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# Maintained improvement of outcomes related to skin clearance, itch, sleep and quality of life with baricitinib in adults with moderate-to-severe Atopic Dermatitis who were treated for up to 200 weeks in a randomized trial

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**ABSTRACT**

**Objective:** To report response maintenance in patients with moderate-to-severe Atopic Dermatitis (AD) upon continuous or downtitrated baricitinib treatment for 200 weeks.

**Methods:** Patients with vIGA-AD® (validated Investigator Global Assessment for Atopic Dermatitis) score ≤2 at Week 52 treated with baricitinib 4 mg were re-randomized (1:1:1) to continue (4 mg), down-titrate (2 mg) or dose withdrawal (placebo). Response to continuous and downtitrated treatment was assessed from Week 52 to 200 in the overall substudy population (vIGA-AD 0,1,2) and in substudy patients with higher response (vIGA-AD 0,1) at Week 52.

**Results:** Efficacy was maintained in Week 52 responders (vIGA-AD 0,1,2) continuing baricitinib 4 mg, as measured by vIGA-AD (0,1) (Week 52 [51.2%], Week 200 [51.2%]); Eczema Area and Severity Index (EASI) 75 (Week 52 [82.1%], Week 200 [79.8%]). Patients with vIGA-AD (0,1) at Week 52 maintained higher response rates during continued treatment and after down-titration compared with overall substudy population.

**Conclusion:** AD symptom improvement was maintained up to Week 200 with baricitinib 4 mg. After down-titration, the vIGA-AD (0,1) response patient subgroup maintained clear or almost clear skin and itch response improvement. Clear or almost clear skin achievement may help identify optimal candidates for down-titration after 52 weeks of full-dose treatment.

**KEY SUMMARY POINTS**

- In BREEZE-AD3, patients continuing baricitinib 4 mg demonstrated a benefit over AD signs and symptoms up to 200 weeks. After down-titration, the subgroup of patients who achieved vIGA-AD (0,1) response, mostly maintained clear or almost clear skin and continued improvement in itch response.
- Achieving clear or almost clear skin may help to identify optimal candidates for down-titration after 52 weeks of full-dose treatment.

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**KEYWORDS**
Atopic Dermatitis; baricitinib; patient-related outcomes; long-term study; Janus kinase inhibitor

## Introduction

Atopic Dermatitis (AD) is a clinically defined common, chronic, relapsing disease with worldwide occurrence of 15% to 20% in children and 7% to 10% in adults (1,2). Many patients can experience variation in disease severity, skin involvement and persistence of symptoms (3,4). Symptoms, such as skin pain, itch and sleep disturbance, can have a detrimental impact on a patients' quality of life (QoL) (1).

Topical corticosteroids (TCS) and topical calcineurin inhibitors are the first-line treatment for patients with moderate-to-severe AD (5), but some patients do not benefit enough from these treatments (6,7). Other treatments, such as emollients and systemic therapies are used, but may not provide adequate disease control or may cause adverse effects. Baricitinib is an oral reversible and selective Janus kinase (JAK)1/JAK2 inhibitor (8) approved for treating moderate-to-severe AD in adult patients in more than 70 countries, and in over 30 countries for adolescents and children from age 2 years with moderate-to-severe AD, who are candidates for systemic therapy (9). The 2022 European guidelines for AD recommend baricitinib as a treatment option in adults with severe disease who are candidates for systemic therapy, alongside other treatment options that include ciclosporin, dupilumab, tralokinumab, abrocitinib and upadacitinib (10). Furthermore, symptoms of AD can fluctuate over time and change with the seasons, creating a potential need for flexible dosing (11). Patients might seek periods without treatment, or dosages may need adjustment to reduce the risk of adverse effects (e.g., dose tapering). As JAK

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inhibitors represent a new class of treatment for moderate-to-severe AD, it is not yet well-understood if treatment may be tapered while achieving maintained response.

BREEZE-AD3 (NCT03334435) is a phase-3, long-term extension, double-blind study that examined the maintenance of efficacy of baricitinib in patients who had completed BREEZE-AD1 (NCT03334396), BREEZE-AD2 (NCT03334422), or BREEZE-AD7 (NCT03733301). Maintenance of endpoints related to skin clearance and QoL were previously reported in BREEZE-AD3 up to 104 weeks in patients who were responders (achieved clear or almost clear skin) or partial responders (achieved mild AD) at Week 52 of BREEZE-AD3 (12).

Here, we report maintenance of response based on skin clearance, itch, sleep and QoL, from Week 52 to Week 200 in patients assigned to baricitinib 4 mg upon entry into BREEZE-AD3 study, who achieved response or partial response at Week 52, and were subsequently re-randomized to continue treatment with baricitinib 4 mg or down-titrated to baricitinib 2 mg. In addition, we report the impact of continuous treatment and dose down-titration in a subgroup of patients with AD who achieved clear or almost clear skin (vIGA-AD of 0 or 1) at Week 52 after treatment with baricitinib 4 mg.

## Methods

Patients who participated in the originating studies, BREEZE-AD1 (NCT03334396), BREEZE-AD2 (NCT03334422), and BREEZE-AD7 (NCT03733301), could enroll in the multicenter, Phase 3, long-term extension study BREEZE-AD3 (NCT03334435). All patients provided written informed consent. Studies were approved by the individual institutional review boards at each participating study center and conducted in accordance with the Good Clinical Practice guidelines and Declaration of Helsinki.

### *Study design and eligibility criteria*

In this substudy, patients assigned to baricitinib 4 mg upon entry into BREEZE-AD3 who achieved response or partial response at Week 52 were re-randomized (1:1:1) to dose continuation (4 mg to 4 mg), dose down-titration (4 mg to 2 mg) or dose withdrawal (4 mg to placebo). Substudy eligibility was assessed at Week 52 and included patients that had a vIGA-AD score ≤2 (clear, almost clear, or mild), had been assigned to baricitinib 4 mg (included in this analysis) or 2 mg (not included in this analysis) at the start of BREEZE-AD3, and had not used high-potency TCS for the previous 14 days nor had an interruption of treatment upon entry to the substudy. Low-and moderate potency TCS use was permitted at investigators' discretion. Outcomes were assessed from Week 52 to 200. This analysis reports data from patients who continued treatment with baricitinib 4 mg or who were downtitrated to baricitinib 2 mg. Patients re-randomized to placebo were excluded from this article, as it was previously described that patients who underwent treatment withdrawal and lost response typically did so within the first 4 weeks (13).

### *Outcomes (patients with vIGA-AD score ≤2)*

Efficacy outcomes included the proportion of patients with a 75% improvement in Eczema Area and Severity Index (EASI75) from baseline of originating study and the proportion of participants with vIGA-AD response of 0 or 1, assessed at Week 52 to 200. The change from baseline (CFB) for the following measures were included: EASI total score, SCORing AD (SCORAD) itch and sleep loss score, at Week 52 through 200. The proportion of patients who achieved at least 4-point improvement in POEM and those with a DLQI score of 0/1 were also evaluated up to Week 200.

### *vIGA-AD (0,1) subgroup outcomes*

Patients treated with daily baricitinib 4 mg for 52 weeks in BREEZE-AD3 who achieved a vIGA-AD scale score of 0 or 1 were blindly re-randomized to continue daily baricitinib 4 mg (continuous dosing, $N=43$), or downtitrated to 2 mg (down-titration, $N=43$). Efficacy was assessed using the same outcomes as for overall substudy population (patients with vIGA-AD score ≤2).

### *Statistical analyses*

For categorical variables, response rate and confidence intervals were reported. Logistic regressions including region, Week 52 vIGA-AD, treatment group and corresponding Week 52 baseline value were used for responder analysis. For continuous variables, Analysis of covariance (ANCOVA) models including geographical region, Week 52 vIGA-AD, treatment group and corresponding Week 52 baseline values were used for CFB. Efficacy measures after permanent study drug discontinuation or rescue therapy were excluded (or set to missing). Data are presented descriptively; missing data were imputed using modified last observation carried forward (mLOCF). The same approach was applied to the vIGA-AD (0,1) subgroup.

## Results

### *Patient disposition and baseline characteristics*

The patient disposition and baseline characteristics for the patient population who entered the substudy of BREEZE-AD3 were reported previously (12), and displayed in Table 1. 42 out of 84 patients (50%) who continued daily baricitinib 4 mg, and 49 out of 84 patients (58.3%) of patients who downtitrated to 2 mg, completed the Week 200 visit. The main reason for discontinuation in these groups were 'study termination by sponsor' as patients were withdrawn from the study due to commercial availability of baricitinib or 'withdrawal by subject.' Baseline demographics and disease characteristics were comparable among patients continuing baricitinib 4 mg and those who downtitrated to baricitinib 2 mg (Table 1). For the vIGA-AD (0,1) subgroup, baseline demographics were comparable across treatment groups and with patients from the overall BREEZE-AD3 substudy population (Tables 1 and 2). At the same time, these patients had lower EASI total score (1.9 and 1.8) and body surface area (BSA) involvement (5.0 and 4.3) (Table 2) at Week 52, compared with all patients entering the substudy.

### *Outcomes (patients with vIGA-AD score ≤2)*

Among patients continuing on baricitinib 4 mg, the proportion who achieved or maintained vIGA-AD (0,1) was stable from Week 52 to 200 (Week 52 [51.2%] to 200 [51.2%]) (Figure 1a). Patients who continued on baricitinib 4 mg also largely maintained EASI75 response (Week 52 [82.1%] to 200 [79.8%]) (Figure 1b). The

**Table 1.** Baseline demographics and disease characteristics of the substudy patients of BREEZE-AD3.

| | BARI 4-mg to BARI 4-mg (*N* = 84) | BARI 4-mg to BARI 2-mg (*N* = 84) |
|---|---|---|
| Age, years | 38.1 (14.3) | 38.8 (15.3) |
| Male, n (%) | 53 (63.1) | 54 (64.3) |
| Race, n (%) | | |
| White | 52 (61.9) | 61 (72.6) |
| Asian | 29 (34.5) | 19 (22.6) |
| BREEZE-AD3 substudy baseline (W52) | | |
| vIGA-AD, n (%) | | |
| 0 | 7 (8.3) | 8 (9.5) |
| 1 | 36 (42.9) | 35 (41.7) |
| 2 | 41 (48.8) | 41 (48.8) |
| EASI total score | 4.2 (3.9) | 4.4 (5.1) |
| BSA % involvement | 8.7 (9.7) | 8.7 (10.8) |
| Itch NRS | 2.7 (2.0) | 2.8 (2.1) |
| DLQI | 5.0 (6.2) | 3.9 (4.0) |
| SCORAD total score | 22.1 (12.5) | 22.6 (12.9) |
| POEM | 9.3 (7.5) | 8.5 (6.8) |

Notes: Data are presented as mean (standard deviation) unless otherwise indicated.
BARI = baricitinib; BSA = body surface area; EASI = Eczema Area and Severity Index; vIGA-AD = validated Investigator Global Assessment for Atopic Dermatitis; NRS = Numeric Rating Scale; DLQI = Dermatology Life Quality Index; POEM = Patient Oriented Eczema Measure; SCORAD = SCORing Atopic Dermatitis.

**Table 2.** Baseline demographics and disease characteristics of the substudy patients of BREEZE-AD3 with IGA (0, 1) at Week 52.

| | BARI 4-mg to BARI 4-mg (*N* = 43)[a] | BARI 4-mg to BARI 2-mg (*N* = 43)[a] |
|---|---|---|
| Age, years | 41.4 (16.0) | 39.9 (16.9) |
| Male, n (%) | 26 (60.5) | 26 (60.5) |
| Race, n (%) | | |
| White | 29 (67.4) | 34 (79.1) |
| Asian | 11 (25.6) | 8 (18.6) |
| American Indian or Alaska native | 1 (2.3) | 1 (2.3) |
| Multiple | 2 (4.7) | 0 (0) |
| BREEZE-AD3 substudy baseline (W52) | | |
| vIGA-AD, n (%) | | |
| 0 | 7 (16.3) | 8 (18.6) |
| 1 | 35 (81.4) | 36 (83.7) |
| EASI total score | 1.8 (1.9) | 1.9 (1.8) |
| BSA % involvement | 4.0 (5.0) | 3.9 (4.3) |
| Itch NRS | 1.7 (1.6) | 2.5 (2.1) |
| DLQI | 3.2 (4.5) | 3.0 (3.6) |
| SCORAD total score | 13.9 (9.2) | 15.4 (10.3) |
| POEM | 7.0 (7.4) | 5.7 (4.9) |

Notes: Data are presented as mean (standard deviation) unless otherwise indicated.
[a]Modified Intent-to-Treat population who entered the substudy with IGA (0, 1).
BARI = baricitinib; BSA = body surface area; EASI = Eczema Area and Severity Index; vIGA-AD = validated Investigator Global Assessment for Atopic Dermatitis; NRS = Numeric Rating Scale; DLQI = Dermatology Life Quality Index; POEM = Patient Oriented Eczema Measure; SCORAD = SCORing Atopic Dermatitis.

reduction of severity based on EASI total score CFB remained stable from Week 52 to 200 (least square mean (LSM), Week 52 [−27.77] to 200 [−26.6]) (Figure 1c).

Among patients who downtitrated to baricitinib 2 mg, 51.2% and 33.3% of patients achieved IGA (0,1) at Week 52 and Week 200, respectively. EASI75 response was 84.5% at Week 52 and 52.4% at Week 200; and improvements in EASI total score CFB was −27.21 at Week 52 and −22.8 at Week 200 (Figure 1a–c).

Among patients continuing treatment with baricitinib 4 mg, improvements in mean CFB in SCORAD itch (LSM, Week 52 [−4.69] to 200 [−4.5]) and sleep loss (LSM, Week 52 [−3.82] to 200 [−3.6]) were observed up to Week 200 (Figure 2a, b). The proportion of patients with a DLQI response of 0 or 1, which indicates no impact on patient's life, was largely maintained from Week 52 to 200 (Week 52 [38.1%] to 200 [34.5%]) in the 4 mg continuation cohort (Figure 2c). POEM ≥4-point improvement was 83.3% at Week 52 and 73.8% at Week 200 (Figure 2d).

For patients downtitrating to baricitinib 2 mg, mean CFB showed a change of less than 2 points from Week 52 to 200 in SCORAD itch (LSM, Week 52 [−4.2] to 200 [−2.7]) (Figure 2a) and SCORAD sleep loss (LSM, Week 52 [−3.6] to 200 [−2.7]) (Figure 2b). 32.1% and 26.2% of patients in this group reported a DLQI response of 0 or 1 Week 52 and Week 200, respectively (Figure 2c), and a POEM ≥4-point improvement was observed in 83.3% at Week 52 and 66.7% at Week 200 (Figure 2d).

### *vIGA-AD (0,1) subgroup outcomes*

Among patients with vIGA-AD (0,1) at Week 52 who continued on baricitinib 4 mg, vIGA-AD (0,1) response was 100.0% at Week 52 and 69.8% at Week 200 (Figure 3a), while EASI75 response was 100.0% at Week 52 and 93.3% at Week 200 (Figure 3b). The reduction of severity based on EASI total score CFB was stable from Week 52 to 200 (LSM, Week 52, [−27.3] to 200 [−26.7]) (Figure 3c), and patients continued to experience improvement in itch symptoms and sleep loss, as measured by SCORAD Itch CFB (LSM, Week 52, [−5.09] to 200 [−5.03]) (Figure 4a) and SCORAD Sleep loss CFB (LSM, Week 52, [−3.74] to 200 [−3.62]) (Figure 4b). The proportion of patients with a DLQI response of 0 or 1 was 58.1% at Week 52 and 46.5% at Week 200 in the 4 mg continuation cohort (Figure 4c); and POEM ≥4-point improvement was observed in 90.7% at Week 52 and 86.0% at Week 200 (Figure 4d).

Among patients with vIGA-AD (0,1) at Week 52 who downtitrated to baricitinib 2 mg, vIGA-AD (0,1) response was 100% at Week 52 and 51.2% at Week 200; and EASI75 response was 100.0% at Week 52 and 67.4% at Week 200. CFB for EASI total score was −30.6 at Week 52 and −26.4 at Week 200 (Figure 3a–c); SCORAD Itch was −4.93 at Week 52 and −3.56 at Week 200; and SCORAD Sleep loss was −4.27 at Week 52 and − 3.39 at Week 200 (Figure 4a, b). The proportion of patients with a DLQI response of 0 or 1 was 46.5% at Week 52 and 37.2% at Week 200; and POEM ≥4-point improvement was observed in 90.7% at Week 52 and 76.7% at Week 200 (Figure 4c, d).

## Discussion

This article reports the maintained response of outcomes related to skin clearance, itch, sleep and QoL for up to 200 weeks in 168 patients who achieved response or partial response at Week 52 on baricitinib 4 mg, and were subsequently re-randomized to continue treatment with baricitinib 4 mg or downtitrated to baricitinib 2 mg.

Maintenance of improvements in vIGA-AD, EASI75, EASI total score DLQI, POEM, SCORAD itch and sleep loss were monitored through up to 200 weeks of continuous treatment, with TCS used at investigators' discretion. These results provide an update to the 104-week results, demonstrating the long-term maintenance of physician- and patient-rated outcomes (12). Clinically meaningful improvements in the signs of AD are reflected by EASI (14). A proportion of patients in both treatment groups maintained their EASI75 response, with a numerical decrease in response of 30% for

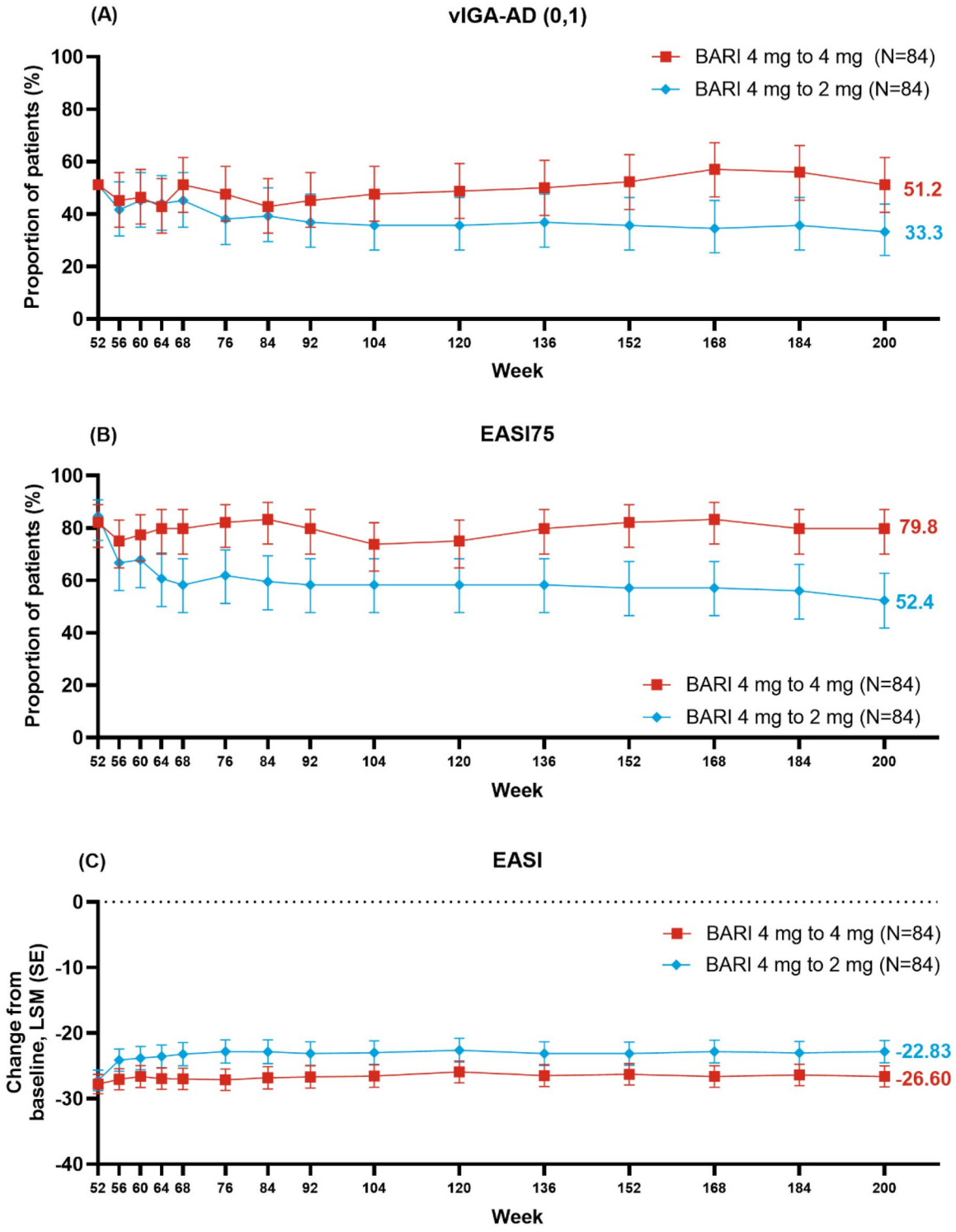


**Figure 1.** Skin response over time for patients from the overall substudy: (a) vIGA-AD (0,1), (b) EASI75, and changes from baseline over time for (c) EASI.
BARI = Baricitinib; EASI = Eczema Area and Severity Index; vIGA-AD = validated Investigator Global Assessment.

patients in the down-titration treatment group. This decrease corresponded with a modest change in absolute EASI scores during the same period, approximately a 4-point difference between Week 52 and 200, which may better capture the sustained improvement in disease control over long-term. When comparing responses between the vIGA-AD ≤2 and vIGA-AD (0,1) groups in both continuous and down-titration treatments, we observed that more patients from the vIGA-AD (0,1) subgroup (i.e.. patients who had a higher clinical response at Week 52) maintained their improvements over time compared with those with vIGA-AD ≤2 scores upon entry into the substudy. This indicates that achieving a greater reduction in inflammation may lead to better long-term control.

In patients with moderate-to-severe AD, lack of efficacy or risk of adverse events with first-line or systemic therapies remains a concern. AD symptoms can also fluctuate temporally and

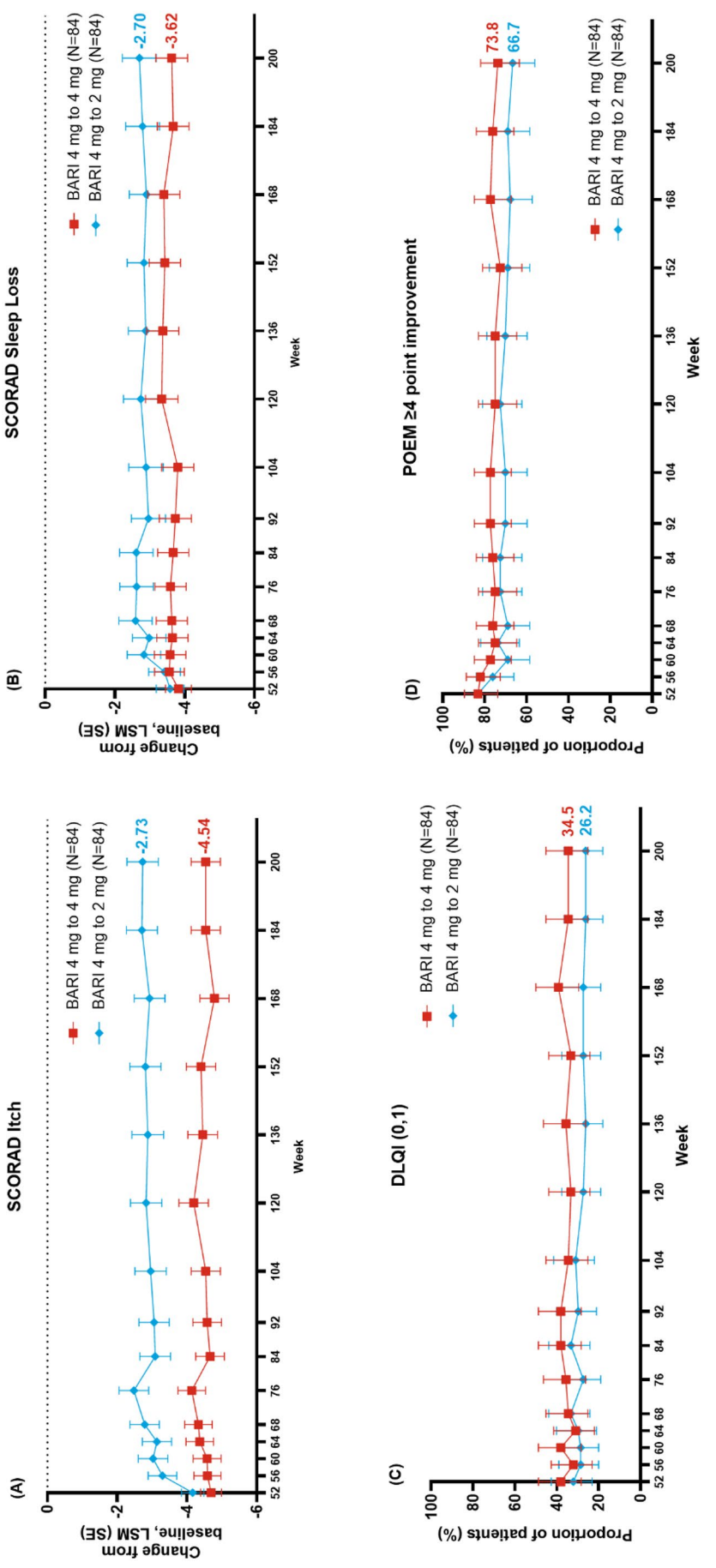


**Figure 2.** Change from baseline over time for patients from the overall substudy: (a) SCORAD Itch, (b) SCORAD sleep loss, and Patient-reported responses over time for patients from the overall substudy: (c) DLQI (0,1), and (d) POEM ≥4-point improvement.
BARI = Baricitinib; DLQI = Dermatology Life Quality Index; POEM = Patient Outcome Eczema Measure; SCORAD = SCORing Atopic Dermatitis.

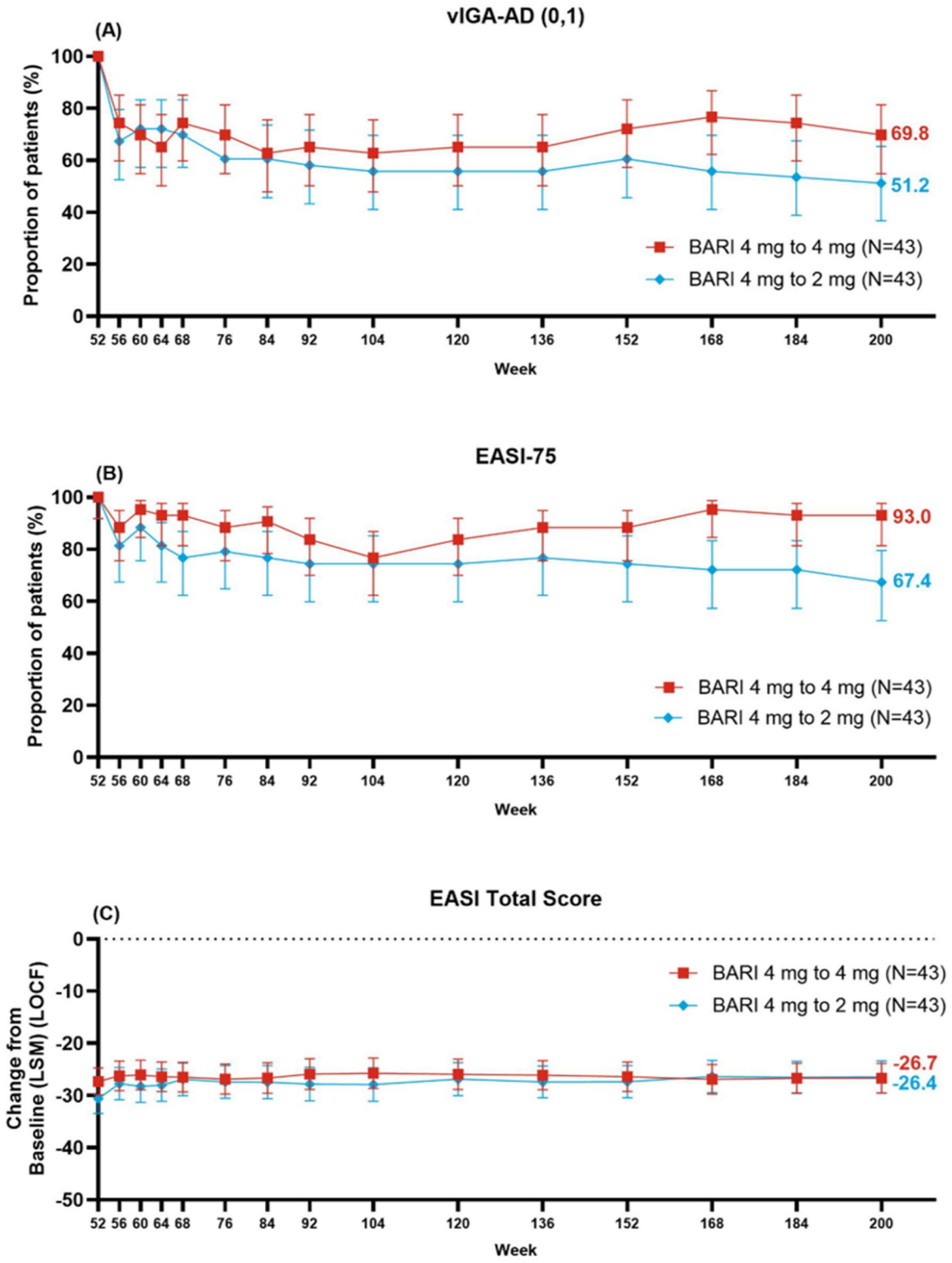


**Figure 3.** Responses over time for patients in the IGA (0,1) subgroup: (a) vIGA-AD (0,1) (b) EASI75 and Change from baseline over time for patients in the IGA (0,1) subgroup: (c) EASI total score.
BARI = Baricitinib; EASI = Eczema Area and Severity Index; vIGA-AD = validated Investigator Global Assessment.

seasonally, whereby patients may have a need for dose tapering. Dose tapering with JAK inhibitors, such as baricitinib, allowing for maintained response in moderate-to-severe AD patients remains poorly understood. This study is the first to report the longest follow-up of AD patients treated with baricitinib, allowing the treatment response to baricitinib after down-titration to be observed over a period of 200 weeks. In the vIGA-AD 0,1 subgroup, almost 70% of patients who downtitrated from 4 mg to 2 mg maintained EASI75 response and improvements in patient-rated outcomes up to Week 200. The high responses noted in patients

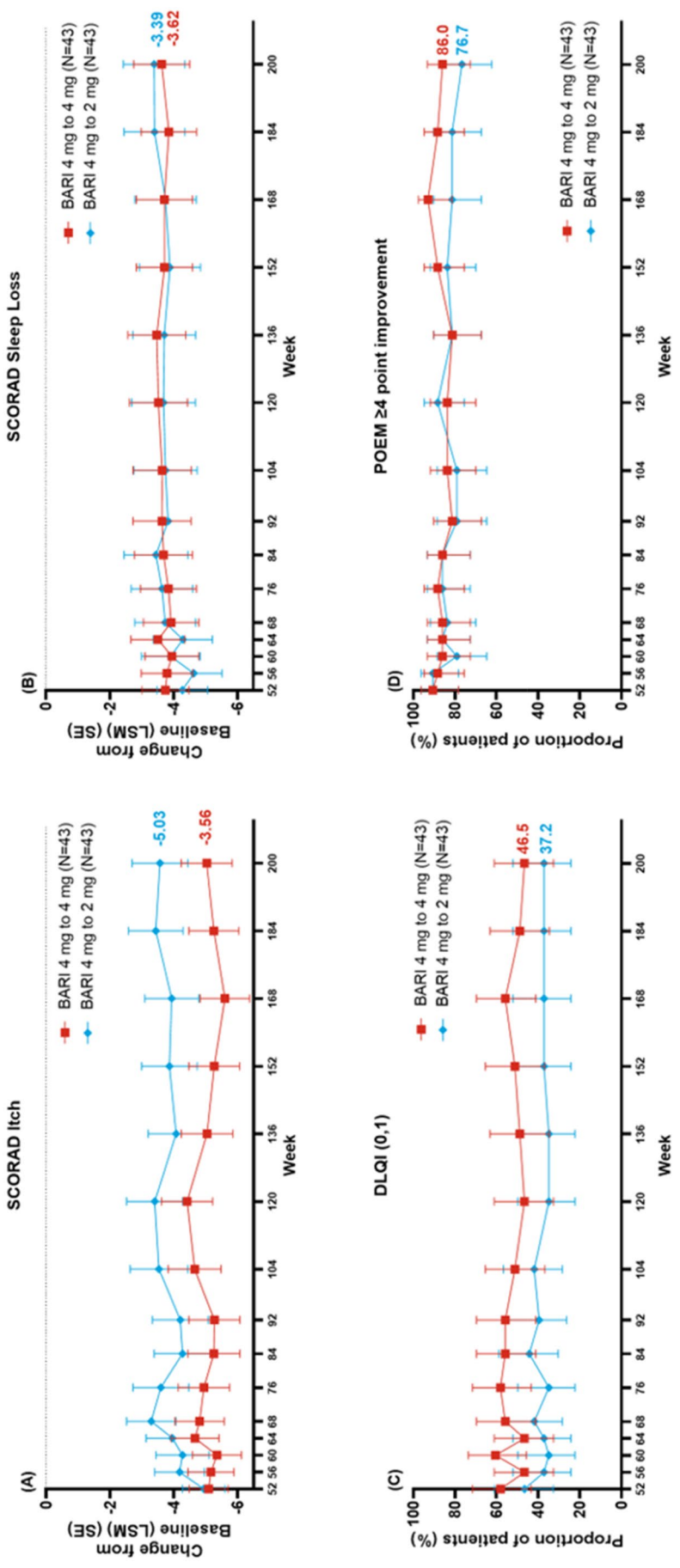


**Figure 4.** Change from baseline over time for patients in the IGA (0,1) subgroup: (a) SCORAD Itch, (b) SCORAD Sleep loss, and Patient-reported responses over time for patients in the IGA (0,1) subgroup: (c) DLQI (0,1), and (d) POEM ≥4-point improvement.
BARI = Baricitinib; SCORAD = SCORing Atopic Dermatitis; DLQI = Dermatology Life Quality Index; POEM = Patient Oriented Eczema Measure; LSM = Least square mean, SE = Standard error.

with clear or almost clear skin upon down-titration, suggest these patients are good candidates for dose reduction and support the flexibility of down-titrating baricitinib treatment. While ultimately the decision to undertake dose tapering should be based on the individual patient's disease history and response to therapy, some patients may seek the option of dose tapering, if available.

This substudy has several limitations. In clinical practice, assessing both the magnitude and stability of a patient's response is important when considering down-titration. However, the design of the BREEZE-AD3 did not consider the stability of response before re-randomization at Week 52. A previous analysis tracked patient relapse (vIGA-AD ≥3) for up to 16 weeks (Weeks 52 to 68) after re-randomization, and results showed that patients with low stability prior Week 52 may have been downtitrated (15). Additionally, this substudy only includes Asian and White patients, with no representation of Black or African American patients. Considering that race might influence the phenotypic expression of AD (16,17), further research is needed to better characterize these outcomes in other ethnicities.

### *Conclusion*

In BREEZE-AD3, patients with moderate-to-severe AD who continued baricitinib 4 mg demonstrated a high level of long-term efficacy in skin clearance, itch, sleep, and QoL from 52 weeks up to 200 weeks of treatment. In the vIGA-AD 0,1 patient subgroup, maintained EASI75 response and improvements in patient-reported outcomes observed upon downtitration would suggest some patients may be good candidates for baricitinib dose reduction. Achieving clear or almost clear skin can help identify optimal candidates for dose reduction after 52 weeks of full-dose treatment.

## Disclosure statement

Andreas Wollenberg has served as an advisor or paid speaker for, or participated in clinical trials (with honoraria paid to the institution) sponsored by AbbVie, Aileens, Almirall, Amgen, Beiersdorf, Bioderma, Bioproject, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, DKSH, Eli Lilly, Galapagos, Galderma, Glenmark, GSK, Hans Karrer, Hexal, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, Maruho, MedImmune, MSD, Mylan, MSD, Novartis, Pfizer, Pierre Fabre, Regeneron, Sandoz, Santen, Sanofi-Aventis, and UCB. Antonio Costanzo has served as an advisory board member, consultant and has received fees and speaker's honoraria or has participated in clinical trials for Abbvie, Almirall, Biogen, LEO Pharma, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi Genzyme, and UCB-Pharma. Christian Vestergaard has acted as a speaker and/or consultant for Almirall, Sanofi A/S, Eli Lilly Denmark A/S, Novartis Healthcare A/S, Janssen-Cilag A/S, LEO Pharma A/S, AstraZeneca A/S, Eli Lilly & Co, Pierre Fabre, Chiesi, Galderma, Pfizer, and Abbvie, he has also received research grants from Sanofi, Pfizer and Almirall. Koji Masuda reports speaking fees from Sanofi, Eli Lilly Japan K.K. Maruho Co. Ltd, Mitsubishi Tanabe Pharma Corporation, and honoraria as an investigator of Eli Lilly Japan K.K. Katarzyna Morawska, Burcu Vardar, Hitendra Pandey and Silvia Sabatino are employees and minor shareholders of Eli Lilly & Company. Jose-Manuel Carrascosa has participated as a Principal Investigator/Senior Investigator and/or as an invited speaker and/or as an invited advisor and/or as a member of steering committees for Gebro, Nordic Pharma, LEO Pharma, AbbVie, Janssen, Novartis, Almirall, UCB, Eli Lilly, Sandoz, Boehringer Ingelheim, Bristol Myers Squibb, Pfizer, Galderma and Amgen.

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Baricitinib is developed by Eli Lilly and Company (Indianapolis, Indiana, USA) under license from Incyte Corporation.

## Data availability statement

Eli Lilly and Company provides access to all individual participant data collected during the trial, after anonymization, with the exception of pharmacokinetic or genetic data. Data are available to request 6 months after the indication studied has been approved in the United States and the European Union and after primary publication acceptance, whichever is later. No expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report and blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at www.vivli.org.

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