Patients With Moderate-to-Severe Atopic Dermatitis Maintained Depth of Response Up to 2 Years With Continuous Abrocitinib Treatment

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BACKGROUND

- Atopic dermatitis (AD) is a chronic, inflammatory skin condition characterized by eczematous skin lesions, intense itch, and impaired quality of life[1,2]
- Patients with moderate-to-severe AD receiving systemic treatments experience a longitudinal disease course with fluctuating severity and recurrent flares over time[3,4]
  - Static efficacy assessments at specific clinical trial time points may not accurately capture the dynamic nature of the disease, which includes recurrent flares and substantial disease burden during these flares
  - There are still unmet needs in clinical practice for AD treatments that provide long-term disease control and improve quality of life for patients
- Abrocitinib is an oral, once-daily, selective Janus kinase (JAK) 1 inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD[5-7]
  - Maintenance treatment with abrocitinib (200 and 100 mg) has been shown to prevent the occurence of flares for up to 40 weeks[8-10]

OBJECTIVE

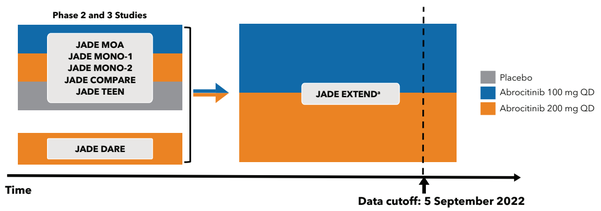
- To assess the frequency and severity of breakthrough disease activity in patients with moderate-to-severe AD receiving continuous, long-term abrocitinib treatment for up to 112 weeks

METHODS

Study Design

- Data were included from patients who participated in the phase 2 JADE MOA (NCT03915496) and phase 3 JADE MONO-1 (NCT03349060), MONO-2 (NCT03575871), COMPARE (NCT03720470), TEEN (NCT03796676), and DARE (NCT04345367) trials and subsequently enrolled in the ongoing long-term extension study, JADE EXTEND (NCT03422822) (**Figure 1**)
- In the parent trials, patients were randomly assigned to abrocitinib (200 or 100 mg) or placebo once daily, as monotherapy or in combination with topical therapy
  - All patients received abrocitinib (200 or 100 mg) in JADE EXTEND
  - If patients received placebo in the qualifying phase 3 trials, they received their first abrocitinib dose in JADE EXTEND
- Patients were included if they had achieved response criteria of Investigator's Global Assessment score of 0 (clear) or 1 (almost clear) with ≥2 points improvement from baseline (IGA 0/1) or ≥75% improvement from baseline in the Eczema Area and Severity Index (EASI-75) at Week 16 of abrocitinib treatment

Figure 1. Study Design



QD, once daily.
[a]JADE EXTEND is an ongoing trial, and not all patients had reached Week 112 visits as of the clinical data cutoff.

Assessments and Statistical Analysis

- Clinical data cutoff for JADE EXTEND was 5 September 2022
- Baseline was defined as the baseline visit from the relevant parent study
- All visits represent time since first abrocitinib dose
- The proportion of patients in the long-term efficacy pool who maintained response for the following outcomes to 112 weeks at 80% and 100% of visits (ie, without excursion) were assessed:
  - EASI-75/-90
  - ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale (PP-NRS4; used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi)
  - PP-NRS score of 0 or 1 (PP-NRS 0/1)
  - ≥4-point improvement from baseline in Dermatology Life Quality Index (DLQI-4)
  - ≥6-point improvement from baseline in Children's Dermatology Life Quality Index (CDLQI-6)
- Data are reported with nonresponder imputation after study discontinuation for any reason

RESULTS

Patients

- A total of 663 patients in the abrocitinib 200-mg arm and 361 patients in the 100-mg arm met the response criteria at Week 16
- Baseline demographics and clinical characteristics are shown in **Table 1**

Table 1. Baseline Demographics and Clinical Characteristics

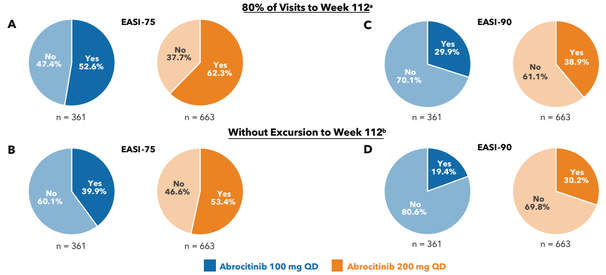
	Abrocitinib 200 mg QD n=663	Abrocitinib 100 mg QD n=361	Total N=1024
Age, mean (SD), years	34.3 (15.5)	33.2 (17.1)	33.9 (16.1)
Sex, n (%)			
Male	353 (53.2)	181 (50.1)	534 (52.1)
Female	310 (46.8)	180 (49.9)	490 (47.9)
Race, n (%)			
American Indian or Alaska Native	4 (0.6)	1 (0.3)	5 (0.5)
Asian	155 (23.4)	81 (22.4)	236 (23.0)
Black or African American	25 (3.8)	28 (7.8)	53 (5.2)
Native Hawaiian or Other Pacific Islander	4 (0.6)	0	4 (0.4)
Multiracial	8 (1.2)	2 (0.6)	10 (1.0)
White	461 (69.5)	248 (68.7)	709 (69.2)
Not reported	6 (0.9)	1 (0.3)	7 (0.7)
Ethnicity, n (%)			
Hispanic or Latino	59 (8.9)	45 (12.5)	104 (10.2)
Not Hispanic or Latino	602 (90.8)	308 (85.3)	910 (88.9)
Not reported	2 (0.3)	8 (2.2)	10 (1.0)
Duration of disease, mean (SD), years	22.4 (15.0)	20.2 (15.9)	21.6 (15.3)
IGA at baseline, n (%)			
3, moderate	420 (63.3)	236 (65.4)	656 (64.1)
4, severe	243 (36.7)	125 (34.6)	368 (35.9)
EASI at baseline, mean (SD)	28.9 (12.1)	28.5 (12.0)	28.8 (12.1)
PP-NRS at baseline, mean (SD)	7.3 (1.7)	7.1 (1.7)	7.2 (1.7)
DLQI at baseline, mean (SD)[a]	14.8 (6.6)	15.3 (6.6)	14.9 (6.6)
CDLQI at baseline, mean (SD)[b]	13.3 (6.2)	13.9 (6.3)	13.6 (6.2)

CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily.
[a]Abrocitinib 200 mg, n=560; abrocitinib 100 mg, n=256; total, n=816.
[b]Abrocitinib 200 mg, n=91; abrocitinib 100 mg, n=92; total, n=183.

Maintenance of Skin Clearance Response With Long-Term Abrocitinib Treatment

- Substantial proportions (≥53%) of patients who received abrocitinib 200 or 100 mg maintained EASI-75 response at 80% of visits, and ≥40% of patients maintained EASI-75 without excursion (ie, at 100% of visits after Week 16) to Week 112 (**Figure 2**)
- Furthermore, one-third of patients (≥30%) maintained the high-threshold response, EASI-90, for 80% of their visits through Week 112 with either dose of abrocitinib (**Figure 2**)

Figure 2. Proportion of Patients Maintaining EASI-75 and EASI-90 Response at 80% of Visits[a] and Without Excursion[a] to Week 112[b]

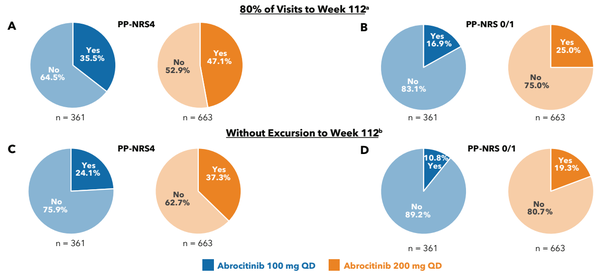


EASI-75/90, ≥75/90% improvement from baseline in Eczema Area and Severity Index; QD, once daily.
Data are reported with nonresponder imputation after study discontinuation for any reason.
JADE EXTEND is an ongoing trial, and not all patients had reached Week 112 visits at the clinical data cutoff date (5 September 2022).
[a]Patients maintained response at 80% of visits up to Week 112 of abrocitinib treatment or until the data cutoff date, whichever was earlier.
[b]Patients maintained response at 100% of visits up to Week 112 of abrocitinib treatment or until the data cutoff date, whichever was earlier.

Maintenance of Itch Relief Response With Long-Term Abrocitinib Treatment

- Over one-third of patients (≥35%) maintained PP-NRS response for 80% of visits with either abrocitinib dose, while ≥24% maintained response without excursion up to Week 112 (**Figure 3**)
- The high-threshold response, PP-NRS 0/1, was maintained for 80% of visits through Week 112 in 16.9% of patients receiving abrocitinib 100 mg and 25.0% receiving abrocitinib 200 mg (**Figure 3**)

Figure 3. Proportion of Patients Maintaining PP-NRS4 and PP-NRS 0/1 Response at 80% of Visits[a] and Without Excursion to Week 112[b]



PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 or 1; PP-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; QD, once daily.
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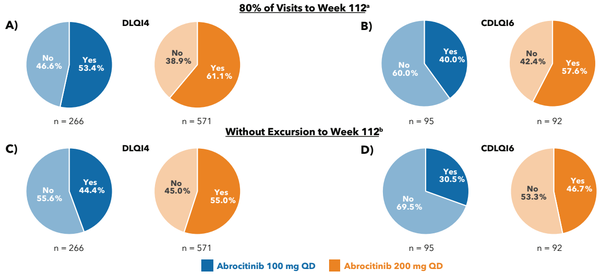
[a]Patients maintained response at 80% of visits up to Week 112 of abrocitinib treatment or until the data cutoff date, whichever was earlier.
[b]Patients maintained response at 100% of visits up to Week 112 of abrocitinib treatment or until the data cutoff date, whichever was earlier.

Maintenance of Quality-Of-Life Response With Long-Term Abrocitinib Treatment

- Over half of adult patients (≥53%) treated with abrocitinib at 100 or 200 mg maintained their DLQI4 response for 80% of visits over 112 weeks of continuous treatment, and ≥44% maintained a DLQI4 for all visits over 112 weeks (**Figure 4**)
- More than 40% of adolescents treated with abrocitinib 100 or 200 mg maintained their CDLQI6 response for 80% of visits over 112 weeks of continuous treatment

Figure 4. Proportion of Patients Maintaining DLQI4 or CDLQI Response at 80% of Visits[a] and Without Excursion to Week 112[b]



CDLQI6, ≥6-point improvement from baseline in Children's Dermatology Life Quality Index ; DLQI4, ≥4-point improvement from baseline in Dermatology Life Quality Index; QD, once daily.
Data are reported with nonresponder imputation after study discontinuation for any reason.
JADE EXTEND is an ongoing trial and not all patients had reached Week 112 visits at the clinical data cut-off date (5 September 2022).
[a]Patients maintained response at 80% of visits up to Week 112 of abrocitinib treatment or until the data cutoff date, whichever was earlier.
[b]Patients maintained response at 100% of visits up to Week 112 of abrocitinib treatment or until the data cutoff date, whichever was earlier.

CONCLUSIONS

- Patients with moderate-to-severe AD achieved and maintained depth of response for skin improvement, itch relief, and quality of life up to 112 weeks with continuous abrocitinib 200 or 100 mg treatment
- Most patients experienced infrequent breakthrough flare activity with continuous treatment up to 112 weeks
- These findings further support the ability of abrocitinib to provide adult and adolescent patients with moderate-to-severe AD with sustained disease control for up to 2 years

REFERENCES

1. Langan SM et al. *Lancet*. 2020;396(10247):345-360.
2. Guttman-Yassky E et al. *Lancet*. 2025;405(10478):583-596.
3. Wei W et al. *Ann Allergy Asthma Immunol*. 2019;123(4):381-388.e2.
4. Hong MR et al. *Ann Allergy Asthma Immunol*. 2020;125(6):686-692.e3.
5. Cibinqo (abrocitinib). Summary of product characteristics. Pfizer Europe MA EEIG; December 2021. https://www.ema.europa.eu/en/documents/product-information/cibinqo-epar-product-information_en.pdf
6. Pfizer Inc. Cibinqo (abrocitinib). Prescribing information. Pfizer Inc; December 2023. https://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=16652
7. Pfizer Limited. Cibinqo 100 mg film-coated tablets (summary of product characteristics). Kent: Pfizer, Limited; 2021.
8. Blauvelt A et al. *J Am Acad Dermatol*. 2022;86(1):104-112.
9. Flohr C et al. *J Dermatol Treat*. 2023;34(1):2200866.
10. Thyssen JP et al. *J Eur Acad Dermatol Venereol*. 2024;38 (11): 2130-2138. .

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