Protocol for an Ongoing Phase 3 Multicenter, Long-Term Extension Study Investigating the Long-Term Safety and Efficacy of Abrocitinib in Adults and Adolescents With Moderate-to-Severe Atopic Dermatitis (JADE EXTEND)

Eric L. Simpson,1 Kristian Reich,2 Jonathan I. Silverberg,3 Adnan Nasir,4 Paulo Ricardo Criado,5 Pinaki Biswas,6 Herwig Koppensteiner,7 Dorothy Fan,6 Ricardo Rojo,8 Saleem Farooqui9

1Oregon Health & Science University, Portland, OR, USA; 2University Medical Center Hamburg-Eppendorf, Hamburg, Germany; 3The George Washington University School of Medicine and Health Sciences, Washington, DC, USA; 4Wake Research Associates, Raleigh, NC, USA; 5Alergoskin Alergia e Dermatologia, Santo André, São Paulo, Brazil; 6Pfizer Inc., New York, NY, USA; 7Pfizer Corporation Austria Gesellschaft m.b.H., Vienna, Austria; 8Pfizer Inc., Groton, CT, USA; 9Pfizer R & D UK Ltd., Sandwich, Kent, United Kingdom

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Introduction and Study Design

Background

- Abrocitinib is a JAK1 selective inhibitor that has been approved for the treatment of moderate-to-severe AD in adults and adolescents in Great Britain and Japan1-3.
- The short-term efficacy and safety of abrocitinib has been demonstrated in multiple phase 3 studies4-8.

Key Eligibility Criteria

- Adolescent and adult patients (≥12 years of age) with moderate-to-severe AD for whom any of the following apply:
  - Completed 1 of the following phase 3 studies: JADE MONO-1, JADE MONO-2, JADE REGIMEN, JADE COMPARE, JADE TEEN, JADE DARE, or JADE MOA.
  - Completed the open-label run-in period of JADE REGIMEN without meeting the protocol-defined response criteria at week 12.
  - Completed the 12-week rescue treatment period of JADE REGIMEN.
- No ongoing safety concerns.
- Provided written informed consent.

Study Design

Ongoing, multicenter, phase 3 long-term extension study to assess the long-term safety and efficacy of abrocitinib.

Objective

JADE EXTEND (NCT03422822) is investigating the long-term safety and efficacy of abrocitinib, with or without concomitant topical treatments, in adult and adolescent patients who previously participated in a qualifying parent study.

4-Week Follow-Up

- Treatment period 1: 92 weeks of treatment; blinding may be maintained if relevant to conserve the blinding of an active qualifying parent study.
- Treatment period 2: patients may continue to receive treatment until commercial availability or until the sponsor terminates the study; treatment will be open-label and at the same dose as that received in treatment period 1.

Medicated and nonmedicated topical treatments for AD are permitted.

Abrocitinib 200 mg QD

Eligible patients seamlessly roll over into JADE EXTEND instead of undergoing 4-week follow-up in parent study.

Abrocitinib 100 mg QD
Dose Allocation in Treatment Period 1: Monotherapy Parent Trials

**JADE MONO-1, MONO-2, or MOA**
DB treatment to week 12

- Abrocitinib 100 mg QD
- Abrocitinib 200 mg QD

**JADE EXTENDa**
Blinding maintained

- Abrocitinib 100 mg QD
- Abrocitinib 200 mg QD

DB treatment to week 12

- Placebo

**JADE REGIMEN**
Open-label run-in treatment to week 12

- Abrocitinib 200 mg QD

Nonresponse at week 12

- Abrocitinib 200 mg QD

Response at week 12

- Abrocitinib 200 mg QD

Blinded randomization

- Abrocitinib 100 mg QD
- Abrocitinib 200 mg QD

DB treatment to week 40

- Placebo

**JADE EXTENDa**
Blinding maintained

- Abrocitinib 100 mg QD
- Abrocitinib 200 mg QD

Blinded randomization

- Abrocitinib 100 mg QD
- Abrocitinib 200 mg QD

As above, in JADE EXTEND treatment allocation is dependent on what participant received during DB treatment period of JADE REGIMEN

- Abrocitinib 200 mg QD

+ topical therapy

DB, double-blinded; R, randomization.

*aMedicated and nonmedicated topical treatments for AD are permitted in JADE EXTEND.
**Dose Allocation in Treatment Period 1: Concomitant Topical Parent Trials**

**JADE COMPARE**
DB treatment to week 20

- **Abrocitinib 100 mg QD** + placebo injection Q2W
- **Abrocitinib 200 mg QD** + placebo injection Q2W
- Placebo injection + oral placebo (to week 16)

**JADE EXTEND**

- Blinding maintained

**JADE TEEN**
DB treatment to week 12

- Blinding maintained
- Placebo injection + oral placebo (to week 16)

**JADE DARE**
DB treatment to week 26

- Blinded randomization

**JADE EXTEND**

- Known dose

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- *Medicated and nonmedicated topical treatments for AD are permitted in JADE EXTEND.*
Endpoints

Primary Endpoints
- Incidence of:
  - TEAEs
  - SAEs and AEs leading to discontinuation
  - Clinical abnormalities
- Change from baseline in:
  - Clinical laboratory values
  - ECG measurements
  - Vital signs

Secondary Endpoints
- Response based on achieving:
  - IGA score of clear (0) or almost clear (1) and reduction of ≥2 points
  - ≥50%, ≥75%, ≥90%, and 100% improvement in EASI
  - ≥4-point improvement in PP-NRS
- Change from baseline in:
  - Patient Global Assessment
  - Dermatology Life Quality Index
  - Patient-Oriented Eczema Measure
  - Hospital Anxiety and Depression Scale
  - European Quality of Life 5-Dimension 5-Level Scale
  - Percentage of affected body surface area
  - Frequency of itching
- Steroid-free days
- Serum hsCRP levels