AA-PEDS
BRAVE-AA1/-AA2
Patients (%)
6.3
51.7
67.7
7.8
32.7
47.6
1.8
14.5
27.8
0.6
9.8
21.3
PBO (n=32)
BARI 2-mg (n=29)
BARI 4-mg (n=31)
PBO (n=166)
BARI 2-mg (n=147)
BARI 4-mg (n=248)
PBO (n=55)
BARI 2-mg (n=55)
BARI 4-mg (n=54)
PBO (n=178)
BARI 2-mg (n=193)
BARI 4-mg (n=267)

*p≤0.05, ***p≤0.001 vs. PBO (Fisher exact test).
Notes: Data are NRI. SALT score 50-94 indicates severe AA, SALT score 95-100 indicates very severe AA.

Proportion of Patients With SALT Score ≤20 at Week 36 by Duration of Current Episode at Baseline


Current Episode <4 Years
Current Episode ≥4 Years
BRAVE-AA-PEDS
BRAVE-AA1/-AA2
Patients (%)
3.3
29.6
48.1
5.7
24.8
39.5
7.7
24.1
32.3
0.9
9.1
24.2
PBO (n=61)
BARI 2-mg (n=54)
BARI 4-mg (n=54)
PBO (n=228)
BARI 2-mg (n=230)
BARI 4-mg (n=329)
PBO (n=26)
BARI 2-mg (n=29)
BARI 4-mg (n=31)
PBO (n=117)
BARI 2-mg (n=110)
BARI 4-mg (n=186)

*p≤0.05, **p<0.01, ***p≤0.001 vs. PBO (Fisher exact test).
Note: Data are NRI.

References
1. Lintzeri DA, et al. J Dtsch Dermatol Ges. 2022;20:59-90. 2. King B, et al. N Engl J Med. 2022;386:1687-1699.

Abbreviations
AA=alopecia areata; AE=adverse event; BARI=baricitinib; ClinRO=clinician-reported outcome; CPK=creatine phosphokinase; Ig=immunoglobulin; IR=incidence rate; JAK=Janus kinase; MedDRA=Medical Dictionary for Regulatory Activities; NRI=non-responder imputation; PBO=placebo; QD=once daily; SALT=Severity of Alopecia Tool; SD=standard deviation; TEAE=treatment-emergent AE

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Safety Profile Was Similar for Adolescents and Adults Through Week 36

	BRAVE-AA-PEDS				BRAVE-AA1/-AA2		
	PBO (n=88)	BARI 2-mg (n=83)	BARI 4-mg (n=85)	Pooled BARI (n=168)	PBO (n=371)	BARI 2-mg (n=365)	BARI 4-mg (n=540)
At least 1 TEAE	47 (53.4)	50 (60.2)	60 (70.6)	110 (65.5)	211 (56.9)	221 (60.5)	341 (63.1)
TEAE severity[a]							
Mild	27 (30.7)	37 (44.6)	43 (50.6)	80 (47.6)	122 (32.9)	136 (37.3)	200 (37.0)
Moderate	18 (20.5)	12 (14.5)	15 (17.6)	27 (16.1)	78 (21.0)	79 (21.6)	120 (22.2)
Severe	2 (2.3)	1 (1.2)	2 (2.4)	3 (1.8)	11 (3.0)	6 (1.6)	21 (3.9)
At least 1 serious AE	3 (3.4)			2 (1.2)	6 (1.6)	8 (2.2)	14 (2.6)
Permanent discontinuation of study drug due to AE	2 (2.3)			1 (0.6)	6 (1.6)	8 (2.2)	12 (2.2)

[a]Patients with multiple occurrences of the same event were counted under the highest severity. A 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.
Notes: Data are presented as n (%). Classifications of AEs are based on the MedDRA (version 27.0). BRAVE-AA-PEDS is an ongoing study and remains double-blinded post the Week 36 PBO period; to maintain the blinding for rare events, it is not possible to provide the details in the grey shaded boxes; hence, the Pooled BARI group is shown.

Most Frequently Reported TEAEs Through Week 36

	BRAVE-AA-PEDS				BRAVE-AA1/-AA2		
	PBO (n=88)	BARI 2-mg (n=83)	BARI 4-mg (n=85)	Pooled BARI (n=168)	PBO (n=371)	BARI 2-mg (n=365)	BARI 4-mg (n=540)
TEAEs reported in ≥5% of patients in any group							
Acne	4 (4.5) [7.0]	7 (8.4) [13.0]	8 (9.4) [14.8]	15 (8.9) [13.9]	4 (1.1) [1.6]	21 (5.8) [9.0]	30 (5.6) [8.5]
Influenza	3 (3.4) [5.2]	10 (12.0) [19.2]	5 (5.9) [9.0]	15 (8.9) [13.9]	7 (1.9) [2.9]	6 (1.6) [2.5]	14 (2.6) [3.9]
Upper respiratory tract infection	6 (6.8) [10.8]	7 (8.4) [13.1]	7 (8.2) [13.0]	14 (8.3) [13.0]	26 (7.0) [11.2]	24 (6.6) [10.3]	41 (7.6) [11.8]
Nasopharyngitis	9 (10.2) [16.3]	7 (8.4) [12.9]	6 (7.1) [10.8]	13 (7.7) [11.9]	19 (5.1) [8.0]	16 (4.4) [6.8]	37 (6.9) [10.7]
Headache	5 (5.7) [8.9]	4 (4.8) [7.2]	7 (8.2) [13.1]	11 (6.5) [10.1]	20 (5.4) [8.4]	20 (5.5) [8.5]	36 (6.7) [10.4]
Rhinitis	3 (3.4) [5.3]	1 (1.2) [1.8]	6 (7.1) [11.1]	7 (4.2) [6.3]	1 (0.3) [0.4]	0	0
Blood CPK increase	2 (2.3) [3.4]			5 (3.0) [4.5]	5 (1.3) [2.0]	3 (0.8) [1.2]	23 (4.3) [6.4]

Notes: Data are presented as n (%) [IR]. IR represents 100 × (the number of patients experiencing the AE divided by the patient-years at risk). Classifications of AE are based on the MedDRA (version 27.0). A 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. BRAVE-AA-PEDS is an ongoing study and remains double-blinded post the Week 36 PBO period; to maintain the blinding for rare events, it is not possible to provide the details in the grey shaded boxes; hence, the Pooled BARI group is shown.

Limitations

- The trajectory of response curves has not yet plateaued at Week 52 for either adults or adolescents. Analyses of the adult population has shown that response may be delayed in some patients, in particular those with very severe AA. Therefore, observations extending beyond 52 weeks will be necessary to fully assess differences in response rates between adults and adolescents