Maintained Improvement in Patient Rated Outcomes With Baricitinib 4-mg in Adults With Moderate-to-Severe Atopic Dermatitis Who Were Treated for up to 104 Weeks in a Randomised Trial

P15

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BACKGROUND

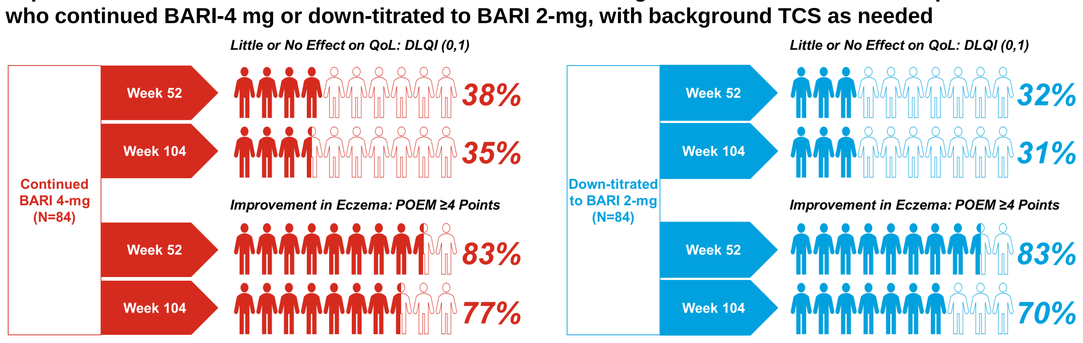
- Atopic dermatitis (AD) is a common, chronic, relapsing and remitting highly symptomatic inflammatory skin disease[1-3] that causes intractable pruritus, sleep disturbance, and pain,[4,5] resulting in poor quality of life (QoL) for many patients[6]
- Baricitinib, an oral selective Janus kinase (JAK)1/JAK2 inhibitor, is approved in many countries for moderate-to-severe AD in adults who are candidates for systemic therapy
- BREEZE-AD3 (NCT03334435) is an ongoing, double-blind, Phase 3 extension study designed to assess the long-term safety and efficacy of baricitinib in patients with moderate-to-severe AD[7]
- Maintenance of efficacy was demonstrated in BREEZE-AD3 through 52 weeks in patients who achieved clear, almost clear, or mild skin response at Week 16 in the originating studies[7]

OBJECTIVE

- This analysis evaluated maintenance of patient-reported outcomes, from Week 52 to Week 104, in patients initially assigned to baricitinib 4-mg upon entry into BREEZE-AD3, who achieved response or partial response at Week 52, and were subsequently re-randomized to continue treatment with baricitinib 4-mg or down-titrate to baricitinib 2-mg

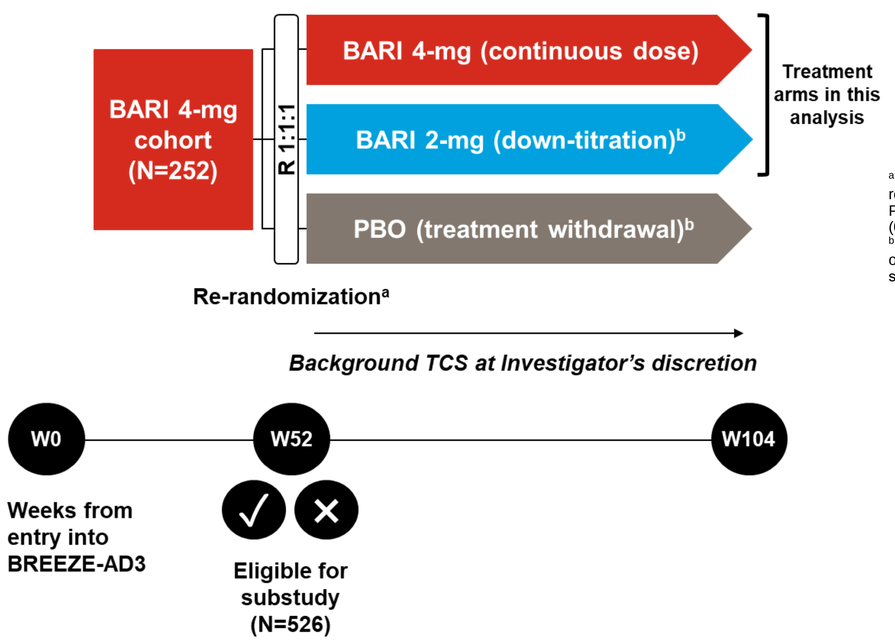
SUMMARY OF KEY FINDINGS

Improvements in PROs were maintained from 52 weeks through 104 weeks of treatment in patients with AD who continued BARI-4 mg or down-titrated to BARI 2-mg, with background TCS as needed



METHODS

Study Design, BREEZE-AD3 Substudy



[a] Substudy eligibility was assessed and re-randomization occurred at Week 52. Patients were stratified by vIGA-AD™ (0/1) vs. (2) when entering the substudy
[b] Patients were re-administered their original BARI dose if their vIGA-AD score became ≥3

Statistical Analyses

- Substudy eligibility was assessed at Week 52:
  - vIGA-AD score ≤2 (clear, almost clear, or mild skin)
  - 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
  - Not on a study treatment interruption
  - No use of high-potency topical corticosteroids in the prior 14 days

Assessments and Statistical Analyses

Population

- Patients originally assigned to BARI 4-mg in BREEZE-AD3 who achieved response or partial response at Week 52 and were re-randomized to continue BARI 4-mg or down-titrate to 2-mg in the substudy

Patient-Reported Outcomes

Maintenance of improvements in PROs from Week 52 through Week 104

- Percentage of patients with:
  - DLQI (0,1): Little or no effect on QoL
  - POEM total score: ≥4-point improvement
  - HADS <8 (anxiety and depression)
- Change from baseline (Week 0) in WPAI (higher scores=greater impairment)
  - Overall work impairment
  - Presenteeism
  - Absenteeism
  - Daily activity impairment

Analysis

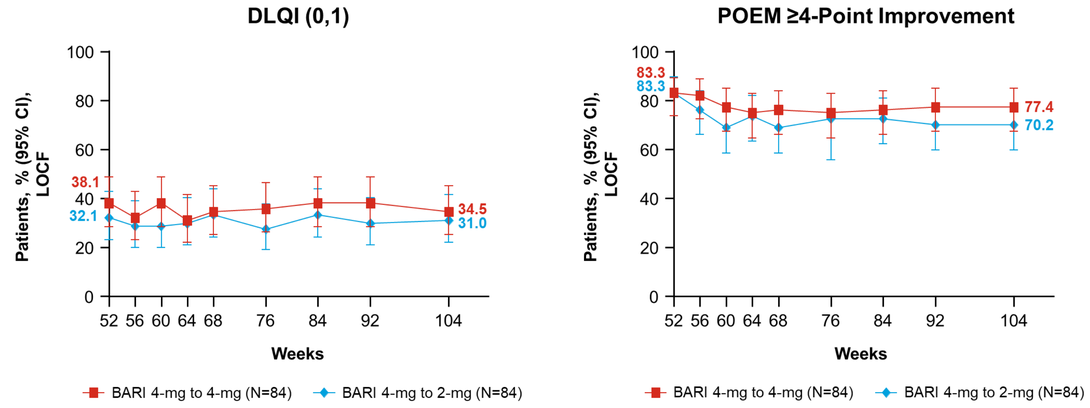
- For categorical variables, response rate and CIs
- For continuous variables, ANCOVA model with region, baseline disease severity (vIGA-AD) at Week 52, treatment group, and baseline value at Week 52 as covariates
- Data are presented descriptively; missing data were imputed using LOCF

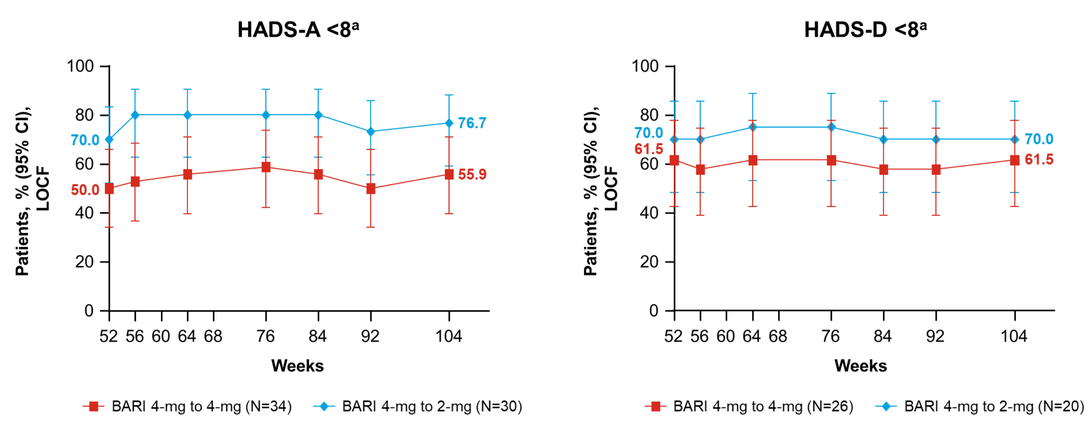
Patient Demographics and Baseline Characteristics[a]

	BARI 4-mg to BARI 2-mg (N=84)	BARI 4-mg to BARI 4-mg (N=84)
Age, years	38.8 (15.3)	38.1 (14.3)
Male, n (%)	54 (64.3)	53 (63.1)
Race, n (%)		
White	61 (72.6)	52 (61.9)
Asian	19 (22.6)	29 (34.5)
BREEZE-AD3 substudy baseline (W52)		
vIGA-AD, n (%)		
0	8 (9.5)	7 (8.3)
1	35 (41.7)	36 (42.9)
2	41 (48.8)	41 (48.8)
EASI	4.4 (5.1)	4.2 (3.9)
BSA % involvement	8.7 (10.8)	8.7 (9.7)

Data are presented as mean (standard deviation) unless otherwise indicated
[a] Modified Intent-to-Treat population who entered the substudy

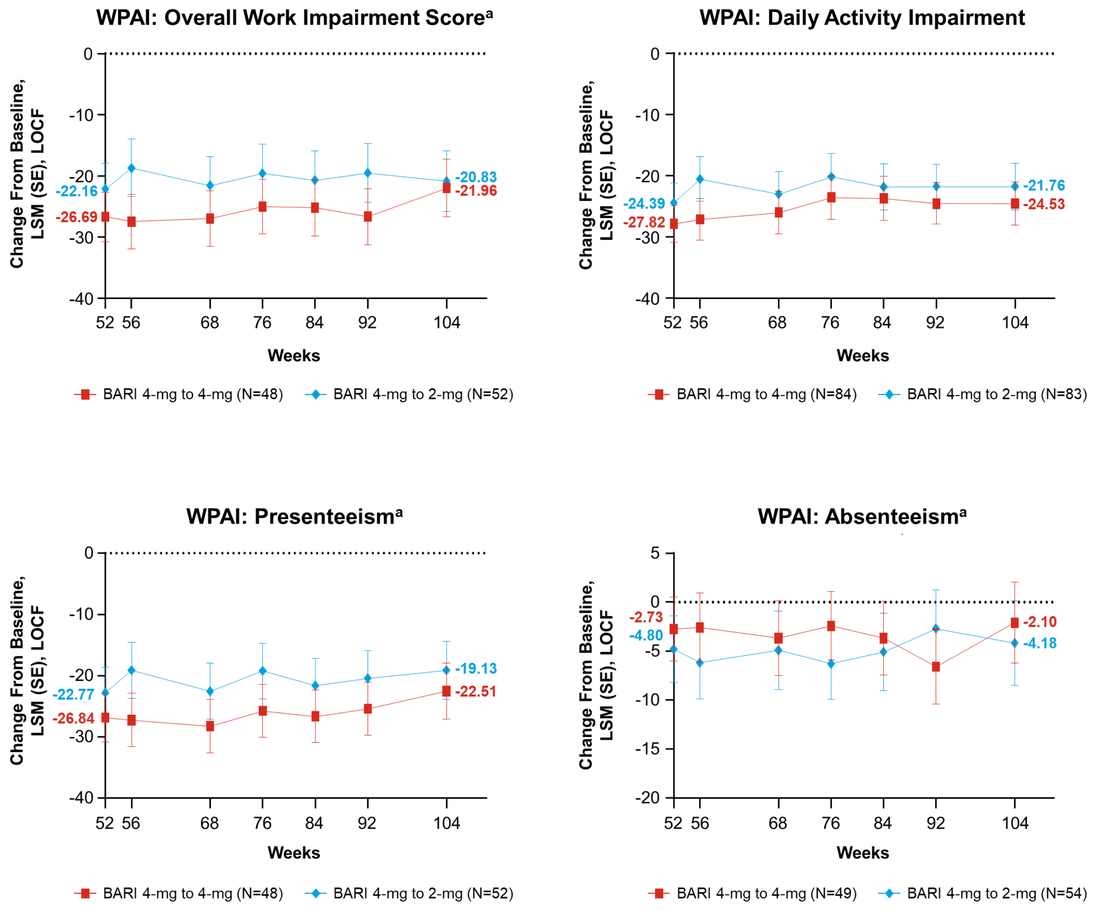
Patients Who Continued BARI 4-mg or Down-titrated to BARI 2-mg Maintained Improvements in DLQI, POEM, and HADS Scores





[a] In patients with borderline or abnormal severity scores at baseline (HADS-A ≥8 or HADS-D ≥8)

Patients Who Continued BARI 4-mg or Down-titrated to BARI 2-mg Maintained Improvements in Work Productivity



[a] Employed patients only

CONCLUSIONS

- Patients with AD who continued baricitinib 4-mg and those who down-titrated to baricitinib 2-mg maintained their improvements in self-rated health-related QoL, disease severity, anxiety and depression, and overall work impairment, presenteeism, absenteeism, and daily activity for up to 104 weeks of treatment

DISCLOSURES

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ABBREVIATIONS:

AD=atopic dermatitis; ANCOVA=analysis of covariance; BARI=baricitinib; BSA=body surface area; CI=confidence interval; DLQI=Dermatology Life Quality Index; DLQI (0,1)=DLQI - no or little effect on QoL; EASI=Eczema Area and Severity Index; HADS=Hospital Anxiety and Depression Scale; HADS-A=HADS-Anxiety; HADS-D=HADS-Depression; LOCF=last observation carried forward; LSM=least squares mean; PBO=placebo; POEM=Patient-Oriented Eczema Measure; PRO=patient-reported outcome; QoL=quality of life; R=randomization; SE=standard error; TCS=topical corticosteroid; W=Week; WPAI=Work Productivity and Activity Impairment

REFERENCES

1. Mack MR and Kim BS. *Trends Immunol.* 2018;39:980-991.
2. Wollenberg A, et al. *J Eur Acad DermatolVenereol.* 2018;32:657-682.
3. Wollenberg A, et al. *J Eur Acad Dermatol Venereol.* 2018;32:850-878.
4. Langenbruch A, et al. *J Eur Acad DermatolVenereol.* 2014;28:719-726
5. Ständer S, et al. *J Drugs Dermatol.* 2020;19:921-926.
6. Ali F, et al. *Acta Derm Venereol.* 2020;100:adv00161.
7. Silverberg JI, et al. *JAMA Dermatol.* 2021;157:691-699.

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