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

Hang Li,[1] Hao Cheng,[2] Qianjin Lu,[3] Wei Lai,[4] Xiaohua Tao,[5] Gerardo A. Encinas,[6] Shefali Vyas,[7] Bo Wang,[7] Xin Luo,[8] Shiqi Li[9]

[1]Peking University First Hospital, National Clinical Research Center for Skin and Immune Diseases, Beijing, China; [2]Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Hangzhou, China; [3]The Second Xiangya Hospital of Central South University, Changsha, China; [4]The Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China; [5]Zhejiang Provincial People's Hospital, Hangzhou Medical College, Hangzhou, China; [6]Pfizer S.A. de C.V., Mexico City, Mexico; [7]Pfizer Inc., New York, NY, USA; [8]Pfizer (China) R&D Co., Ltd, Shanghai, China; [9]Pfizer PBG, Shanghai, China

Background: In the multicenter induction, randomized withdrawal, and retreatment phase 3 JADE REGIMEN trial (NCT03627767), abrocitinib demonstrated efficacy and was well tolerated in patients with moderate-to-severe atopic dermatitis (AD).

Objective: To analyze data from Chinese patients who were enrolled in the JADE REGIMEN trial with the aim of further characterizing the efficacy and safety of abrocitinib in Chinese patients with moderate-to-severe AD.

Methods: In JADE REGIMEN, patients aged ≥12 years with moderate-to-severe AD who responded to abrocitinib 200 mg during open-label induction for 12 weeks (defined as achieving an Investigator Global Assessment score of 0 [clear] or 1 [almost clear] with a ≥2-grade improvement from baseline [IGA 0/1] and a ≥75% improvement from

baseline on the Eczema Area and Severity Index [EASI-75]), were randomly assigned 1:1:1 to blinded abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 40 weeks (maintenance period). Patients who experienced a flare in the maintenance period (defined as a ≥50% loss of initial EASI response at week 12 with a new IGA score ≥2) entered a 12-week open-label rescue period of abrocitinib 200 mg with medicated topical therapy. This analysis included data from Chinese patients enrolled in mainland China; evaluated endpoints were the probability of flare and median time to flare during the maintenance period and ≥75% improvement from rescue baseline on the EASI (recapture of EASI-75 response) at week 12 of the rescue period. Safety was assessed by adverse event monitoring.

Results: Of 1233 patients treated in the induction period, 118 were enrolled from China (median age [interquartile range, IQR], 24.0 [19.0-31.0] years; median duration since onset of AD [IQR], 8.0 [3.0-11.3] years). At week 12 of the induction period, 82 (69.5%), 83 (70.3%), 100 (84.7%), and 70 (67.3%) patients achieved IGA 0/1 and EASI-75; IGA 0/1; EASI-75; and a ≥4-point improvement from baseline in Peak Pruritus Numerical Assessment Scale (PP-NRS4; used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi), respectively, consistent with the overall JADE REGIMEN population (**Table 1**). A total of 81 (68.6%) patients were randomly assigned to the maintenance period (median age [IQR], 22.0 [18.0-30.0] years). At week 52, the probability of experiencing a flare was 13.8% (95% CI, 5.4-32.7), 41.5% (25.4-62.4) and 76.0% (55.7-91.8) in the abrocitinib 200 mg, abrocitinib 100 mg, and placebo arms, respectively. The median time to flare was 28.5 (95% CI,

22-119) days and 323 (154-323) days in the placebo and abrocitinib 100 mg treatment arms, respectively. It was not possible to estimate the median time to flare in the abrocitinib 200 mg treatment arm because too few flaring events (*n*=4) were reported in that group. At the end of the maintenance period, the proportions of Chinese patients in both abrocitinib treatment arms who maintained IGA 0/1, EASI-75, and PP-NRS4 responses achieved during induction were consistent with those observed in the overall population (**Table 1**). After 12 weeks of rescue treatment, 75% of all Chinese patients who experienced a flare recaptured EASI-75 response (**Table 1**). In the maintenance period, 86.2% and 71.9% of Chinese patients experienced adverse events in the abrocitinib 200 mg and 100 mg arms, respectively. No new safety signals were identified in patients from China compared to the overall population; there were no adjudicated malignancy events and no deaths.

Conclusions: The results of this post hoc analysis of patients from China were consistent with the overall JADE REGIMEN study population. 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 were well tolerated in Chinese patients. Rescue treatment effectively recaptured response in most patients who experienced a flare.

Keywords: abrocitinib, atopic dermatitis, China, JADE REGIMEN.

Table 1. Proportions of patients who achieved IGA 0/1, EASI-75, and PP-NRS4 during the open-label induction, maintenance, and rescue periods in JADE REGIMEN

n/N (%)	Chinese Population			Overall JADE REGIMEN Population		
	Placebo	Abrocitinib 100 mg	Abrocitinib 200 mg	Placebo	Abrocitinib 100 mg	Abrocitinib 200 mg
Open-label induction period, Week 12[a]						
IGA 0/1	NA	NA	83/118 (70.3)	NA	NA	809/1227 (65.9)
EASI-75	NA	NA	100/118 (84.7)	NA	NA	927/1227 (75.6)
IGA 0/1 and EASI-75	NA	NA	82/118 (69.5)	NA	NA	800/1227 (65.2)
PP-NRS4	NA	NA	70/104 (67.3)	NA	NA	642/940 (68.3)
Double-blinded maintenance period, Week 52[b,c]						
IGA 0/1	2/19 (10.5)	10/31 (32.3)	17/29 (58.6)	31/264 (11.7)	95/258 (36.8)	139/257 (54.1)
EASI-75	2/19 (10.5)	17/31 (54.8)	21/29 (72.4)	37/264 (14.0)	120/258 (46.5)	169/257 (65.8)
PP-NRS4	1/19 (5.3)	7/29 (24.1)	16/26 (61.5)	21/252 (8.3)	59/216 (27.3)	100/204 (49.0)
Rescue Period, Week 12[d,e,f]						
IGA 0/1	11/14 (78.6)	3/11 (27.3)	0/3 (0.0)	160/196 (81.6)	60/102 (58.8)	15/41 (36.6)
EASI-75	14/14 (100)	7/11 (63.6)	0/3 (0.0)	180/196 (91.8)	76/102 (74.5)	22/40 (55.0)
PP-NRS4	5/11 (45.5)	3/10 (30.0)	0/2 (0.0)	60/82 (73.2)	18/51 (35.3)	6/20 (30.0)

EASI-75, ≥75% improvement on the Eczema Area and Severity Index from baseline; IGA 0/1, score of 0 (clear) or 1 (almost clear) per the Investigator's Global Assessment; NA, not assessed; PP-NRS4, ≥4-point improvement in Peak Pruritus Numerical Rating Scale score.

[a]Of 1233 patients treated in the open-label induction period in JADE REGIMEN, 118 were enrolled from China.

[b]Of the population of patients from China, 29, 32, and 20 patients were randomly assigned to receive abrocitinib 200 mg, abrocitinib 100 mg, and placebo during the maintenance period, respectively.

[c]In JADE REGIMEN, 266, 265, and 267 patients were randomly assigned to receive abrocitinib 200 mg, abrocitinib 100 mg, or placebo during the maintenance period, respectively.

[d]Of the population of patients from China, 4, 13, and 15 patients who were randomly assigned to receive abrocitinib 200 mg, abrocitinib 100 mg, or placebo, respectively, during the maintenance period experienced flare and received rescue treatment.

[e]In JADE REGIMEN, 43, 104, and 204 patients who were randomly assigned to receive abrocitinib 200 mg, abrocitinib 100 mg, or placebo, respectively, during the maintenance period experienced flare and received rescue treatment.

[f]Patients received abrocitinib 200 mg plus medicated topical therapy.

Acknowledgments: This study was sponsored by Pfizer. Editorial/medical writing support under the guidance of the authors was provided by Amanda Mabhula, PhD, at Apothecom, San Francisco, CA, USA, and was funded by Pfizer Inc., New York, NY, USA, in accordance with Good Publication Practice (GPP 2022) guidelines (*Ann Intern Med*. 2022; 10.7326/M22-1460).