Durability of Response After Pausing Abrocitinib Treatment in Patients With Moderate-to-Severe Atopic Dermatitis

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BACKGROUND

- Atopic dermatitis (AD) is a common, chronic, inflammatory skin disorder that is characterized by recurrent eczematous skin lesions and pruritus with heterogenous skin manifestations, symptoms, and severity[1,2]
  - The heterogeneous nature of AD necessitates flexibility in tailoring treatment regimens to manage changes in the signs and symptoms of AD over time
- 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[3-5]
- In the phase 3 trial JADE REGIMEN (NCT03627767), patients who achieved an initial response with abrocitinib 200 mg in the induction period were then randomly assigned to receive maintenance treatment with abrocitinib 200 mg, 100 mg, or placebo (treatment withdrawal) for 40 weeks[6]
  - Most of these initial responders who were randomized to either abrocitinib 200 mg or 100 mg maintained their responses over 40 weeks follow-up
  - Among the 267 patients who initially responded and then received placebo, 76.4% flared and received rescue therapy for 12 weeks; at week 12 of rescue, 91.8% recaptured EASI-75 response
- Long-term follow-up is needed to understand how flexibility in abrocitinib treatment, particularly dose pausing, affects outcomes

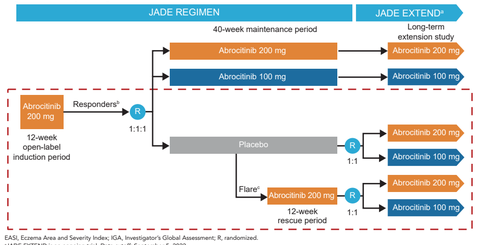
OBJECTIVE

- To assess durability of response after treatment interruption in patients with moderate-to-severe AD receiving abrocitinib

METHODS

- This analysis included patients from JADE REGIMEN who received abrocitinib 200 mg for 12 weeks, were responders (defined as Investigator's Global Assessment [IGA] score of 0/1 with ≥2-point reduction from baseline and ≥75% improvement from baseline in Eczema Area and Severity Index [EASI-75]), and then received placebo for 40 weeks (**Figure 1**)
  - In case of flare (defined as ≥50% loss of initial EASI response at Week 12 with a new IGA score ≥2), patients restarted abrocitinib as rescue therapy (abrocitinib 200 mg plus topical therapy) for 12 weeks
- Patients then entered the ongoing long-term extension study, JADE EXTEND (NCT03422822, data cutoff: September 5, 2022), and were randomly assigned to abrocitinib 200 mg or 100 mg, with topical therapies permitted if needed[7]
- Assessments included EASI-75, ≥90% improvement from baseline in EASI (EASI-90), Peak Pruritus Numerical Rating Score of 0 or 1 (PP-NRS 0/1) and the composite endpoint EASI-90+PP-NRS 0/1
- All data are reported as observed

Figure 1. Study Design and Cohorts



EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; R, randomized.
[a]JADE EXTEND is an ongoing trial. Data cutoff: September 5, 2022.
[b]Patients who achieved an IGA score of 0 (clear) or 1 (almost clear) with a ≥2-grade improvement from baseline and ≥75% improvement from baseline in EASI after 12 weeks of treatment with abrocitinib 200 mg.
[c]Patients who experienced a flare (≥50% loss of week 12 EASI response and new IGA score ≥2) during the maintenance period of JADE REGIMEN entered a 12-week open-label rescue period (abrocitinib 200 mg + topical medicated treatment).

RESULTS

Patient Populations

- Overall, this analysis included 234 patients who received placebo in JADE REGIMEN (ie, withdrawn from abrocitinib) and subsequently entered JADE EXTEND (**Table 1**)
  - Of these patients receiving placebo, 42 (18%) did not have flares for 40 weeks and then received abrocitinib 200 mg (n=16) and 100 mg (n=26) in EXTEND
  - The remaining 192 patients experienced a flare while receiving placebo and were treated with rescue therapy: 49 and 143 received abrocitinib 200 mg and 100 mg, respectively, in EXTEND

Table 1. Baseline Characteristics[a]

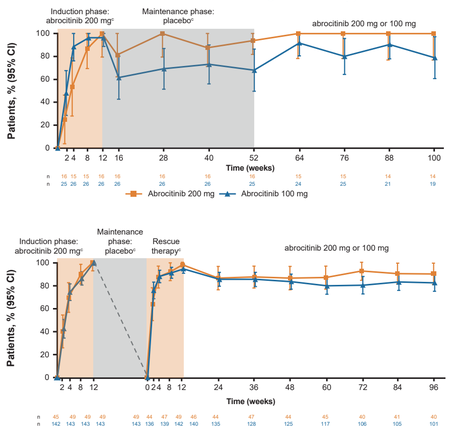
Treatment in JADE REGIMEN:	Received Placebo Without Flare (N=42)		Received Placebo and Required Rescue Therapy (N=192)	
Treatment in JADE EXTEND:	Abrocitinib 200 mg (N=16)	Abrocitinib 100 mg (N=26)	Abrocitinib 200 mg (N=49)	Abrocitinib 100 mg (N=143)
Age, years				
mean (SD)	32.9 (14.5)	29.2 (13.0)	31.4 (14.6)	32.5 (14.0)
<18, n (%)	2 (12.5)	4 (15.4)	11 (22.4)	19 (13.3)
18 to <65, n (%)	13 (81.3)	22 (84.6)	37 (75.5)	120 (83.9)
≥65, n (%)	1 (6.3)	0 (0.0)	1 (2.0)	4 (2.8)
Sex, n (%)				
Male	10 (62.5)	12 (46.2)	31 (63.3)	72 (50.3)
Female	6 (37.5)	14 (53.8)	18 (36.7)	71 (49.7)
Race, n (%)				
White	14 (87.5)	24 (92.3)	35 (71.4)	114 (79.7)
Black or African American	1 (6.3)	1 (3.8)	2 (4.1)	8 (5.6)
Asian	1 (6.3)	1 (3.8)	9 (18.4)	20 (14.0)
EASI, mean (SD)	33.3 (15.3)	29.4 (11.6)	31.1 (15.5)	30.1 (10.9)
% BSA, mean (SD)	48.8 (22.1)	43.5 (20.2)	46.9 (23.9)	47.2 (19.2)
PP-NRS, mean (SD)	7.7 (1.3)	7.3 (1.7)	7.2 (1.8)	7.4 (1.8)
SCORAD, mean (SD)	69.2 (12.6)	65.9 (11.0)	68.9 (14.0)	66.7 (13.1)
IGA, n (%)				
3, moderate	9 (56.3)	19 (73.1)	30 (61.2)	94 (65.7)
4, severe	7 (43.8)	7 (26.9)	19 (38.8)	49 (34.3)

% BSA, percentage of body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Score; SCORAD, SCORing Atopic Dermatitis.
[a]Patient subgroups were defined by the treatment journey through both JADE REGIMEN and JADE EXTEND; please see **Figure 1** for more detail.

Skin Clearance

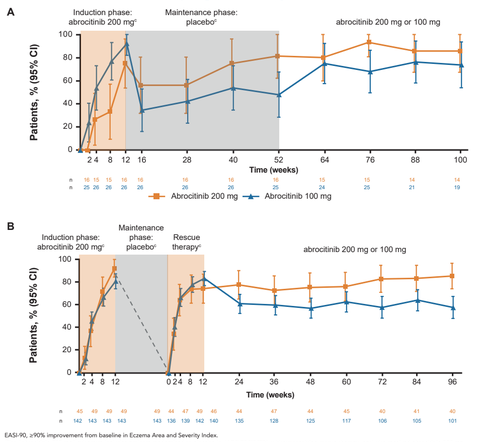
- The majority of patients who did not flare while receiving placebo for 40 weeks maintained EASI-75 response at last assessment on placebo (**Figure 2A**)
  - At week 100, 100% (14/14) and 78.9% (15/19) of patients achieved EASI-75 with abrocitinib 200 mg and 100 mg, respectively
- At last assessment on placebo, 81.3% (13/16) and 48.0% (12/25) of flare-free patients in the abrocitinib 200 mg/100 mg groups, respectively, achieved EASI-90 response (**Figure 3A**)
  - At week 100, the majority of patients achieved EASI-90 with either abrocitinib dose
- Among patients who experienced a flare at any point during the placebo period, response was quickly recaptured after 12 weeks of rescue therapy (**Figure 2B**)
  - At week 96 since initiating rescue therapy, 90.0% (36/40) and 82.2% (83/100) achieved EASI-75 with abrocitinib 200 mg and 100 mg, respectively
- Among patients who flared, a greater proportion of patients achieved EASI-90 with abrocitinib 200 mg than 100 mg at week 96 since initiating rescue therapy (**Figure 3B**)

Figure 2. Proportion of patients achieving EASI-75 among patients who paused abrocitinib treatment, A) without flare[a] or B) requiring rescue therapy[b]



EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index.
[a]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 100 mg in JADE EXTEND. [b]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 100 mg in JADE EXTEND. All patients in this analysis received abrocitinib 200 mg during the induction phase and placebo during the maintenance phase of JADE REGIMEN. In case of flare, patients received abrocitinib 200 mg plus topic therapy as rescue therapy.

Figure 3. Proportion of patients achieving EASI-90 among patients who paused abrocitinib treatment, A) without flare[a] or B) requiring rescue therapy[b]

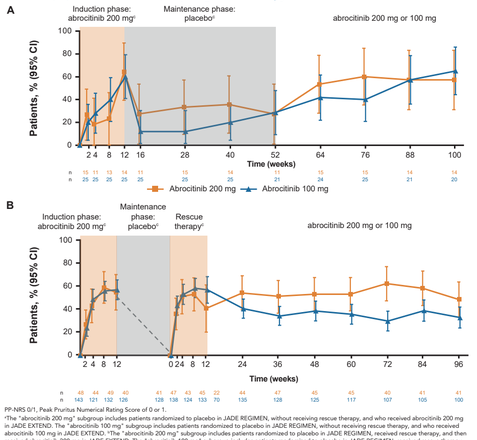


EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index.
[a]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 100 mg in JADE EXTEND. [b]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 100 mg in JADE EXTEND. All patients in this analysis received abrocitinib 200 mg during the induction phase and placebo during the maintenance phase of JADE REGIMEN. In case of flare, patients received abrocitinib 200 mg plus topic therapy as rescue therapy.

Itch-Free State

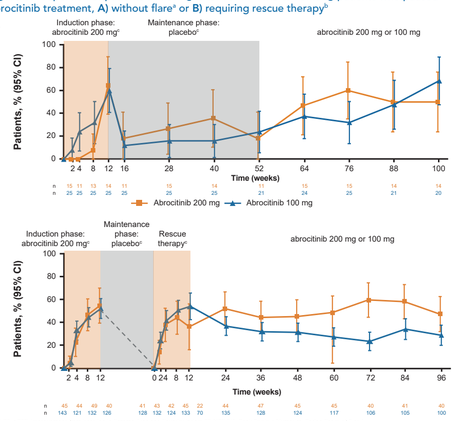
- Large proportions of patients achieved PP-NRS 0/1 (ie. an itch-free state), after reinitiating abrocitinib at either dose (**Figure 4**)
- Similarly, notable proportions of patients achieved the composite endpoint EASI-90+PP-NRS 0/1 (ie. skin clearance and an itch-free state) (**Figure 5**)

Figure 4. Proportion of patients achieving PP-NRS 0/1 among patients who paused abrocitinib treatment, A) without flare[a] or B) requiring rescue therapy[b]



PP-NRS 0/1, Peak Pruritus Numerical Rating Score of 0 or 1.
[a]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 100 mg in JADE EXTEND. [b]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 100 mg in JADE EXTEND. All patients in this analysis received abrocitinib 200 mg during the induction phase and placebo during the maintenance phase of JADE REGIMEN. In case of flare, patients received abrocitinib 200 mg plus topic therapy as rescue therapy.

Figure 5. Proportion of patients achieving EASI-90+PP-NRS 0/1 among patients who paused abrocitinib treatment, A) without flare[a] or B) requiring rescue therapy[b]



EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Score of 0 or 1.
[a]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, without receiving rescue therapy, and who received abrocitinib 100 mg in JADE EXTEND. [b]The "abrocitinib 200 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 200 mg in JADE EXTEND. The "abrocitinib 100 mg" subgroup includes patients randomized to placebo in JADE REGIMEN, received rescue therapy, and then received abrocitinib 100 mg in JADE EXTEND. All patients in this analysis received abrocitinib 200 mg during the induction phase and placebo during the maintenance phase of JADE REGIMEN. In case of flare, patients received abrocitinib 200 mg plus topic therapy as rescue therapy.

LIMITATIONS

- The subgroup of patients randomized to placebo who did not flare was small
- Sample sizes between subgroups in this posthoc analysis were not equivalent

CONCLUSIONS

- For some patients receiving abrocitinib, treatment may be interrupted without experiencing a loss of response
- In case of flare, restarting abrocitinib is an effective, fast rescue therapy
- Restarting abrocitinib treatment showed good response at 200 or 100 mg, although response rates were numerically higher with abrocitinib 200 mg

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DISCLOSURES

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