Baricitinib Provides Sustained, Long-Term Efficacy With Consistent Safety for Up to 5 Years of Treatment in Adults With Severe Alopecia Areata: Final Results From BRAVE-AA1 and BRAVE-AA2

Scan the QR code for a list of all Lilly content presented at the congress.

Ruth Ann Vleugels[1], Bianca Maria Piraccini[2], Natasha Mesinkovska[3], Arash Mostaghimi[1-4], Yutaka Shimomura[5], Angelina Sontag[6], Fionn McSwiney[6], Hitendra Pandey[6], Karen Denning[6], Brett King[7]

[1]Brigham and Women's Hospital, Boston, USA, [2]Private Dermatology Practice, Bologna, Italy, [3]University of California, Irvine, USA, [4]Harvard Medical School, Boston, USA, [5]Yamaguchi University, Yamaguchi, Japan, [6]Eli Lilly and Company, Indianapolis, USA, [7]Dermatology Physicians of Connecticut, Fairfield, USA

Sponsored by Eli Lilly and Company, under license from Incyte Corporation

OBJECTIVE

- To report the final long-term efficacy and safety results for baricitinib in patients with severe alopecia areata (AA) through 5 years of treatment

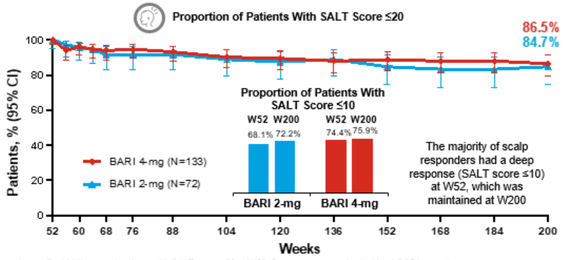
CONCLUSIONS

- Among patients with severe AA who achieved a Severity of Alopecia Tool (SALT) score ≤20 at Week (W)52, ~85% maintained that response through ~4 years of treatment
  - The majority of scalp responders at W52 maintained a deep response (SALT score ≤10) at W200
  - Further, of these patients, the proportion who achieved full or nearly full eyebrows or eyelashes continued to increase from W52 to W200
- This safety analysis in patients with severe AA, including up to 5 years of data, was consistent with previously reported data from the baricitinib AA clinical trial program

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

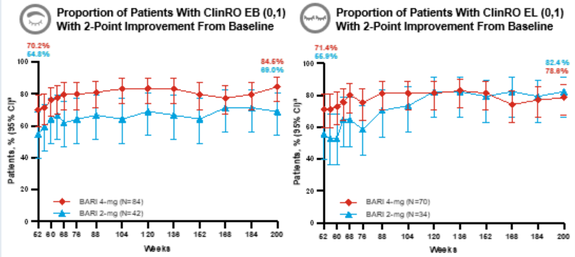
RESULTS

A High Proportion of W52 Scalp Responders (SALT Score ≤20) Maintained a Response at W200



Notes: Baricitinib-treated patients with SALT score ≤20 at W52. Data were summarized with mLOCF imputation.

Among W52 Scalp Responders, Eyebrow and Eyelash Response Continued to Improve Through W200



[a]Baricitinib-treated patients with SALT score ≤20 at W52 who had ClinRO EB/EL score ≥2 at baseline.
Note: Data were summarized with mLOCF imputation.

Overview of AEs Through W200/W248

n [IR]	Extended BARI AA: BARI 2-mg (N=383) PYE=546.1	Extended BARI AA: BARI 4-mg (N=565) PYE=1184.8	All BARI AA: All BARI Doses (N=1303) PYE=3047.7
Any TEAE	274 [132.1]	449 [116.5]	1035 [105.0]
Mild	147 [38.0]	216 [24.4]	500 [22.7]
Moderate	117 [26.2]	197 [21.8]	461 [19.7]
Severe	10 [1.8]	36 [3.0]	74 [2.4]
SAEs	12 [2.1]	34 [2.8]	77 [2.5]
Permanent discontinuation of study drug due to AE	11 [1.9]	23 [1.9]	47 [1.5]
Deaths	0	0	0

Common TEAEs[a] Through W200/W248

n [IR]	Extended BARI AA: BARI 2-mg (N=383)	Extended BARI AA: BARI 4-mg (N=565)	All BARI AA: All BARI Doses (N=1303)
COVID-19	36 [6.7]	94 [8.6]	296 [10.8]
Upper respiratory tract infection	49 [9.5]	67 [6.0]	168 [5.9]
Headache	30 [5.5]	56 [5.0]	115 [4.0]
Nasopharyngitis	26 [4.7]	60 [5.3]	114 [3.9]
Acne	26 [4.8]	38 [3.3]	96 [3.3]
Urinary tract infection	25 [4.6]	37 [3.2]	95 [3.2]
Blood CPK increased	6 [1.1]	46 [4.0]	79 [2.6]
Herpes zoster	11 [2.0]	18 [1.5]	53 [1.7]
Arthralgia	14 [2.5]	20 [1.7]	51 [1.7]
Nausea	12 [2.1]	19 [1.6]	47 [1.5]
Cough	8 [1.4]	18 [1.5]	46 [1.5]
Folliculitis	11 [1.9]	19 [1.6]	46 [1.5]
Back pain	10 [1.8]	23 [1.9]	43 [1.4]
Influenza	7 [1.2]	25 [2.1]	42 [1.4]
Hypercholesterolemia	11 [2.0]	14 [1.2]	40 [1.3]
Hypertension	4 [0.7]	20 [1.7]	40 [1.3]

[a]TEAEs reported by ≥3% of patients in the All-BARI AA population.

AEs of Special Interest at W200/W248

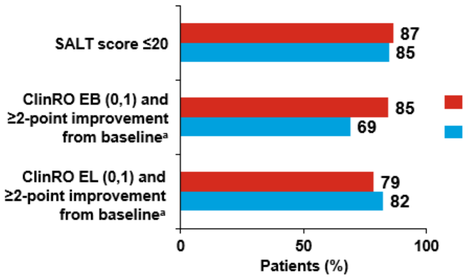
n [IR]	Extended BARI AA: BARI 2-mg (N=383)	Extended BARI AA: BARI 4-mg (N=565)	All BARI AA: All BARI Doses (N=1303)
Serious infections	2 [0.3]	6 [0.5]	17 [0.5]
Opportunistic infections	0	0	1 [0.0]
Tuberculosis	0	0	0
Herpes zoster	11 [2.0]	18 [1.5]	53 [1.7]
Herpes simplex	11 [2.0]	18 [1.5]	43 [1.4]
NMSC	1 [0.2]	0	4 [0.1]
Malignancies other than NMSC	0	3 [0.2]	7 [0.2]
MACE[a]	1 [0.2]	0	1 [0.0]
DVT and/or PE	1 [0.2]	0	2 [0.1]
Appendicitis with perforation	0	0	1 [0.0]

- Since the W152 report:
  - No new reports of opportunistic infections, herpes zoster, MACE, DVT/PE, or malignancy other than NMSC
  - 2 new serious infections (1 in a patient with a previous serious infection)[b] and 1 new NMSC[c] were reported
- No deaths or cases of tuberculosis have been reported in the trial

[a]MACE was defined as a cardiovascular death, myocardial infarction, or stroke as adjudicated by an independent clinical event committee; [b]One case of worsening of chronic rhinitis; 1 patient who had a previously reported serious COVID-19 event subsequently reported an unspecified viral infection that was serious; [c]NMSC occurred in 1 patient with fair skin and significant sun exposure who reported 3 squamous cell carcinoma events. The patient recovered and completed the study.

SUMMARY OF KEY FINDINGS

Efficacy at W200 in Patients With SALT Score ≤20 at W52



Safety at W200/W248 vs. W152

NO new safety signals
NO new malignancy other than NMSC
NO new MACE events
NO new DVT/PE events
NO reported deaths

1 new NMSC
2 new serious infections

Baricitinib efficacy and safety data through 5 years of exposure in the BRAVE-AA1 and BRAVE-AA2 trials support long-term continuous use in severe AA

[a]Among patients with ClinRO EB or EL ≥2 at baseline.

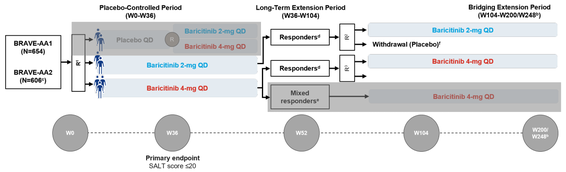
Background

- AA is an autoimmune disorder that causes hair loss, primarily on the scalp, but can occur on any hair-bearing location, including the eyebrows and eyelashes[1]
- Severe AA tends to have a chronic course that often requires long-term therapy[2]
- Baricitinib, a selective and reversible Janus kinase inhibitor approved for the treatment of AA, improved scalp and eyebrow/eyelash hair regrowth and has demonstrated a consistent safety profile in patients with severe AA[3,4]
- Maintenance of efficacy has previously been reported through W104[4] and safety has been reported through W152[5]

Methods

Study Design: BRAVE-AA1 and BRAVE-AA2[a]

- Key eligibility criteria have been reported previously[3]
- The efficacy analysis included pooled data from BRAVE-AA1 and BRAVE-AA2 patients who were W52 scalp responders and remained on the same baricitinib dosage through W200 (patients in the placebo arm were excluded)



[a]Figure is not the full BRAVE-AA1 and BRAVE-AA2 program; [b]In BRAVE-AA1 and BRAVE-AA2, there was a study addendum implemented up to W248 in Mexico and Argentina, respectively, to allow continued access to baricitinib for an additional 48 weeks; [c]BRAVE-AA2 includes 60 Maximized Extended Enrollment patients from China; [d]Baricitinib 4-mg–treated and 2-mg–treated patients with SALT score ≤20 at W52; [e]Baricitinib 4-mg–treated patients who had a SALT score >20 at W52 but had reached SALT score ≤20 at prior visit(s), and/or patients with ClinRO EB/EL scores ≥2 at baseline who had achieved a ClinRO EB/EL improvement from baseline of ≥2 points at W52; [f]BRAVE-AA1 only; [g]BRAVE-AA2 only.
Notes: R[1]: 2:2:3 (placebo:2-mg:4-mg); R[2]: BRAVE-AA1: 3:1 (2-mg [same dose]:placebo [withdrawal from 2-mg]); BRAVE-AA2: All responders continued on 2-mg (same dose, no randomization); R[3]: BRAVE-AA1: 3:1 (4-mg [same dose]:placebo [withdrawal from 4-mg]); BRAVE-AA2: 1:1 (4-mg [same dose]:2-mg [down-titration from 4-mg]).

Statistical Analyses

Efficacy Analysis

- Data were pooled from BRAVE-AA1 and BRAVE-AA2 and included patients randomized to baricitinib 4-mg or 2-mg who achieved a SALT score ≤20 at W52 (scalp responders) and remained on the same baricitinib dosage through W200
- The proportion of patients maintaining a SALT score ≤20 and the proportion of patients achieving a ClinRO EB/EL score of 0 or 1 with ≥2-point improvement from baseline was assessed from W52 through W200
- Data were censored after treatment discontinuation; missing or censored data for efficacy analysis were imputed with LOCF

Safety Analysis

- Safety data are reported for all patients who received ≥1 dose of baricitinib (1-mg, 2-mg, or 4-mg) during the BRAVE trials through W200/W248 of treatment[a]
  - Extended BARI AA: Includes patients remaining on continuous treatment with baricitinib 2-mg or 4-mg from baseline to data cut-off in the Long-Term Extension and Bridging Extension Periods
  - All BARI AA: Includes all patients exposed to any baricitinib dose (1-mg, 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 Long-Term Extension Period
- IRs per 100 patient-years were calculated based on time at risk
- Data cut-offs were March 3, 2025 for BRAVE-AA1 and February 3, 2025 for BRAVE-AA2

[a]In BRAVE-AA1 and BRAVE-AA2, there was a study addendum implemented up to W248 in Mexico and Argentina, respectively, to allow continued access to baricitinib for an additional 48 weeks.

Abbreviations

AA=alopecia areata; AE=adverse event; BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; COVID-19=coronavirus disease 2019; CPK=creatine phosphokinase; DVT=deep vein thrombosis; EB=eyebrow; EL=eyelash; IR=incidence rate; LOCF=last observation carried forward; mLOCF=modified LOCF; MACE=major adverse cardiovascular event; n=number of patients; NMSC=non-melanoma skin cancer; PE=pulmonary embolism; PYE=patient-years of exposure; QD=once daily; R=randomization; SAE=serious AE; SALT=Severity of Alopecia Tool; TEAE=treatment-emergent AE; W=Week

References

1. King B, et al. *J Am Acad Dermatol*. 2021;85:847-853.
2. Lintzeri DA, et al. *J Dtsch Dermatol Ges*. 2022;20:59-90.
3. King B, et al. *N Engl J Med*. 2022;386:1687-1699.
4. Senna M, et al. *J Eur Acad Dermatol Venereol*. 2024;38:583-593.
5. King B, et al. *Am J Clin Dermatol*. 2025;26:611-622.

Results

Patient Disposition and Study Drug Exposure Through W200/W248

	Extended BARI AA: BARI 2-mg (N=383)	Extended BARI AA: BARI 4-mg (N=565)	All BARI AA: All BARI Doses (N=1303)
Disposition, n (%)			
Completed	169 (44.1)	250 (44.2)	569 (43.7)
Switched dose	120 (31.3)	68 (12.0)	17 (1.3)
Permanently discontinued study drug	214 (55.9)	315 (55.8)	734 (56.3)
Exposure			
Total patient-years	546.1	1184.8	3047.7
Median exposure, days	364.0	380.0	953.0
Maximum exposure, days	1742	1755	1826

- The most common reasons for permanent discontinuation of study drug in the All BARI AA dataset were automatic discontinuation (19.8%),[a] withdrawal by subject (14.3%), lack of efficacy (7.7%), lost to follow-up (5.4%) and adverse event (4.1%)

[a]Patients who were non-responders (SALT score> 20) at W52 and W76 were automatically discontinued from the study at W76 unless they had a ≥2-point improvement from baseline in the clinician-reported outcome measure for eyebrow or eyelash hair loss.[5]

Disclosures

R. A. Vleugels has been a consultant for: AbbVie, AstraZeneca, Eli Lilly and Company, and Priovant Therapeutics; **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, Olistic, Pfizer, and Pierre Fabre-Ducray; **N. Mesinkovska** has provided professional services for: AbbVie, Arena Pharmaceuticals, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, La Roche-Posay, and Pfizer; **A. Mostaghimi** has been a consultant for: AbbVie, Concert Pharmaceuticals, Digital Diagnostics, Eli Lilly and Company, and Pfizer; **Y. Shimomura** has been an investigator for: Eli Lilly and Company; **A. Sontag, F. McSwiney, H. Pandey,** and **K. Denning** are current employees and shareholders of: Eli Lilly and Company; **B. King** has served on advisory boards, 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

Medical writing assistance was provided by Heather Taft, PhD, of Envision Catalyst, an Envision Medical Communications agency, a part of Envision Pharma Group, and was funded by Eli Lilly and Company

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

Baricitinib Provides Sustained, Long-Term Efficacy With Consistent Safety for Up to 5 Years of Treatment in Adults With Severe Alopecia Areata: Final Results From BRAVE-AA1 and BRAVE-AA2

Ruth Ann Vleugels,[1] Bianca Maria Piraccini,[2] Natasha Mesinkovska,[3] Arash Mostaghimi,[1-4] Yutaka Shimomura,[5] Angelina Sontag,[6] Fionn McSwiney,[6] Hitendra Pandey,[6] Karen Denning,[6] Brett King[7]

[1]Brigham and Women's Hospital, Boston, USA, [2]Private Dermatology Practice, Bologna, Italy, [3]University of California, Irvine, USA, [4]Harvard Medical School, Boston, USA, [5]Yamaguchi University, Yamaguchi, Japan, [6]Eli Lilly and Company, Indianapolis, USA, [7]Dermatology Physicians of Connecticut, Fairfield, USA

Sponsored by Eli Lilly and Company under license from Incyte Corporation

BACKGROUND AND OBJECTIVE

Background

- AA is an autoimmune disorder that causes hair loss, primarily on the scalp, but can occur on any hair-bearing location, including the eyebrows and eyelashes[1]
- Severe AA tends to have a chronic course that often requires long-term therapy[2]
- Baricitinib, a selective and reversible Janus kinase inhibitor approved for the treatment of AA, improved scalp and eyebrow/eyelash hair regrowth and has demonstrated a consistent safety profile in patients with severe AA[3,4]
- Maintenance of efficacy has previously been reported through W104[4] and safety has been reported through W152[5]

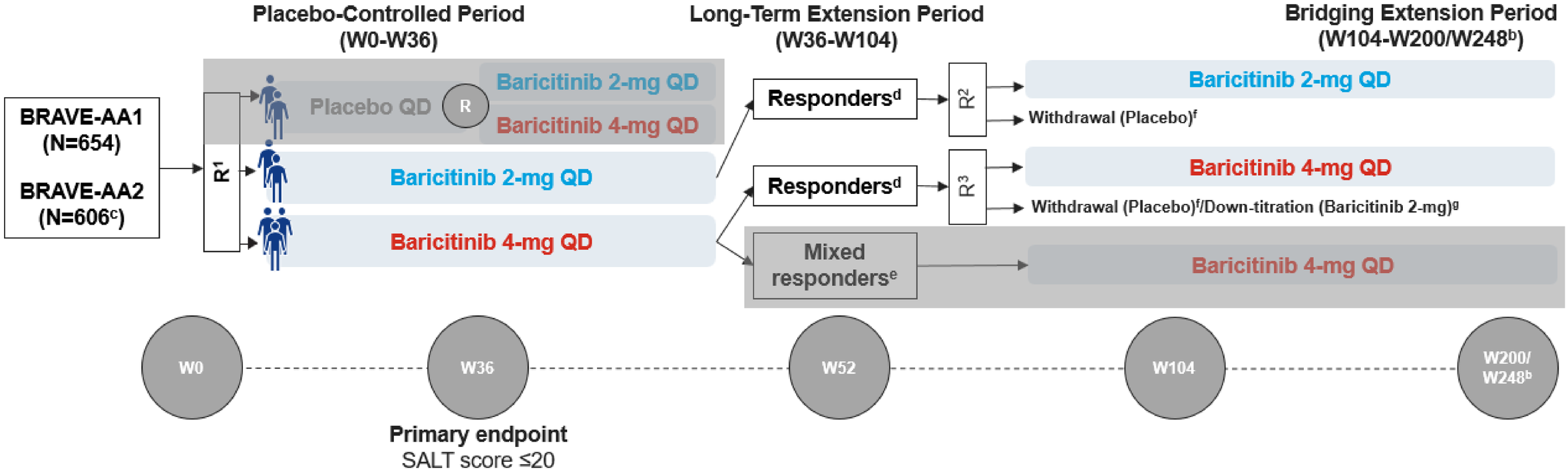
Objective

- To report the final long-term efficacy and safety results for baricitinib in patients with severe AA through 5 years of treatment

AA=alopecia areata; W=Week.

METHODS
Study Design: BRAVE-AA1 and BRAVE-AA2[a]

- Key eligibility criteria have been reported previously[3]
- The efficacy analysis included pooled data from BRAVE-AA1 and BRAVE-AA2 patients who were W52 scalp responders and remained on the same baricitinib dosage through W200 (patients in the placebo arm were excluded)



[a]Figure is not the full BRAVE-AA1 and BRAVE-AA2 program; [b]In BRAVE-AA1 and BRAVE-AA2, there was a study addendum implemented up to W248 in Mexico and Argentina respectively, to allow continued access to baricitinib for an additional 48 weeks; [c]BRAVE-AA2 includes 60 Maximized Extended Enrollment patients from China; [d]Baricitinib 4-mg–treated and 2-mg–treated patients with SALT score ≤20 at W52; [e]Baricitinib 4-mg–treated patients who had SALT score >20 at W52 but had reached SALT score ≤20 at prior visit(s) and/or patients with ClinRO EB/EL scores ≥2 at baseline who had achieved a ClinRO EB/EL improvement from baseline of ≥2 points at W52; [f]BRAVE-AA1 only; [g]BRAVE-AA2 only.

Notes: R^1: 2:2:3 (placebo:2-mg:4-mg); R^2: BRAVE-AA1: 3:1 (2-mg [same dose]:placebo [withdrawal from 2-mg]); BRAVE-AA2: All responders continued on 2-mg (same dose, no randomization); R^3: BRAVE-AA1: 3:1 (4-mg [same dose]:placebo [withdrawal from 4-mg]); BRAVE-AA2: 1:1 (4-mg [same dose]:2-mg [down-titration from 4-mg]).

ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; QD=once daily; R=randomization; SALT=Severity of Alopecia Tool; W=Week.

Statistical Analyses

Efficacy Analysis

- Data were pooled from BRAVE-AA1 and BRAVE-AA2 and included patients randomized to baricitinib 4-mg or 2-mg who achieved a SALT score ≤20 at W52 (scalp responders) and remained on the same baricitinib dosage through W200
- The proportion of patients maintaining a SALT score ≤20 and the proportion of patients achieving a ClinRO EB/EL score of 0 or 1 with ≥2-point improvement from baseline was assessed from W52 through W200
- Data were censored after treatment discontinuation; missing or censored data for efficacy analysis were imputed with LOCF

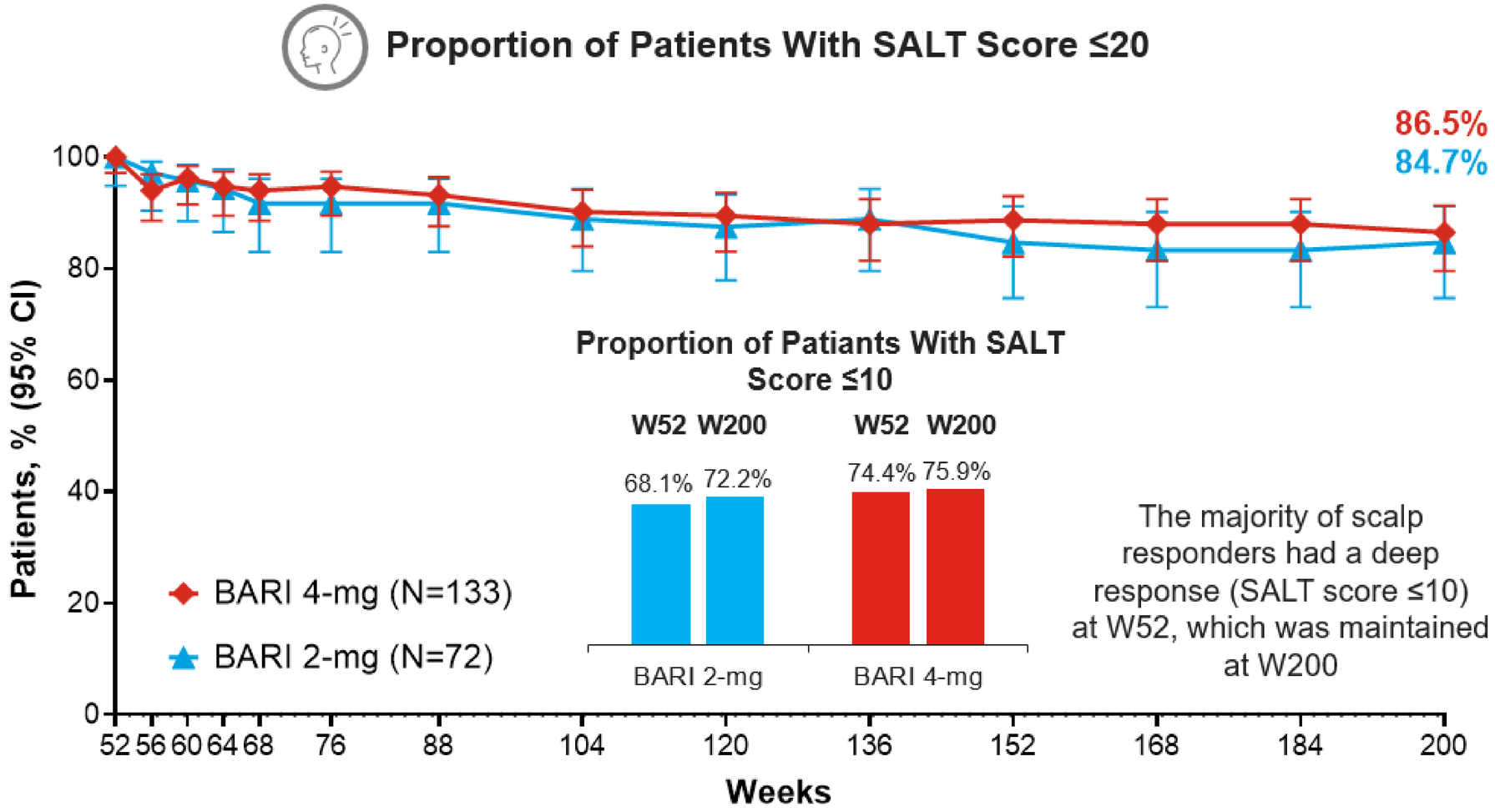
Safety Analysis

- Safety data are reported for all patients who received ≥1 dose of baricitinib (1-mg, 2-mg, or 4-mg) during the BRAVE trials through W200/W248 of treatment[a]
  - Extended-BARI AA: Includes patients remaining on continuous treatment with baricitinib 2-mg or 4-mg from baseline to data cut-off in the Long-Term Extension and Bridging Extension Periods
  - All-BARI AA: Includes all patients exposed to any baricitinib dose (1-mg, 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 Long-Term Extension Period
- IRs per 100 patient-years were calculated based on time at risk
- Data cut-offs were March 3, 2025 for BRAVE-AA1 and February 3, 2025 for BRAVE-AA2

[a]In BRAVE-AA1 and BRAVE-AA2, there was a study addendum implemented up to W248 in Mexico and Argentina, respectively, to allow continued access to baricitinib for an additional 48 weeks.

AA=alopecia areata; BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; SALT=Severity of Alopecia Tool; IR=incidence rate; LOCF=last observation carried forward; W=Week

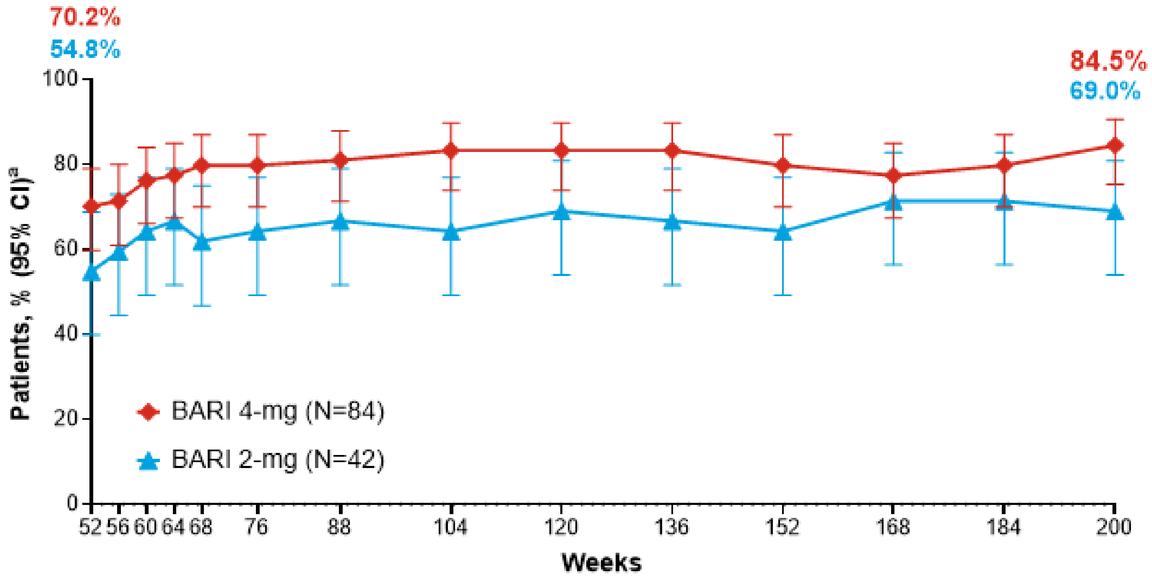
RESULTS
A High Proportion of W52 Scalp Responders (SALT Score ≤20) Maintained a Response at W200



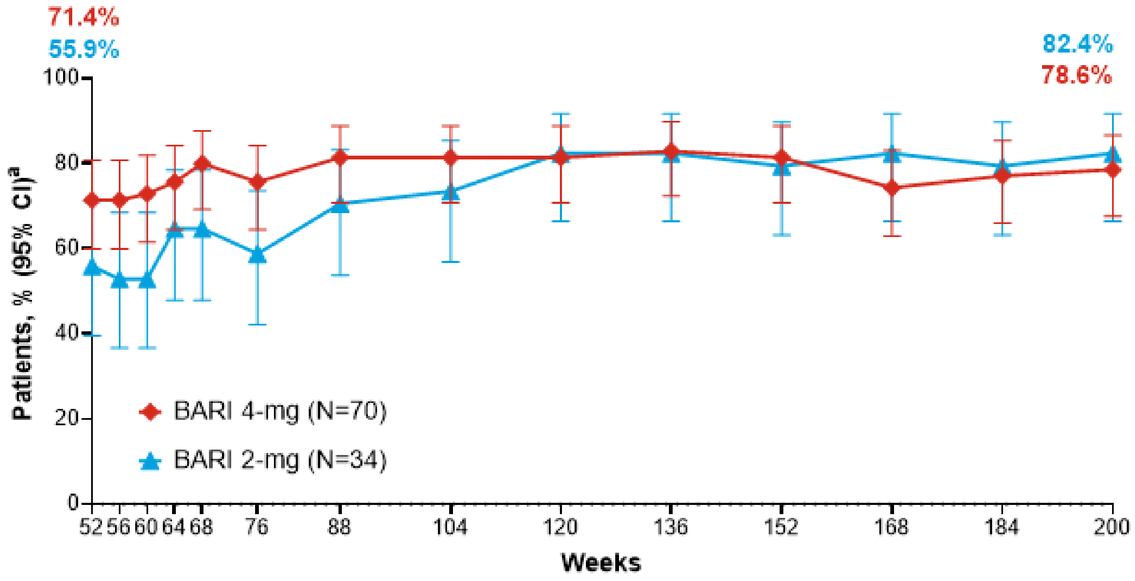
Notes: Baricitinib-treated patients with SALT score ≤20 at W52. Data were summarized with mLOCF imputation.
BARI=baricitinib; CI=confidence interval; mLOCF=modified last observation carried forward; SALT=Severity of Alopecia Tool; W=Week.

Among W52 Scalp Responders, Eyebrow and Eyelash Response Continued to Improve Through W200

Proportion of Patients With ClinRO EB (0,1) With 2-Point Improvement From Baseline



Proportion of Patients With ClinRO EL (0,1) With 2-Point Improvement From Baseline



[a]Baricitinib-treated patients with SALT score ≤20 at W52 who had ClinRO EB/EL score ≥2 at baseline.
Note: Data were summarized with mLOCF imputation.
BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; mLOCF=modified last observation carried forward; SALT=Severity of Alopecia Tool; W=Week.

Participant Disposition and Study Drug Exposure Through W200/W248

	Extended BARI AA		All BARI AA
	BARI 2-mg (N=383)	BARI 4-mg (N=565)	All BARI Doses (N=1303)
Disposition, n (%)			
Completed	169 (44.1)	250 (44.2)	569 (43.7)
Switched dose	120 (31.3)	68 (12.0)	17 (1.3)
Permanently discontinued study drug	214 (55.9)	315 (55.8)	734 (56.3)
Exposure			
Total patient-years	546.1	1184.8	3047.7
Median exposure, days	364.0	380.0	953.0
Maximum exposure, days	1742	1755	1826

- The most common reasons for permanent discontinuation of study drug in the All BARI AA dataset were automatic discontinuation (19.8%),[a] withdrawal by subject (14.3%), lack of efficacy (7.7%), lost to follow-up (5.4%) and adverse event (4.1%)

[a]Patients who were non-responders (SALT score> 20) at W52 and W76 were automatically discontinued from the study at W76 unless they had a ≥2-point improvement from baseline in the clinician-reported outcome measure for eyebrow or eyelash hair loss.[5]

AA=alopecia areata; BARI=baricitinib; n=number of patients; W=Week.

Overview of AEs Through W200/W248

n [IR]	Extended BARI AA		All-BARI AA
	BARI 2-mg (N=383) PYE=546.1	BARI 4-mg (N=565) PYE=1184.8	All BARI Doses (N=1303) PYE=3047.7
Any TEAE	274 [132.1]	449 [116.5]	1035 [105.0]
Mild	147 [38.0]	216 [24.4]	500 [22.7]
Moderate	117 [26.2]	197 [21.8]	461 [19.7]
Severe	10 [1.8]	36 [3.0]	74 [2.4]
SAEs	12 [2.1]	34 [2.8]	77 [2.5]
Permanent discontinuation of study drug due to AE	11 [1.9]	23 [1.9]	47 [1.5]
Deaths	0	0	0

AA=alopecia areata; AE=adverse event; BARI=baricitinib; IR=incidence rate; n=number of patients; PYE=patient-years of exposure; SAE=serious AE; TEAE=treatment-emergent AE; W=Week.

Common TEAEs[a] Through W200/W248

n [IR]	Extended BARI AA		All-BARI AA
	BARI 2-mg (N=383)	BARI 4-mg (N=565)	All BARI Doses (N=1303)
COVID-19	36 [6.7]	94 [8.6]	296 [10.8]
Upper respiratory tract infection	49 [9.5]	67 [6.0]	168 [5.9]
Headache	30 [5.5]	56 [5.0]	115 [4.0]
Nasopharyngitis	26 [4.7]	60 [5.3]	114 [3.9]
Acne	26 [4.8]	38 [3.3]	96 [3.3]
Urinary tract infection	25 [4.6]	37 [3.2]	95 [3.2]
Blood CPK increased	6 [1.1]	46 [4.0]	79 [2.6]
Herpes zoster	11 [2.0]	18 [1.5]	53 [1.7]
Arthralgia	14 [2.5]	20 [1.7]	51 [1.7]
Nausea	12 [2.1]	19 [1.6]	47 [1.5]
Cough	8 [1.4]	18 [1.5]	46 [1.5]
Folliculitis	11 [1.9]	19 [1.6]	46 [1.5]
Back pain	10 [1.8]	23 [1.9]	43 [1.4]
Influenza	7 [1.2]	25 [2.1]	42 [1.4]
Hypercholesterolemia	11 [2.0]	14 [1.2]	40 [1.3]
Hypertension	4 [0.7]	20 [1.7]	40 [1.3]

[a]TEAEs reported by ≥3% of patients in the All-BARI AA population.

AA=alopecia areata; BARI=baricitinib; COVID-19=coronavirus disease 2019; CPK=creatine phosphokinase; IR=incidence rate; TEAE=treatment-emergent adverse event; W=Week.

AEs of Special Interest at W200/W248

n [IR]	Extended BARI AA		All-BARI AA
	BARI 2-mg (N=383)	BARI 4-mg (N=565)	All BARI Doses (N=1303)
Serious infections	2 [0.3]	6 [0.5]	17 [0.5]
Opportunistic infections	0	0	1 [0.0]
Tuberculosis	0	0	0
Herpes zoster	11 [2.0]	18 [1.5]	53 [1.7]
Herpes simplex	11 [2.0]	18 [1.5]	43 [1.4]
NMSC	1 [0.2]	0	4 [0.1]
Malignancies other than NMSC	0	3 [0.2]	7 [0.2]
MACE[a]	1 [0.2]	0	1 [0.0]
DVT and/or PE	1 [0.2]	0	2 [0.1]
Appendicitis with perforation	0	0	1 [0.0]

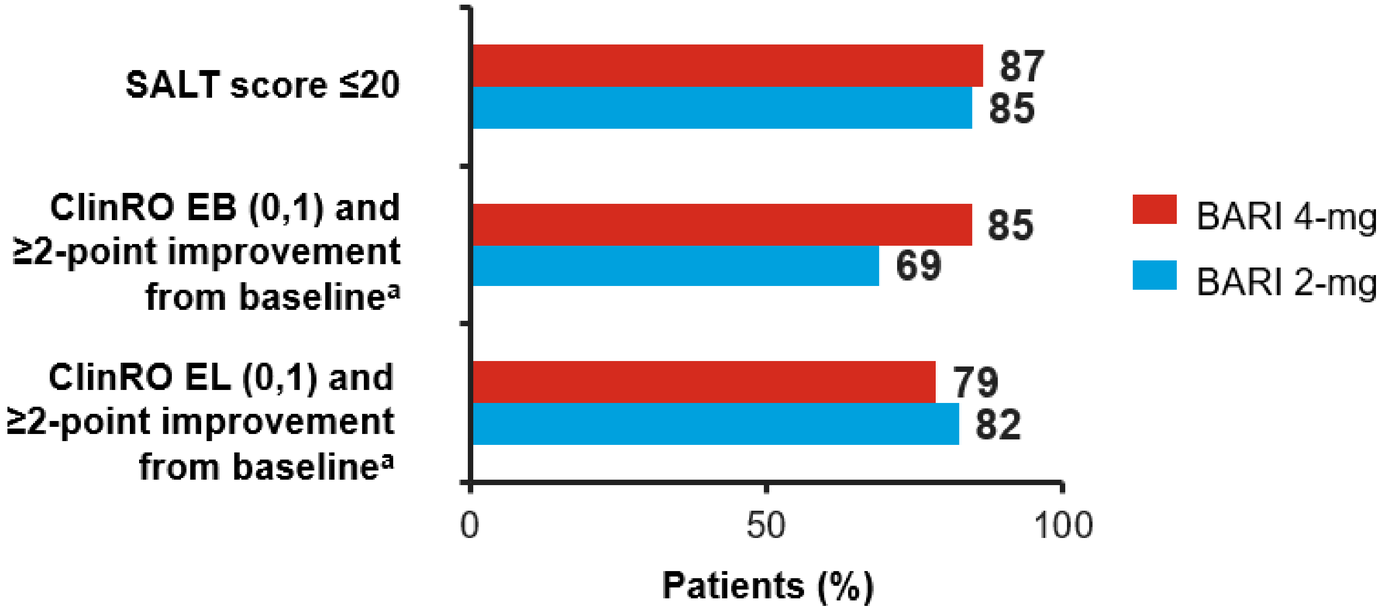
- Since the W152 report:
  - No new reports of opportunistic infections, herpes zoster, MACE, DVT/PE, or malignancy other than NMSC
  - 2 new serious infections (1 in a participant with a previous serious infection)[b] and 1 new NMSC[c] were reported
- No deaths or cases of tuberculosis have been reported in the trial

[a]MACE was defined as a cardiovascular death, myocardial infarction, or stroke as adjudicated by an independent clinical event committee; [b]One case of worsening of chronic rhinitis; 1 patient who had a previously reported serious COVID-19 event subsequently reported an unspecified viral infection which was serious; [c]NMSC occurred in one patient with fair skin and significant sun exposure who reported 3 squamous cell carcinoma events. The patient recovered and completed the study.

AA=alopecia areata; AE=adverse event; BARI=baricitinib; DVT=deep vein thrombosis; IR=incidence rate; MACE=major adverse cardiovascular event; n=number of patients; NMSC=non-melanoma skin cancer; PE=pulmonary embolism; W=Week.

Summary of Key Findings

Efficacy at W200 in Patients With SALT Score ≤20 at W52



Safety at W200/W248 vs. W152

NO new safety signals
NO new malignancy other than NMSC
NO new MACE events
NO new DVT/PE events
NO reported deaths

1 new NMSC
2 new serious infections

Baricitinib efficacy and safety data through 5 years of exposure in the BRAVE-AA1 and BRAVE-AA2 trials support long-term continuous use in severe AA

[a]Among patients with ClinRO EB or EL ≥2 at baseline.

AA=alopecia areata; BARI=baricitinib; ClinRO=clinician-reported outcome; EB=eyebrow; EL=eyelash; DVT=deep vein thrombosis; MACE=major adverse cardiovascular event; NMSC=non-melanoma skin cancer; PE=pulmonary embolism; SALT=Severity of Alopecia Tool; W=Week.

CONCLUSIONS

- Among patients with severe AA who achieved a SALT score ≤20 at W52, ~85% maintained that response through ~4 years of treatment
  - The majority of scalp responders at W52 maintained a deep response (SALT score ≤10) at W200
  - Further, of these patients, the proportion who achieved full or nearly full eyebrows or eyelashes continued to increase from W52 to W200
- This safety analysis in patients with severe AA, including up to 5 years of data, was consistent with previously reported data from the baricitinib AA clinical trial program

AA=alopecia areata; SALT=Severity of Alopecia Tool; W=Week.

Abbreviations

AA=alopecia areata; AE=adverse event; BARI=baricitinib; CI=confidence interval; ClinRO=clinician-reported outcome; COVID-19=coronavirus disease 2019; CPK=creatine phosphokinase; DVT=deep vein thrombosis; EB=eyebrow; EL=eyelash; IR=incidence rate; LOCF=last observation carried forward; mLOCF=modified LOCF; MACE=major adverse cardiovascular event; n=number of patients; NMSC=non-melanoma skin cancer; PE=pulmonary embolism; PYE=patient-years of exposure; QD=once daily; R=randomization; SAE=serious AE; SALT=Severity of Alopecia Tool; TEAE=treatment-emergent AE; W=Week

References

1. King B, et al. *J Am Acad Dermatol*. 2021;85:847-853.
2. Lintzeri DA, et al. *J Dtsch Dermatol Ges*. 2022;20:59-90.
3. King B, et al. *N Engl J Med*. 2022;386:1687-1699.
4. Senna M, et al. *J Eur Acad Dermatol Venereol*. 2024;38:583-593.
5. King B, et al. *Am J Clin Dermatol.* 2025;26:611-622.

Disclosures

- **R. A. Vleugels** has been a consultant for: AbbVie, AstraZeneca, Eli Lilly and Company, and Priovant Therapeutics; **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, Olistic, Pfizer, and Pierre Fabre-Ducray; **N. Mesinkovska** has provided professional services for: AbbVie, Arena Pharmaceuticals, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, La Roche-Posay, and Pfizer; **A. Mostaghimi** has been a consultant for: AbbVie, Concert Pharmaceuticals, Digital Diagnostics, Eli Lilly and Company, and Pfizer; **Y. Shimomura** has been an investigator for: Eli Lilly and Company; **A. Sontag**, **F. McSwiney**, **H. Pandey**, and **K. Denning** are current employees and shareholders of: Eli Lilly and Company; **B. King** has served on advisory boards, 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
- Medical writing assistance was provided by Heather Taft, PhD, of Envision Catalyst, an Envision Medical Communications agency, a part of Envision Pharma Group, and was funded by Eli Lilly and Company