Baricitinib Provides Holistic Improvement in Scalp, Eyebrow and Eyelash Regrowth in Adolescents With Severe Alopecia Areata

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OBJECTIVES

- To report the frequency of eyebrow and eyelash (EB/EL) involvement at baseline among adolescents in the BRAVE-AA-PEDS trial, and assess EB/EL response to baricitinib treatment through 52 weeks among patients with varying degrees of scalp response

CONCLUSIONS

- In an adolescent population (12 to <18 years) with severe alopecia areata (AA), baricitinib was efficacious in achieving a holistic response across all 3 hair-bearing sites (scalp, EB, and EL) in the majority of Week 52 scalp responders
- Significant EB and/or EL response was also observed among adolescents with partial or non-response to baricitinib
- A holistic response to treatment could lessen the psychosocial burden of the disease and improve treatment satisfaction among patients with AA and EB/EL involvement

BACKGROUND

- AA can affect any hair-bearing site, including EB/EL in approximately 75% of patients with severe AA,[1,2] which can add to the psychosocial burden of the disease[3-5]
- EB/EL can be defining features of the face, and their loss can result in physical symptoms such as eye irritation[5-8]
- EB/EL involvement is an important consideration in the assessment of AA severity[9] as well as the response to treatment[6]
- Holistic regrowth across scalp, EB and/or EL is important to patients;
  ~ one-third of patients with AA reported extreme satisfaction with EB or scalp hair regrowth alone, whereas 90% reported extreme satisfaction if regrowth occurred at both hair bearing sites[10]
- Baricitinib, an oral, selective, and reversible JAK inhibitor approved for the treatment of severe AA in adult patients,[11] was efficacious in achieving a holistic response across the scalp and EB/EL in a majority of Week 52 adult scalp hair responders in the BRAVE-AA1 and BRAVE-AA2 trials[12]

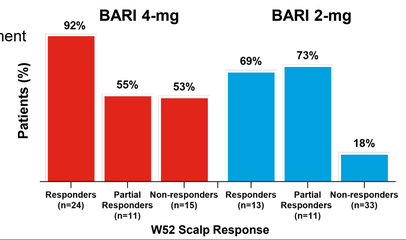
KEY FINDINGS

In Adolescents With Severe AA Treated With Baricitinib Through 52 Weeks

- >70% of patients had EB/EL involvement at baseline
- A holistic response across scalp, EB, and EL was achieved in the majority of Week 52 scalp responders
- Significant EB and/or EL response was also observed among those with partial or no scalp response to baricitinib

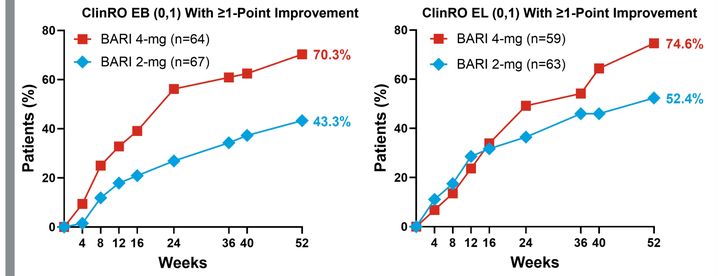
[a]Among patients with ClinRO EB and EL score ≥1 at baseline.

Achievement of Simultaneous EB/EL Regrowth at Week 52, by Week 52 Scalp Response[a]



RESULTS

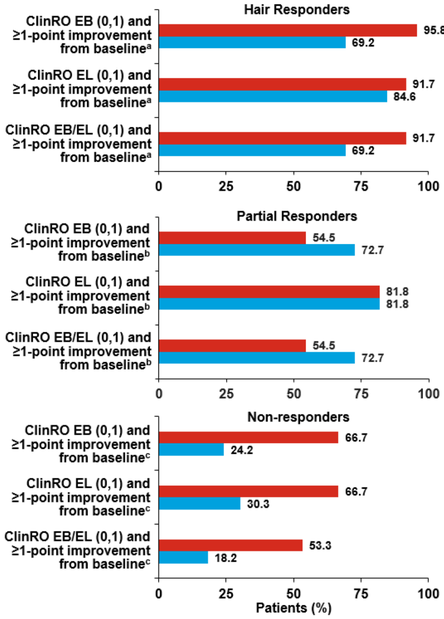
EB and EL Regrowth Occurred Early in Treatment and Continued to Increase Through Week 52



Notes: Data are NRI. Analysis population includes patients with ClinRO EB or EL ≥1 at baseline for each respective analysis.

RESULTS

EB, EL, and EB/EL Regrowth Among Scalp Hair Responders, Partial Responders, and Non-responders at Week 52



- The majority of scalp hair responders achieved simultaneous EB and EL regrowth

[a]Baricitinib-treated patients with SALT score ≤20 at Week 52 who had ClinRO EB and EL score ≥1 at baseline.

- The majority of scalp hair partial responders achieved EB and EL regrowth

[b]Baricitinib-treated patients with SALT score >20 and ≥30% SALT score improvement at Week 52 ($SALT_{30}$) who had ClinRO EB and EL score ≥1 at baseline.

- The majority of scalp hair non-responders achieved EB and EL regrowth with baricitinib 4-mg

[c]Baricitinib-treated patients with SALT score >20, without ≥30% SALT score improvement at Week 52 who had ClinRO EB and EL score ≥1 at baseline.

Notes: Data are NRI. Primary censoring rule excludes data collected after permanent study drug discontinuation or during temporary interruptions due to prohibited medication.

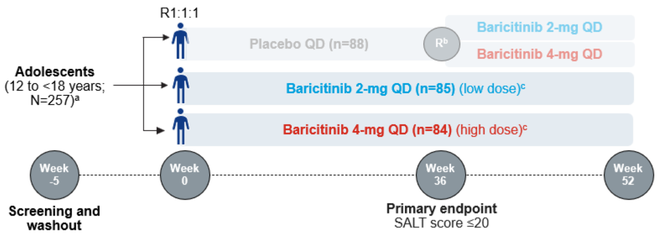
Methods

Key Eligibility Criteria

- Age 12 to <18 years
- 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[b]
- History of psychological counseling related to AA
- History of psychological impact from refractory AA as reported by the investigator, parent, or patient
- No spontaneous improvement of AA over the past 6 months
- Not primarily a "diffuse" type of AA

[a]Patients 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 prior to randomization; topical JAK inhibitors within 4 weeks prior to randomization; systemic corticosteroids, immunosuppressants, intra-lesional or intra-articular corticosteroid injections, or oral JAK inhibitor within 8 weeks prior to randomization; monoclonal antibody <5 half-lives prior to randomization; probenecid at the time of randomization. Oral/topical minoxidil was permitted if on stable dose for ≥12 months and anticipated to remain on stable dose up until Week 36.

Study Design: BRAVE-AA PEDS



- BRAVE-AA-PEDS (NCT05723198) is the largest ongoing, placebo-controlled, Phase 3 trial of pediatric patients (6 to <18 years) with severe AA

[a]Figure is not the full study design; pediatric population aged 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]For patients weighing ≥30 kg: 4-mg QD=high dose, 2-mg QD=low dose; for patients weighing <30 kg: 2-mg QD=high dose, 1-mg QD=low dose.

Assessments and Statistical Analyses

- The intent-to-treat population consisted of adolescents 12 to <18 years of age
- Outcomes at Week 52 were assessed using ClinRO Measures for Eyebrow Hair Loss™ and Eyelash Hair Loss™ (ClinRO 0,1 with ≥1 point improvement) among patients with a ClinRO score of ≥1 at baseline, overall, and among patients with varying degrees of scalp response
- Scalp response was assessed using the SALT score among scalp responders (SALT score ≤20), scalp partial responders (SALT score >20 with $SALT_{30}$), and scalp non-responders (SALT score >20 without $SALT_{30}$)
- Outcomes were reported as the proportion of baricitinib responders in each group
- Analysis of categorical outcomes was performed using logistic regression
- Missing data were handled by NRI, and data collected after permanent study drug discontinuation were excluded

Results

Baseline Demographics and Characteristics

Characteristic	BARI 2-mg (n=84)	BARI 4-mg (n=85)	Total (N=257)[a]
Age, mean (SD), years	14.9 (1.6)	14.6 (1.8)	14.7 (1.7)
Female	39 (46.4)	41 (48.2)	127 (49.4)
Race			
White	52 (61.9)	52 (61.2)	155 (60.3)
Asian	23 (27.4)	23 (27.1)	72 (28.0)
Black or African American	5 (6.0)	8 (9.4)	19 (7.4)
Other, multiple, or not reported	4 (4.8)	2 (2.4)	11 (4.3)
SALT category			
Severe (SALT score 50-94)	29 (34.5)	31 (36.5)	92 (35.8)
Very severe (SALT score 95-100)	55 (65.5)	54 (63.5)	164 (63.8)
ClinRO EB (≥1)	67 (79.8)	64 (75.3)	199 (77.4)
ClinRO EL (≥1)	63 (75.0)	59 (69.4)	181 (70.4)

[a]Includes 88 patients randomized to placebo.
Note: Data are n (%) unless otherwise stated.

References

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Abbreviations

AA=alopecia areata; BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EB/EL=eyebrow and eyelash; EL=eyelash; JAK=Janus kinase; NRI=non-responder imputation; QD=once daily; R=randomization; SALT=Severity of Alopecia Tool; $SALT_{30}$=at least 30% SALT score improvement from baseline; SD=standard deviation; W=Week

Disclosures

B. M. Piraccini has received honoraria from or been a consultant for: Almirall, Difa Cooper, Dercos-L'Oreal, Eli Lilly and Company, Giuliani Pharma, ISDIN, Legacy Healthcare, Pfizer, Pierre Fabre-Ducray, and Olistic; **M. Ohyama** has received lecture and advisory fees from: AbbVie GK, Bristol Myers Squibb Japan, Eli Lilly and Company, Kyowa Kirin, Maruho Co., Pfizer Japan, ROHTO Pharmaceutical, Sanofi, and Taisho Pharmaceutical; and has received research grants not directly related to the submitted work from: Advantest Corporation, Maruho, Shiseido, and Sun Pharma Japan; **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; **A. Mostaghimi** has been a consultant for: AbbVie, Concert Pharmaceuticals, Digital Diagnostics, Eli Lilly and Company, and Pfizer; **A. Sontag**, **K. Singh**, and **T. Das** are current employees and shareholders of: Eli Lilly and Company; **J. Soung** has received honoraria and/or grants as a speaker, advisory board member, and/or investigator for: AbbVie, Amgen, Boehringer Ingelheim, Cassopeia 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

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EB/EL=eyebrow and eyelash.

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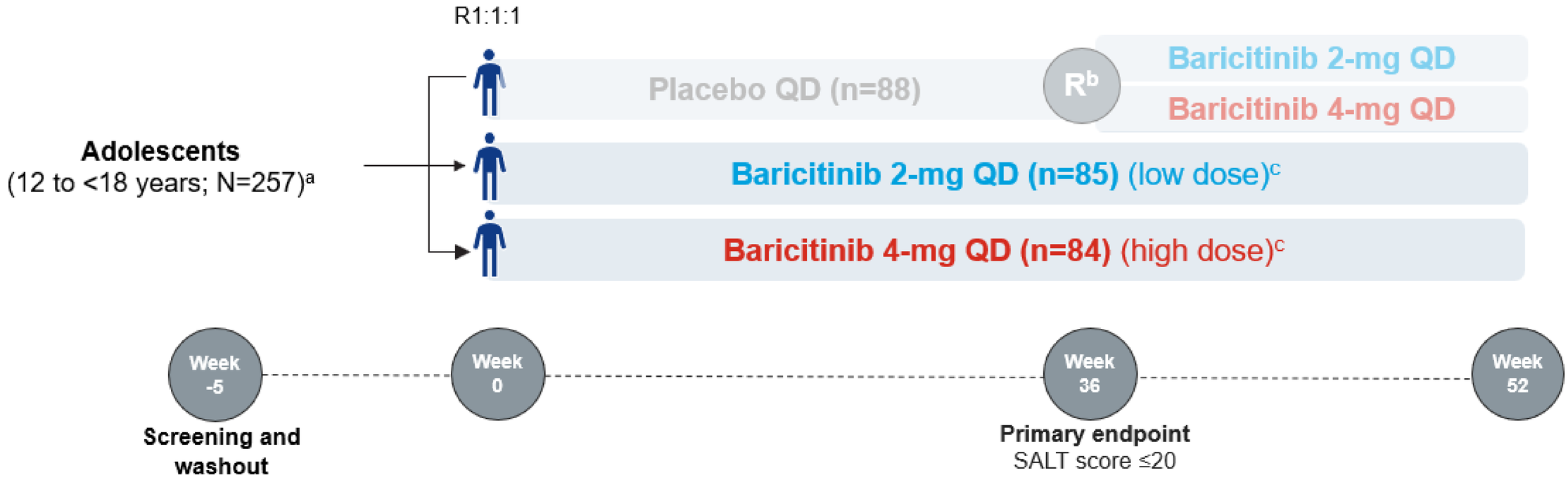

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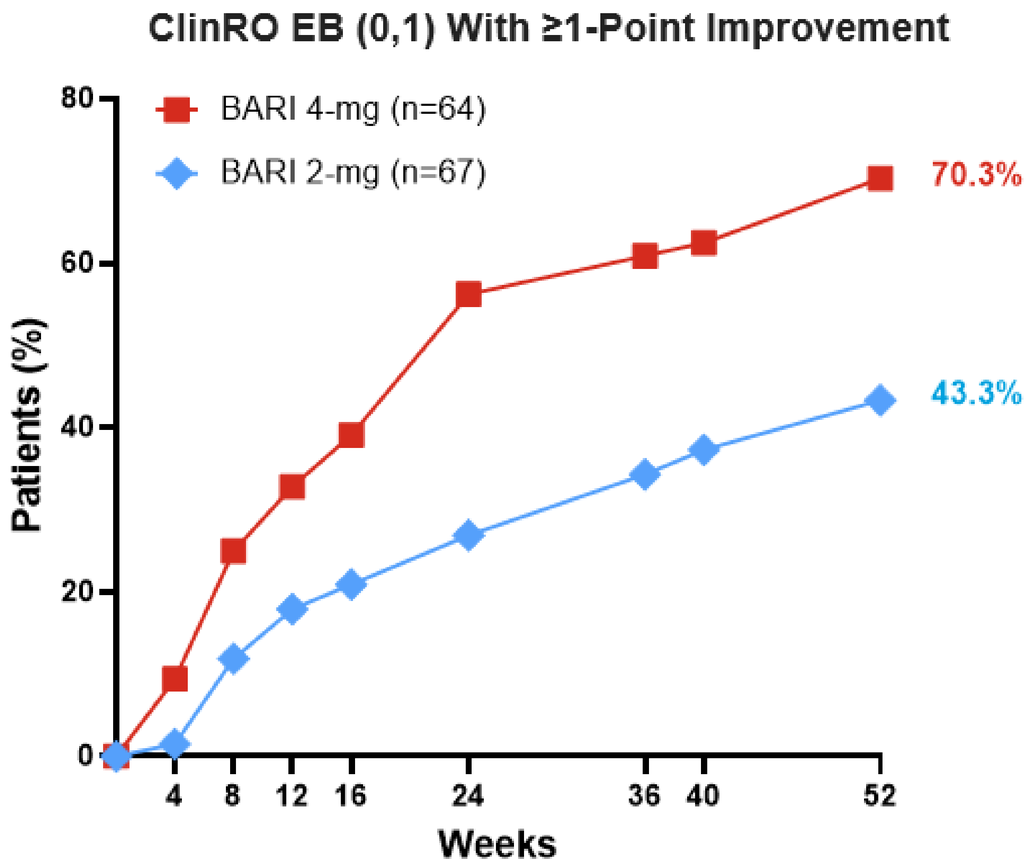
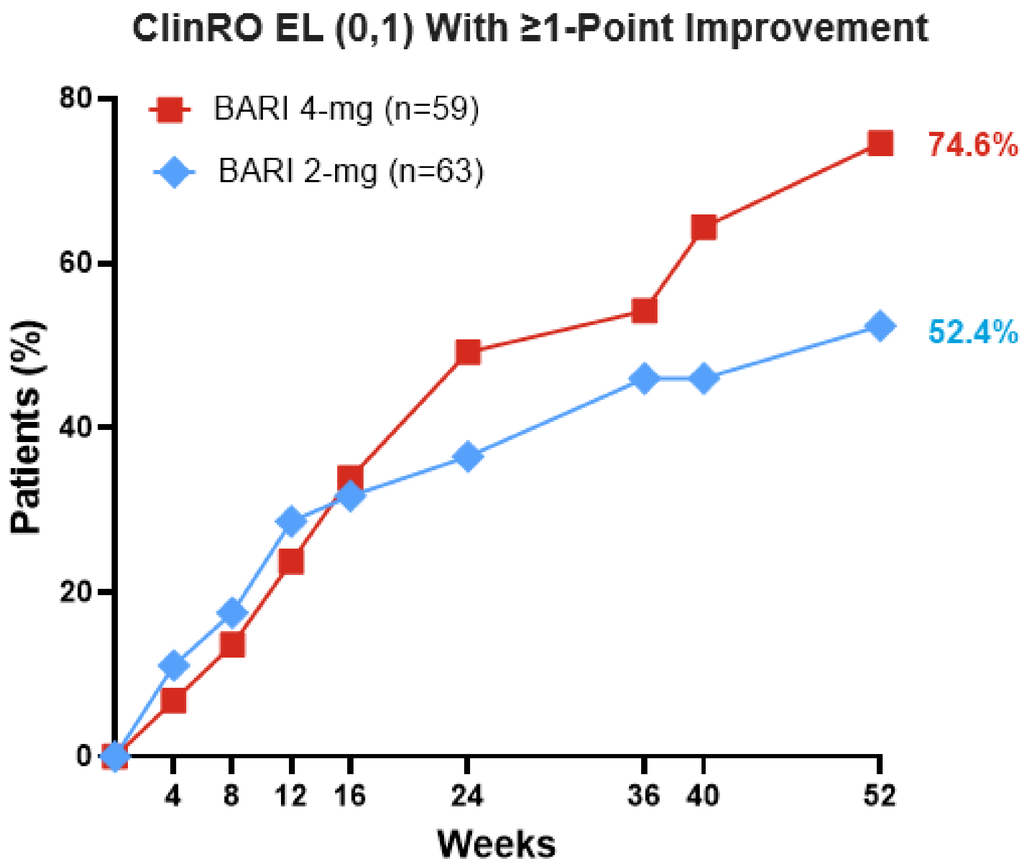
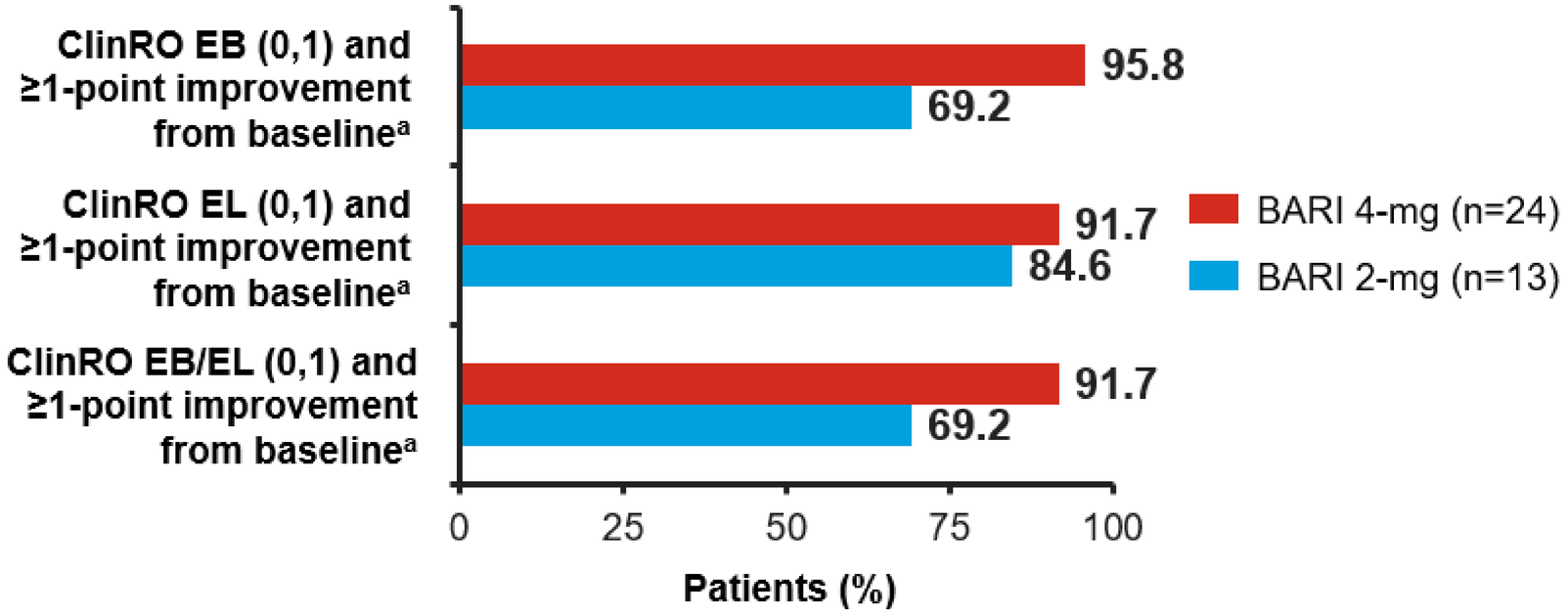
EB and EL Regrowth Occurred Early in Treatment and Continued to Increase Through Week 52





Notes: Data are NRI. Analysis population includes patients with ClinRO EB or EL ≥1 at baseline for each respective analysis.
BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; NRI=non-responder imputation.

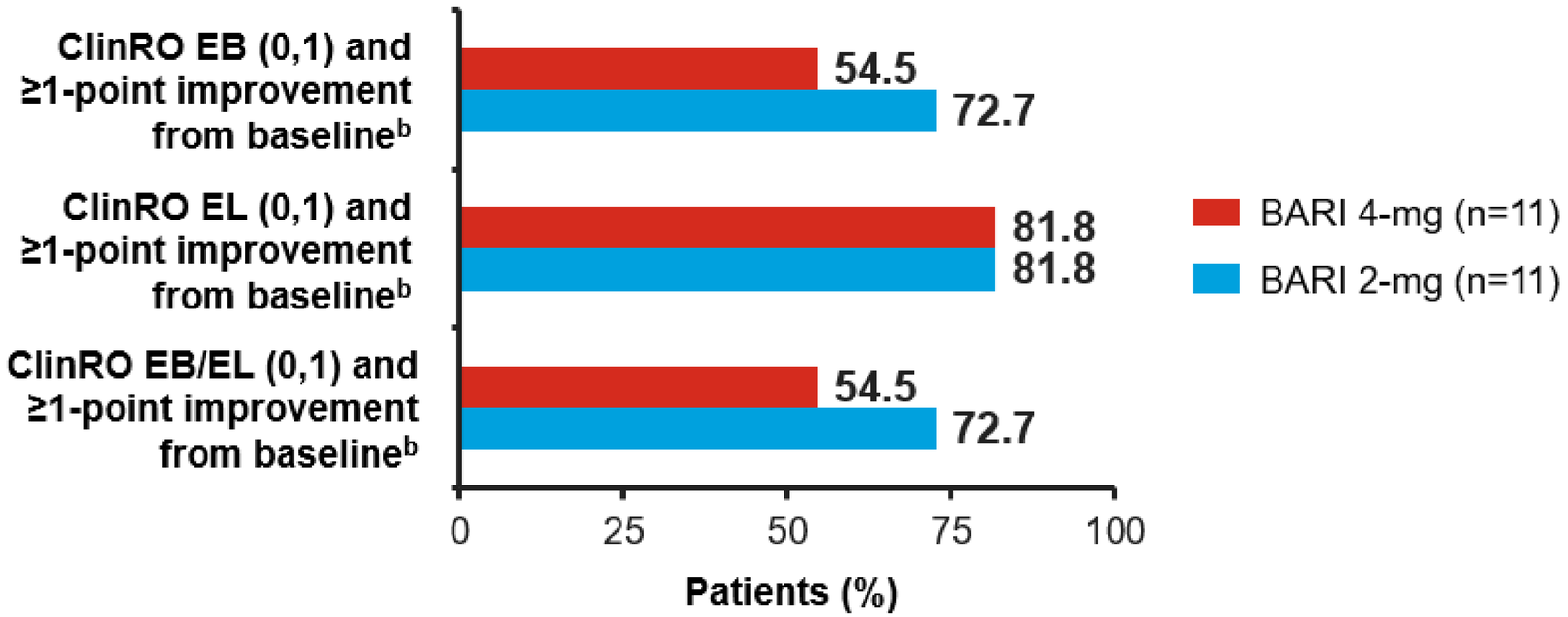
EB, EL, and EB/EL Regrowth Among Scalp Hair Responders[a] at Week 52



- The majority of scalp hair responders achieved simultaneous EB and EL regrowth

[a]BARI-treated patients with SALT score ≤20 at Week 52 who had ClinRO EB and EL score ≥1 at baseline.
Notes: Data are NRI. Primary censoring rule excludes data collected after permanent study drug discontinuation or during temporary interruptions due to prohibited medication.
BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; EB/EL=eyebrow and eyelash; NRI=non-responder imputation; SALT=Severity of Alopecia Tool.

EB, EL, and EB/EL Regrowth Among Scalp Hair Partial Responders[a] at Week 52



- The majority of scalp hair partial responders achieved EB and EL regrowth

[b]BARI-treated patients with SALT score >20 and ≥30% SALT score improvement at Week 52 ($SALT_{30}$) who had ClinRO EB and EL score ≥1 at baseline.
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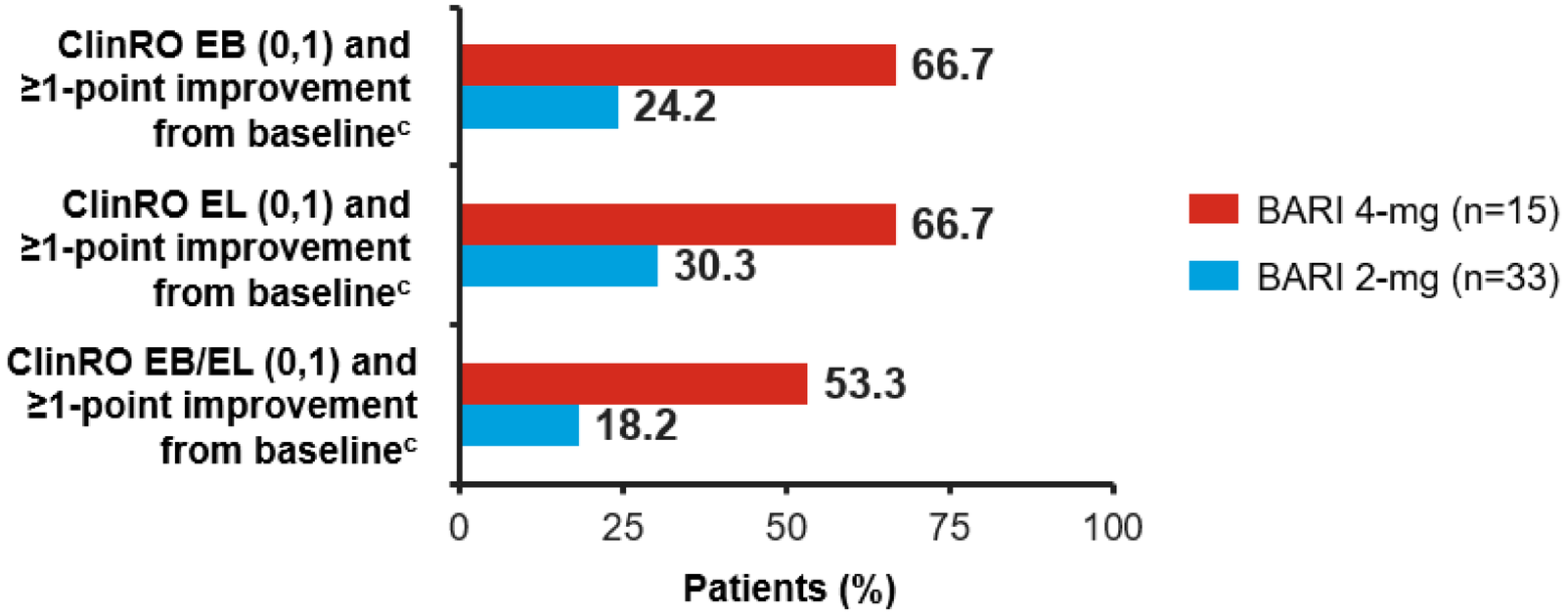
EB, EL, and EB/EL Regrowth Among Scalp Hair Non-responders[a] at Week 52



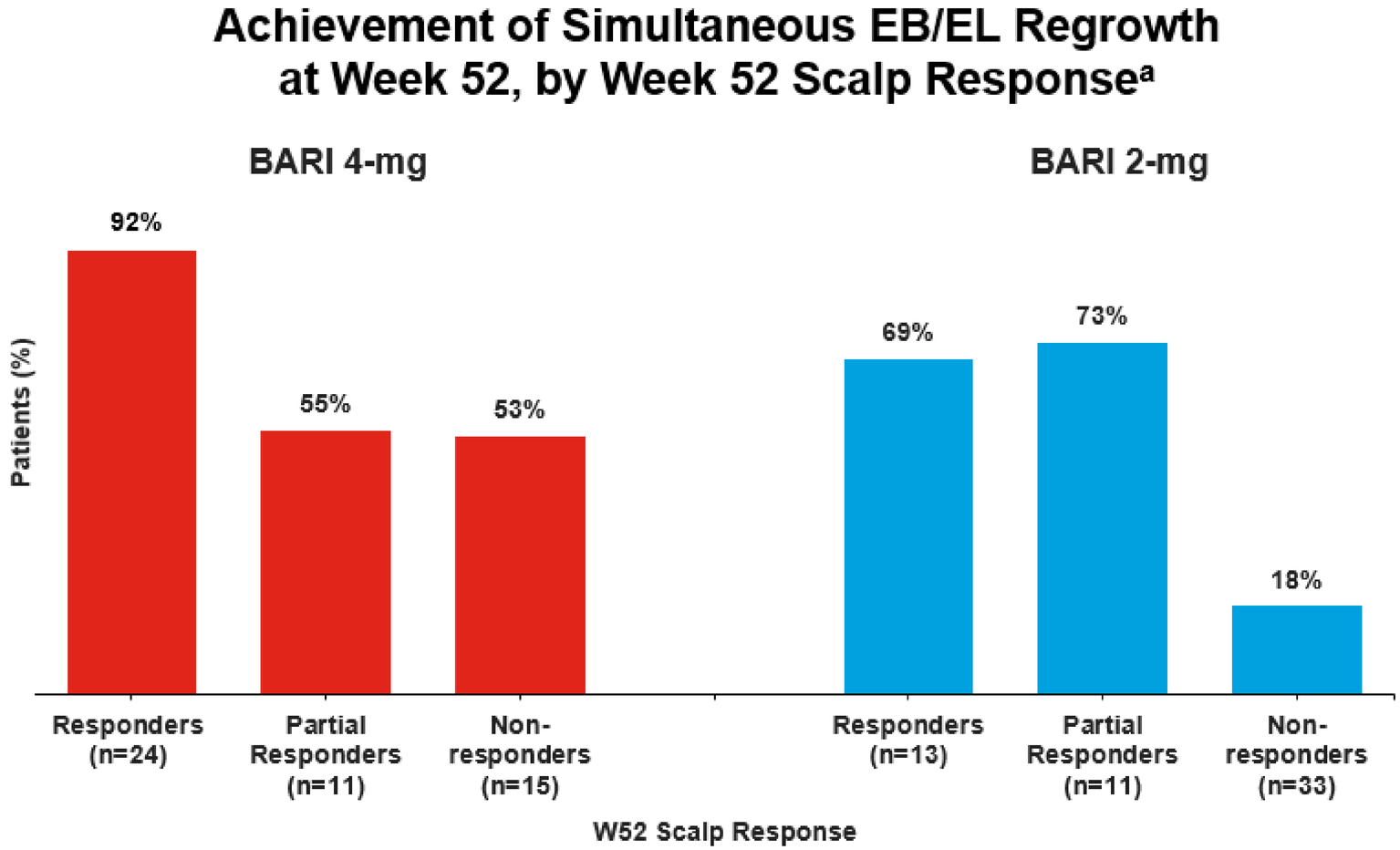
- The majority of scalp hair non-responders achieved EB and EL regrowth with baricitinib 4-mg

[c]BARI-treated patients with SALT score >20, without ≥30% SALT score improvement at Week 52 who had ClinRO EB and EL score ≥1 at baseline.
Notes: Data are NRI. Primary censoring rule excludes data collected after permanent study drug discontinuation or during temporary interruptions due to prohibited medication.
BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; EB/EL=eyebrow and eyelash; NRI=non-responder imputation; SALT=Severity of Alopecia Tool.

Summary of Key Findings

In Adolescents With Severe AA Treated With Baricitinib Through 52 Weeks

- >70% of patients had EB/EL involvement at baseline
- A holistic response across scalp, EB, and EL was achieved in the majority of Week 52 scalp responders
- Significant EB and/or EL response was also observed among those with partial or no scalp response to baricitinib



[a]Among patients with ClinRO EB and EL score ≥1 at baseline.
AA=alopecia areata; EB=eyebrow; EL=eyelash, W=Week.

CONCLUSIONS

- In an adolescent population (12 to <18 years) with severe AA, baricitinib was efficacious in achieving a holistic response across all 3 hair-bearing sites (scalp, EB, and EL) in the majority of Week 52 scalp responders
- Significant EB and/or EL response was also observed among adolescents with partial or non-response to baricitinib
- A holistic response to treatment could lessen the psychosocial burden of the disease and improve treatment satisfaction among patients with AA and EB/EL involvement

AA=alopecia areata; EB=eyebrow; EL=eyelash.

Abbreviations

AA=alopecia areata; BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EB/EL=eyebrow and eyelash; EL=eyelash; JAK=Janus kinase; NRI=non-responder imputation; QD=once daily; SALT=Severity of Alopecia Tool; $SALT_{30}$=at least 30% SALT score improvement from baseline; SD=standard deviation; W=Week

References

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