Efficacy and Safety of Abrocitinib in Chinese Patients With Moderate-to-Severe Atopic Dermatitis: A Post Hoc Analysis of the JADE REGIMEN Phase 3 Trial

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Disclosures: HL has served as the Chinese leading principal investigator at the National Clinical Research Center for Skin and Immune Diseases at Peking University First Hospital. HC has served as the principal investigator at Sir Run Run Shaw Hospital and Zhejiang University School of Medicine. QL has served as the principal investigator at Second Xiangya Hospital and Central South University. WL has served as the principal investigator at the Third Affiliated Hospital of Sun Yat-sen University. XT has served as the principal investigator at Zhejiang Provincial People's Hospital. GAE, SV, BW, XL, and SL are employees of Pfizer Inc. and hold stocks and/or stock options.

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Introduction, Objective, and Study Design

Introduction and Objective

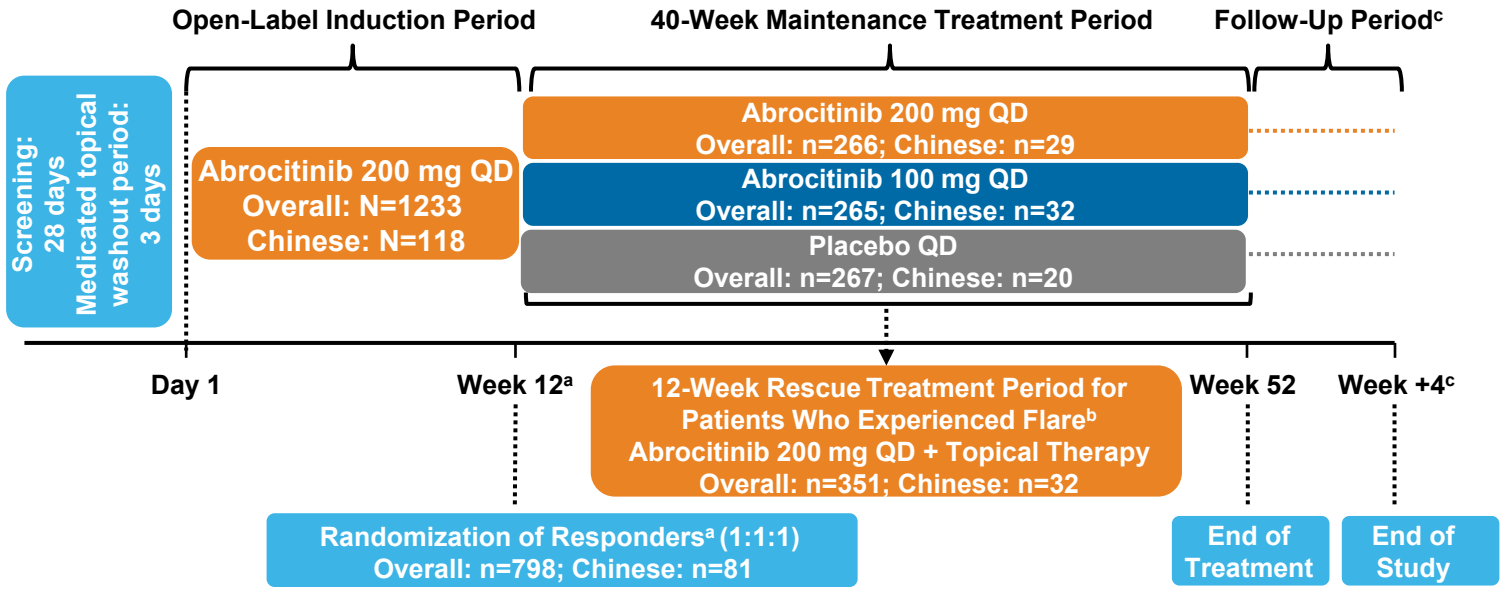
- Abrocitinib, an oral, once-daily, Janus kinase 1–selective inhibitor, was effective in maintaining response to treatment and recapturing response after a flare and was well tolerated in patients with moderate-to-severe AD in the phase 3 JADE REGIMEN trial (NCT03627767)[1]
- This study was conducted to evaluate the efficacy and safety of abrocitinib in patients who were enrolled in JADE REGIMEN from mainland China

Study Design

- The multicenter, induction, randomized withdrawal, and retreatment phase 3 JADE REGIMEN trial[1] comprised:
  - An **open-label induction period** in which patients received abrocitinib 200 mg once daily for 12 weeks
  - A **maintenance period** in which responders[a] to induction were randomly assigned to receive abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 40 weeks
  - A **rescue period** in which patients who experienced a flare[b] during maintenance received rescue therapy (abrocitinib 200 mg plus topical therapy) for 12 weeks

Eligibility Criteria

- Adults and adolescents (aged 12 years and older) with AD for ≥1 year
- Moderate-to-severe AD (%BSA ≥10, IGA ≥3, EASI ≥16, and PP-NRS ≥4)
- Recent (≤6 months) history of inadequate response or intolerance to topical AD treatment or requirement for systemic therapy to control AD



Endpoints

- Proportions of patients who achieved IGA 0/1 and EASI-75; IGA 0/1 alone; EASI-75 alone; and PP-NRS4 at week 12 of the induction period
- Probability of experiencing a flare during maintenance treatment
- Proportions of patients who recaptured EASI-75 response during rescue
- Safety: AE monitoring

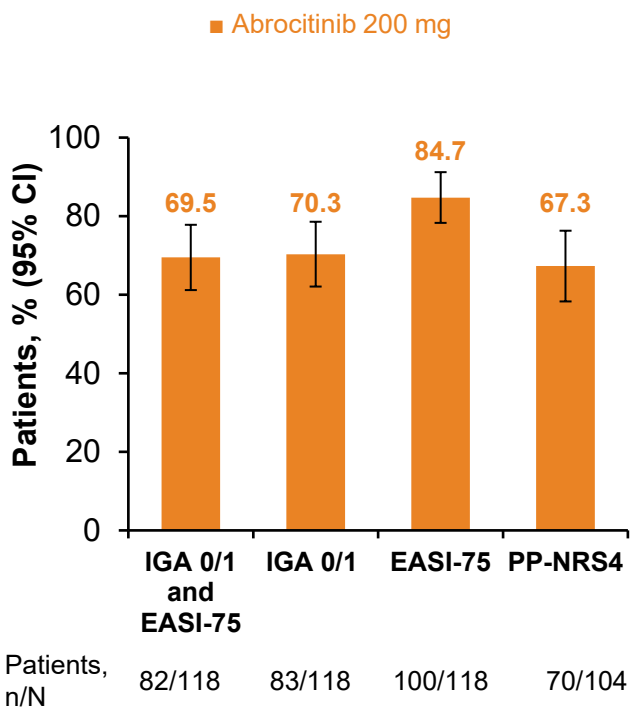
%BSA, percentage of body surface area; AD, atopic dermatitis; AE, adverse event; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale (used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi); PP-NRS4, a ≥4-point improvement from baseline in PP-NRS. QD, once-daily. [a]Patients who achieved an IGA score of 0 (clear) or 1 (almost clear) with a ≥2-point reduction from baseline and ≥75% improvement from baseline in EASI response. [b]Defined as a ≥50% loss of the initial EASI response at week 12 with a new IGA score ≥2. [c]Patients who were ineligible for randomization to the maintenance period; discontinued treatment during the induction, maintenance, or rescue phases; or did not enter the long-term extension study were followed up in the 4-week untreated period.

1. Blauvelt A et al. *J Am Acad Dermatol* 2022;86:104-112.

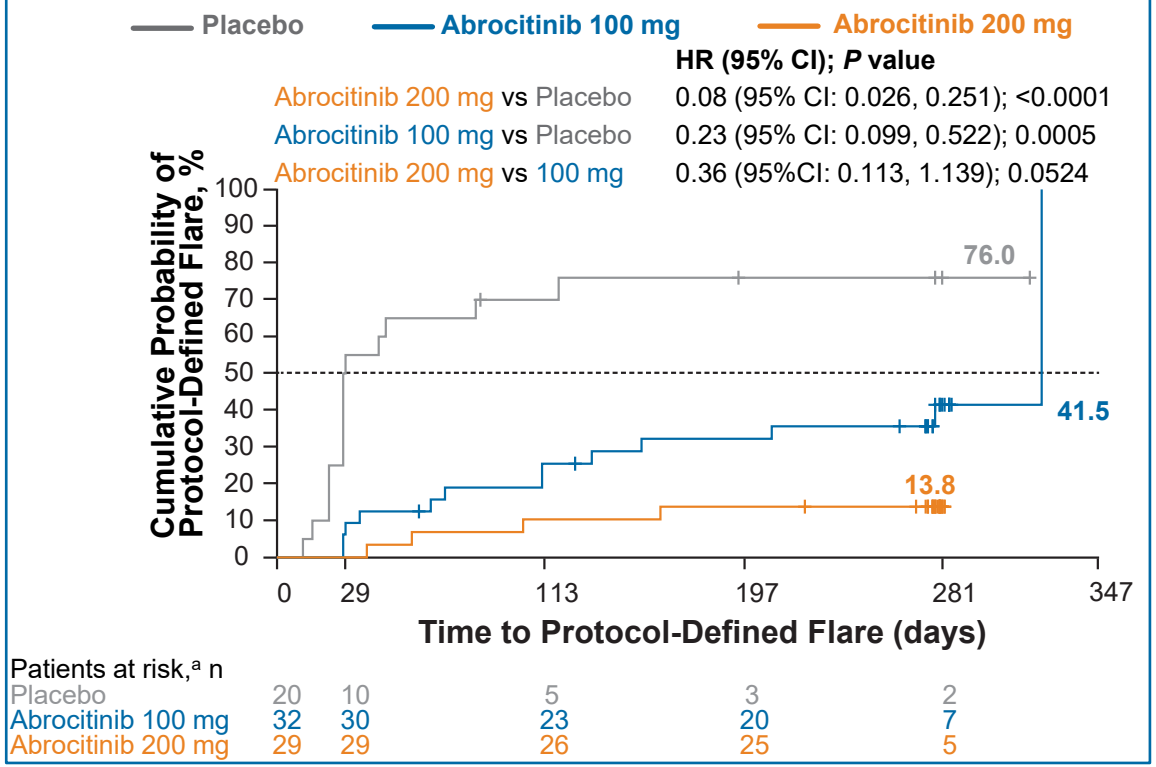
Patients and Efficacy

- Of 1233 patients treated in the induction period, 118 (10%) were from mainland China (median [IQR] age, 24 [19-31] years; severe disease at baseline, 53%)
- A total of 81 of these 118 patients (69%) responded to induction and were randomly assigned to the maintenance period
  - Median time to flare was 28.5 days (95% CI, 22-119) and 323 days (95% CI, 154-323) in the placebo and abrocitinib 100 mg treatment arms, respectively, and could not be estimated in the abrocitinib 200 mg treatment arm because too few flare events (n=4) were reported in that group
- Of those patients who experienced a protocol-defined flare and received rescue therapy, 21 of 28 (75%) recaptured EASI-75 response by week 12 of rescue

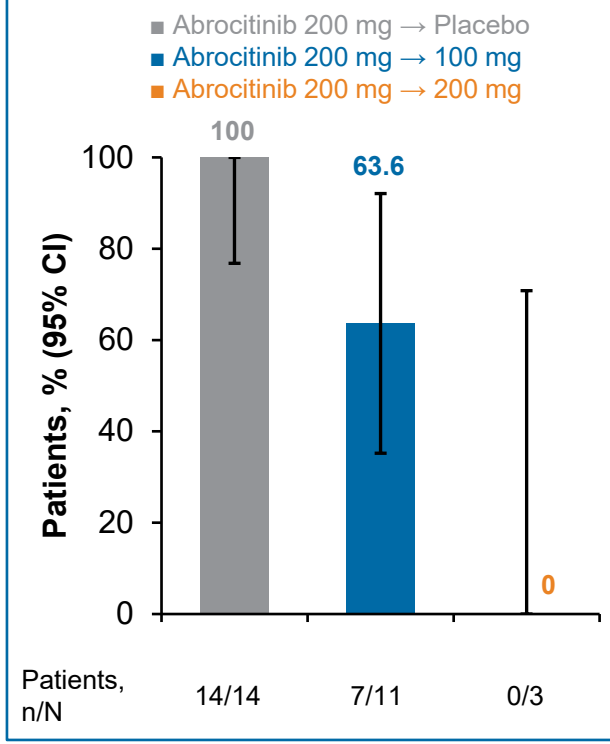
Week 12 Response
Open-Label Induction Phase



Time to Protocol-Defined Flare
Maintenance Period



Week 12 Recovery of EASI-75
Rescue Period



IQR, interquartile range. [a]Defined as patients who did not experience a flare and were continuing treatment.

Summary of Adverse Events and Conclusions

Safety Summary[a]

Patients, n (%)	Open-Label Induction Period N=118	Randomized Maintenance Period				Rescue period n=32
		All n=81	Placebo n=20	Abrocitinib 100 mg n=32	Abrocitinib 200 mg n=29	
AEs	103 (87.3)	56 (69.1)	8 (40.0)	23 (71.9)	25 (86.2)	26 (81.2)
Serious AEs	2 (1.7)	1 (1.2)	0	0	1 (3.4)	0
Severe AEs	2 (1.7)	2 (2.5)	0	1 (3.1)	1 (3.4)	1 (3.1)
AEs leading to discontinuation from study[b]	3 (2.5)	1 (1.2)	1 (5.0)	0	0	0
AEs leading to temporary discontinuation from study drug	13 (11.0)	7 (8.6)	0	2 (6.2)	5 (17.2)	4 (12.5)

Conclusions

- The results of this post hoc analysis of patients from mainland China were consistent with the overall JADE REGIMEN study population[1]
- Induction with abrocitinib 200 mg and continuous or reduced-dose maintenance with abrocitinib 200 mg or 100 mg were effective in reducing the risk of flare and rescue treatment effectively recaptured response in most patients who experienced a flare
- The safety profile of abrocitinib in Chinese patients was generally comparable with the overall JADE REGIMEN study population[1]
- Further research with larger samples is warranted

[a]Excludes events of atopic dermatitis. [b]Patients who had an AE record that indicated that the AE caused the subject to be discontinued from the study.

1. Blauvelt A et al. *J Am Acad Dermatol* 2022;86:104-112.