Flexible Dosing of Abrocitinib in Patients With Moderate-to-Severe Atopic Dermatitis: Initial Results From the Real-World–Simulating Expanded Access Protocol Study, JADE REAL

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BACKGROUND

- Atopic dermatitis (AD) is a chronic inflammatory skin disorder with a relapsing/remitting disease course necessitating long-term treatment, including systematic therapies in patients with moderate-to-severe AD[1-3]
- Abrocitinib, an oral, once-daily, Janus kinase 1 (JAK1)-selective inhibitor, is approved in patients aged ≥12 years at the recommended doses of 100 mg and 200 mg for the treatment of moderate-to-severe AD in multiple countries including the United States[4]
- JADE REAL (NCT04564755) was a global, open-label, expanded access protocol study initiated in 2020 (completed September 2024) to provide access to abrocitinib to patients with moderate-to-severe AD who did not have adequate options available for treatment at the time of enrollment
- This unique study design integrates elements from both clinical and real-world studies and may therefore simulate the real-world use of JAK inhibitors in tailored treatment regimens with temporal flexibility to manage AD

OBJECTIVE

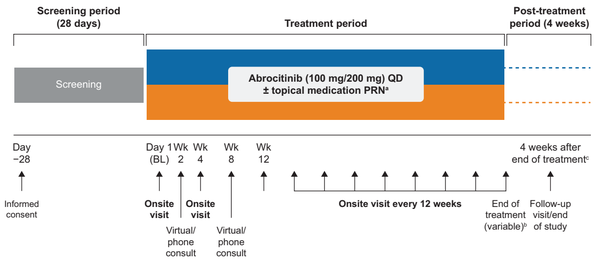
- To evaluate the dosing patterns of abrocitinib (consistent dosing vs dose escalation and reduction) and incidence of treatment-emergent adverse events (TEAEs) leading to a change in dose of abrocitinib in adolescent and adult patients with moderate-to-severe AD in an expanded access protocol simulating real-world use of abrocitinib

METHODS

Patients and Study Design

- Eligible patients aged ≥12 years with moderate-to-severe AD (Investigator's Global Assessment score of ≥3 or an Eczema Area and Severity Index score of ≥16 at baseline) were initiated on once-daily abrocitinib 100 mg or 200 mg per investigator's discretion (**Figure 1**)
  - Abrocitinib dose could be changed throughout the treatment period
  - Concomitant topical medication was used as needed

Figure 1. JADE REAL Study Design



BL, baseline; PRN, as needed; QD, once daily; Wk, week.

[a]The abrocitinib dose could be increased from 100 mg QD to 200 mg QD or decreased from 200 mg QD to 100 mg QD at the investigator's discretion pursuant to instructions in the protocol.

[b]The maximum total treatment duration for individual participants may differ, as a participant could continue to receive abrocitinib until availability of commercial product in their country or until the sponsor terminated the study in that country. Unscheduled visits could be completed at any time to assess any perceived safety issues.

[c]Participants who permanently discontinued treatment entered a 4-week post-treatment follow-up period.

Assessments

- Initial dosing and the proportion of patients with continuous dosing, ≥1 dose change, and >1 dose change were assessed
- Safety was assessed via TEAE monitoring

RESULTS

Patients

- Of the 312 patients included in the trial, 120 (38.5%) and 192 (61.5%) patients were initiated on abrocitinib 100 mg and 200 mg, respectively
  - Mean (SD) treatment duration was 379.1 days (203.3)
- More patients of ages 12 to <18 and ≥65 years, Black/African American race, and with moderate AD initiated abrocitinib 100 mg, while more patients of ages 18 to <65 years, Asian race, and with severe AD initiated abrocitinib 200 mg (**Table 1**)

Table 1. Patient Demographics by Initial Abrocitinib Dose

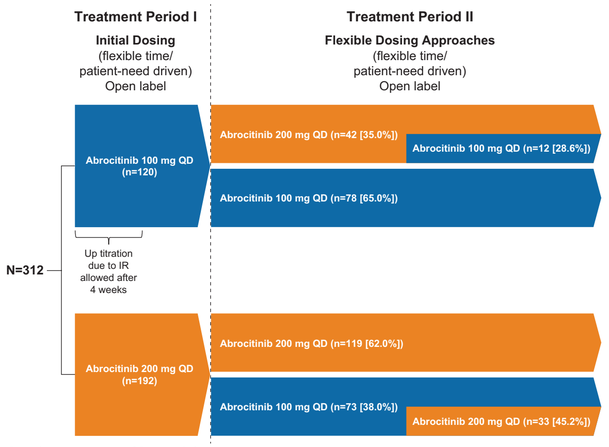
	Abrocitinib 100 mg n=120	Abrocitinib 200 mg n=192
Age, n (%), years		
12 to <18	20 (16.7)	13 (6.8)
18 to <65	81 (67.5)	164 (85.4)
≥65	19 (15.8)	15 (7.8)
Age, mean (SD), years	38.8 (19.6)	37.5 (17.8)
Sex, n (%)		
Male	56 (46.7)	111 (57.8)
Female	64 (53.3)	81 (42.2)
Race, n (%)		
Asian	10 (8.3)	34 (17.7)
Black or African American	24 (20.0)	19 (9.9)
White	82 (68.3)	135 (70.3)
Other[a]	4 (3.3)	4 (2.1)
Ethnicity, n (%)		
Hispanic or Latino	15 (12.5)	28 (14.6)
Not Hispanic or Latino	97 (80.8)	164 (85.4)
Not reported	8 (6.7)	0

AD, atopic dermatitis.

[a]Other includes Native Hawaiian or Other Pacific Islander, Multiracial, and race not reported.

- Of patients initiated on abrocitinib 100 mg and 200 mg, 78 (65.0%) and 119 (62.0%) received continuous dosing, and 42 (35.0%) and 73 (38.0%) patients had ≥1 dose change, including 12 (28.6%) and 33 (45.2%) patients with >1 dose change, respectively (**Figure 2**)

Figure 2. Flexible Dosing in JADE REAL



IR, inadequate response; QD, once daily.

Safety

- TEAEs led to dose reduction in 27 patients and dose escalation in 12 patients (**Table 2**)
  - TEAEs occurring in ≥1% of patients that led to dose reduction included nausea, thrombocytopenia, acne, fatigue, and folliculitis
  - AD was the only TEAE that occurred in ≥1% of patients which led to a dose escalation

Table 2. Treatment-Emergent Adverse Events Leading to Abrocitinib Dose Change

n (%)	Abrocitinib 100 mg or 200 mg QD N=312
TEAEs leading to a dose reduction occurring in ≥1% of patients	
Any TEAE	27 (8.7)
Nausea	4 (1.3)
Thrombocytopenia	4 (1.3)
Acne	3 (1.0)
Fatigue	3 (1.0)
Folliculitis	3 (1.0)
TEAEs leading to a dose increase occurring in ≥1% of patients	
Any TEAE	12 (3.8)
AD	10 (3.2)

AD, atopic dermatitis; QD, once-daily; TEAE, treatment-emergent adverse event.

Patients were only counted once per treatment per event.

Includes data up to 28 days after last dose of study drug.

CONCLUSIONS

- Most patients remained on a consistent abrocitinib dose throughout the study
- TEAEs were not the primary reason leading to dose reduction
- These results may support clinical decision-making around initial dose selection and dose changes
- JADE REAL demonstrated the potential benefits of flexible dosing and may simulate the real-world use of oral Janus kinase inhibitors

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