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Long-Term Efficacy of Abrocitinib Down-Titration in Patients With Moderate-to-Severe Atopic Dermatitis

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Disclosures: S. Weidinger is a speaker, advisory board member, and/or investigator for AbbVie, Almirall, Boehringer Ingelheim, Eli Lilly and Company, Galderma, GSK, LEO Pharma, Pfizer, Regeneron, and Sanofi; and has received institutional research grants from LEO Pharma, Pfizer, and Sanofi. **B.S. Kim** is a consultant and advisor for Pfizer Inc., AbbVie, Boehringer Ingelheim, Cara Therapeutics, Kiniksa, VYNE Therapeutics, and Sanofi Regeneron; has received research grants from Cara Therapeutics, Celgene, and LEO Pharma; and is a founder of and stockholder in Nuogen Pharma. **H. Murota** was a speaker and/or consultant and/or investigator for Maruho, Sanofi, Regeneron, Kyowa Kirin, Amgen, AbbVie, Eli Lilly, LEO Pharma, Pfizer, Torii, Kao, Shiseido, and Daiichi Sankyo Health Care. **Y. Koike** has received institutional research grants from Pfizer and LEO Pharma; has lectured at educational events sponsored by AbbVie, LEO Pharma, Novartis, Bristol Myers Squibb, Sun Pharma, Eli Lilly, Amgen, Kyowa Kirin, and UCB; and has participated in clinical trials sponsored by multiple pharmaceutical companies that manufacture drugs used for the treatment of inflammatory skin diseases**. I. Lazariciu** is an employee of IQVIA, which was a paid contractor to Pfizer Inc. in the development of this poster and in providing statistical support. **G. Encinas, M. Watkins, and H. Koppensteiner** are employees and shareholders of Pfizer. This study was funded by Pfizer.

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Background and Objective

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 allows for flexible 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 JADE REGIMEN trial (NCT03627767), patients who achieved an initial response[a] with abrocitinib 200 mg in the open-label induction period were randomized to receive maintenance treatment with abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 40 weeks[6]
  - Most Week 12 responders who were randomized to receive either abrocitinib 200 mg or 100 mg maintained their responses over the 40-week follow-up period
- Longer-term follow-up is needed to understand how flexibility in abrocitinib treatment, particularly dose reduction, affects outcomes

Objective

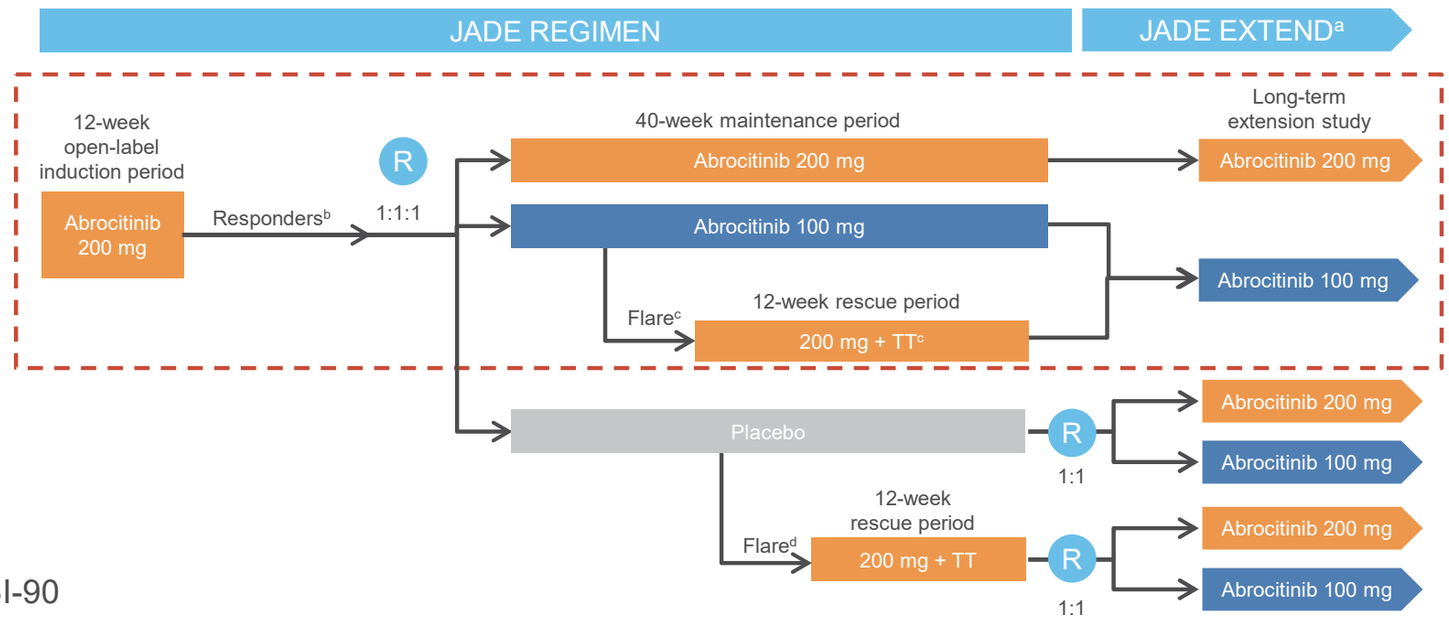
- To assess the long-term durability of response in patients with moderate-to-severe AD who received abrocitinib 100 mg after initial response to 200 mg

EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA 0/1, IGA, Investigator's Global Assessment score of 0 or 1.
[a]Response was defined as IGA 0/1 response (with ≥2-grade improvement) and EASI-75 response.
1. Weidinger S, et al. *Lancet.* 2016;387:1109-1122. 2. Abuabara K, et al. *Allergy.* 2018;73:696-704. 3. Cibinqo (abrocitinib). Summary of product characteristics. Pfizer, Ltd; 2025. 4. European Medicines Agency. Cibinqo (abrocitinib). Summary of product characteristics. Pfizer Europe MA EEIG; 2024. 5. Cibinqo (abrocitinib). Prescribing information. Pfizer Inc.; 2023. 6. Blauvelt A, et al. *J Am Acad Dermatol.* 2022;86:104-112.

Study Design, Assessments, and Patient Populations

Study Design

- In JADE REGIMEN, patients received abrocitinib 200 mg for a 12-week induction[1]
- Patients who were initial responders[b] were randomized to abrocitinib (200 or 100 mg) or placebo for 40 weeks, with rescue therapy (abrocitinib 200 mg plus topical therapy for 12 weeks) for protocol-defined flares,[d] before entering an ongoing long-term extension study (JADE EXTEND)[a] and continuing the dose from JADE REGIMEN[1,2]



Assessments

- Assessments included achievement of EASI-75 and EASI-90
- Nonresponder imputation was applied for missing data in JADE REGIMEN. Patients withdrawn from the study were counted as nonresponders after discontinuation. No imputation was performed for JADE EXTEND; data were reported as observed

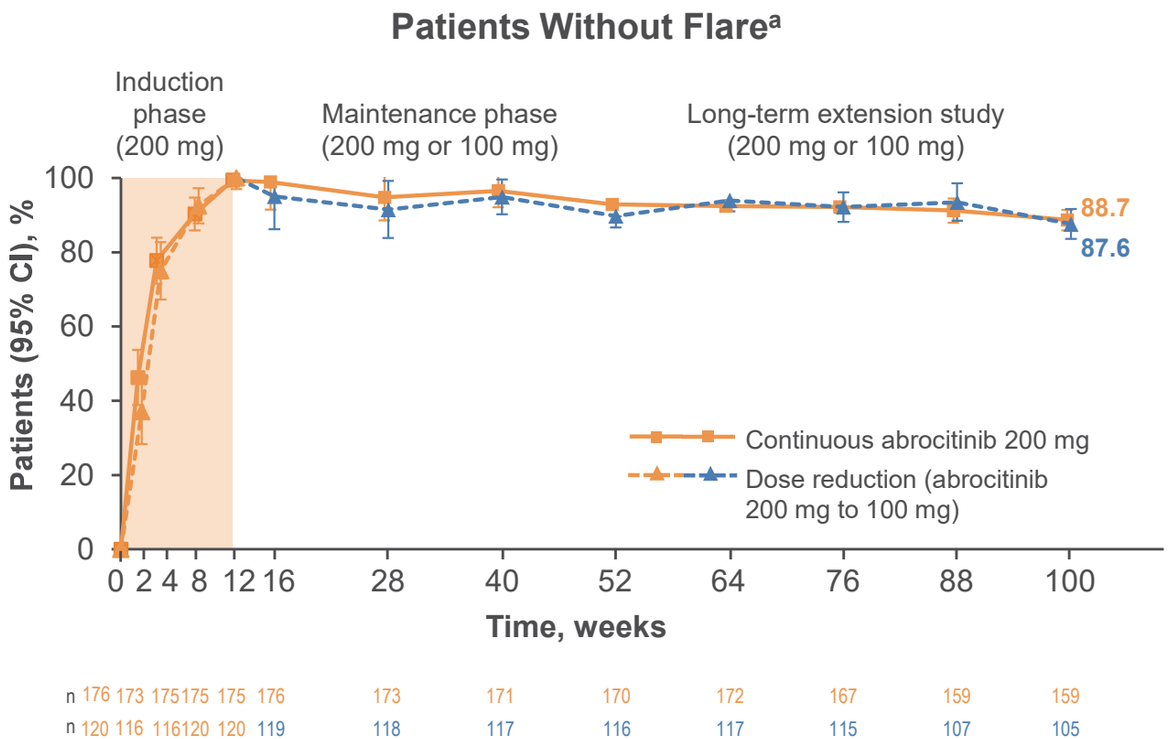
Patient Populations

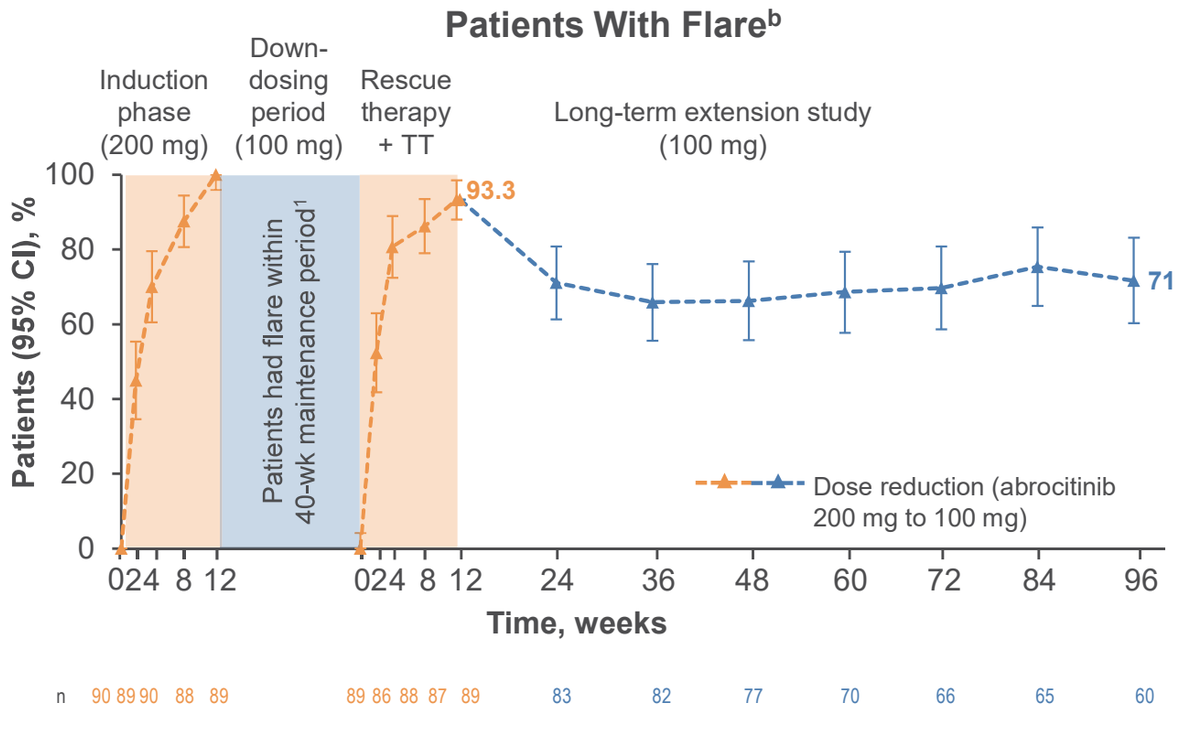
- Among patients who responded to abrocitinib 200 mg at Week 12 and entered JADE EXTEND, 176 continued to receive abrocitinib 200 mg through the maintenance period and the extension study, and 210 received abrocitinib 100 mg
- Of the 210 patients receiving abrocitinib 100 mg, 120 (57.1%) had no flares for 40 weeks, while 90 (42.9%) required rescue therapy before resuming abrocitinib 100 mg during the long-term extension study

EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; R, randomized; TT, topical therapy.
ClinicalTrials.gov Identifiers: NCT03627767 (JADE REGIMEN); NCT03422822 (JADE EXTEND).
[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 EASI-75 after 12 weeks of treatment with abrocitinib 200 mg. [c]Topical therapy included topical corticosteroids of any potency, calcineurin inhibitors, and topical PDE4 inhibitors. [d]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).
1. Blauvelt A, et al. *J Am Acad Dermatol.* 2022;86:104-112. 2. Reich K, et al. *J Eur Acad Dermatol Venereol.* 2023;37:2056-2066.

EASI-75 Response Was Maintained After Down-Titration

- EASI-75 response after the open-label induction period was maintained up to Week 100 in patients without flare,[a] including most patients receiving 200-mg continuous dose (89%) and patients without flare receiving abrocitinib 100 mg (88%)
- After 12 weeks of abrocitinib 200 mg + TT rescue therapy, 93% of patients with flare[b] achieved EASI-75 response; after resuming abrocitinib 100 mg, 72% maintained response at Week 96 post flare



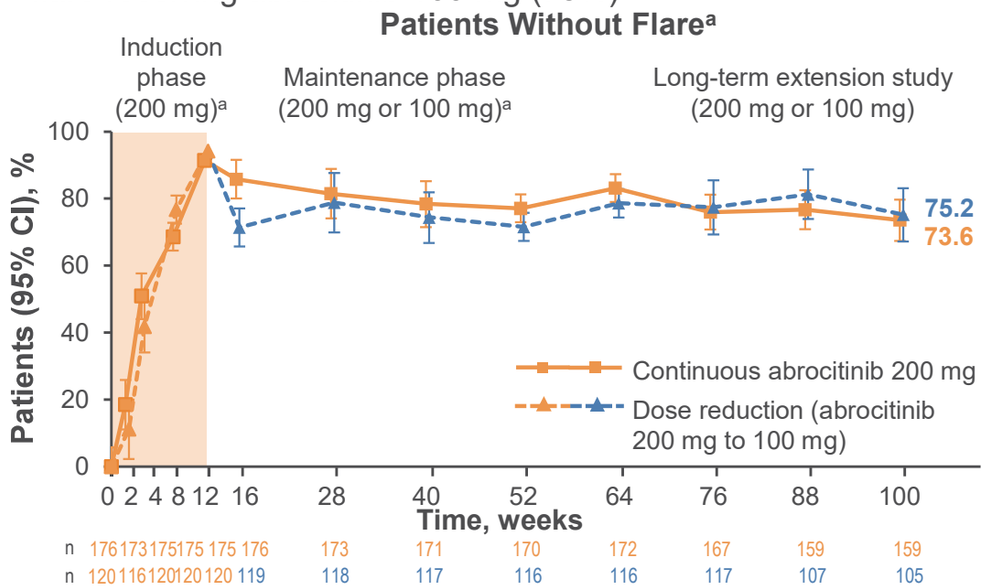


EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; TT, topical therapy.
Nonresponder imputation was applied for missing data in JADE REGIMEN; patients withdrawn from the study were counted as nonresponders after discontinuation. No imputation was performed for JADE EXTEND.
[a]The nonflaring cohort received abrocitinib 200 mg during the induction phase of JADE REGIMEN, were considered responders (achieved IGA 0/1 response with ≥2-grade improvement and EASI-75 response), and were randomized to receive abrocitinib 200 mg or 100 mg during the 40-week maintenance phase. Patients did not experience flare during the maintenance period and continued on the same dose into JADE EXTEND. [b]The flaring cohort included patients who received abrocitinib 200 mg during the induction phase of JADE REGIMEN, were considered responders (achieved IGA 0/1 response with ≥2-grade improvement and EASI-75 response). and were randomized to receive abrocitinib 100 mg during the 40-week maintenance phase (down dosing). These patients experienced flare (had ≥50% loss of Week 12 EASI response and new IGA score ≥2) and received rescue therapy (abrocitinib 200 mg plus topical therapy) for 12 weeks. Subsequently, they received abrocitinib 100 mg once daily in JADE EXTEND.

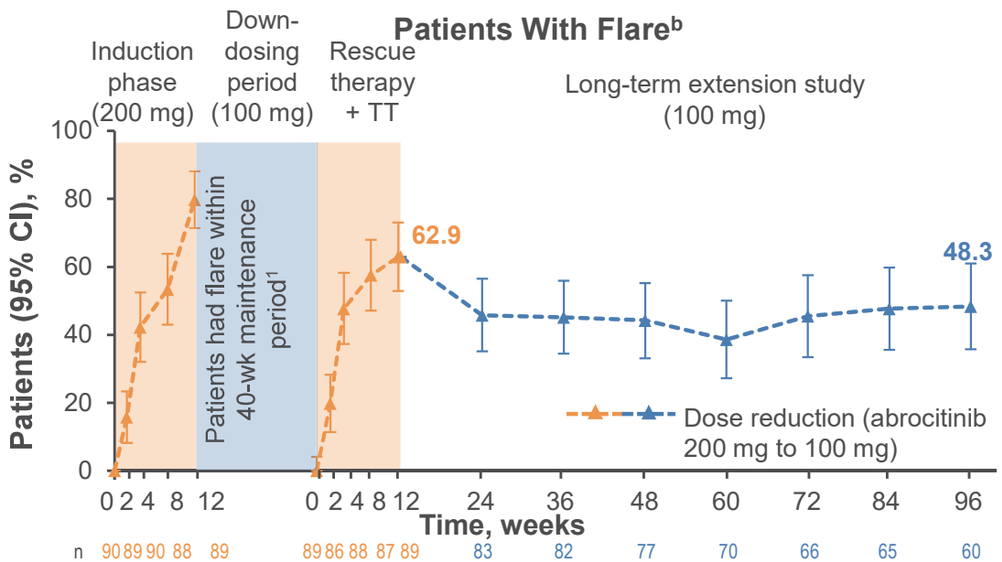
1. Blauvelt A, et al. *J Am Acad Dermatol*. 2022;86:104-112.

EASI-90 Response Was Maintained After Down-Titration

- After the open-label induction period, EASI-90 response was maintained up to Week 100 in patients without flare,[a] including most patients receiving 200-mg continuous dose (74%) and patients without flare receiving abrocitinib 100 mg (75%)



- After 12 weeks of abrocitinib 200 mg + TT rescue therapy, 63% of patients with flare achieved EASI-90 response; after resuming abrocitinib 100 mg, 48% maintained response at Week 96 post flare



Conclusion

- Dose selection can be consistent or variable for patients treated with abrocitinib to meet patient needs and provide the opportunity to maintain response on the lowest effective dose
- For patients achieving disease suppression following abrocitinib induction, maintenance at a lower dose—with the option of up-dosing as effective, fast rescue therapy for breakthrough activity—could be an effective management strategy, while some patients might need to stay on the higher dose to maintain their response

EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; TT, topical therapy.
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[a]The nonflaring cohort received abrocitinib 200 mg during the induction phase of JADE REGIMEN, were considered responders (achieved IGA 0/1 response with ≥2-grade improvement and EASI-75 response), and were randomized to receive abrocitinib 200 mg or 100 mg during the 40-week maintenance phase. Patients did not experience flare during the maintenance period and continued on the same dose into JADE EXTEND. [b]The flaring cohort included patients who received abrocitinib 200 mg during the induction phase of JADE REGIMEN, were considered responders (achieved IGA 0/1 response with ≥2-grade improvement and EASI-75 response), and were randomized to receive abrocitinib 100 mg during the 40-week maintenance phase (down dosing). These patients experienced flare (had ≥50% loss of Week 12 EASI response and new IGA score ≥2) and received rescue therapy (abrocitinib 200 mg plus topical therapy) for 12 weeks. Subsequently, they received abrocitinib 100 mg QD in JADE EXTEND.
1. Blauvelt A, et al. *J Am Acad Dermatol*. 2022;86:104-112.