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)

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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 Japan[1-3]
- The short-term efficacy and safety of abrocitinib has been demonstrated in multiple phase 3 studies[4-8]

Objective

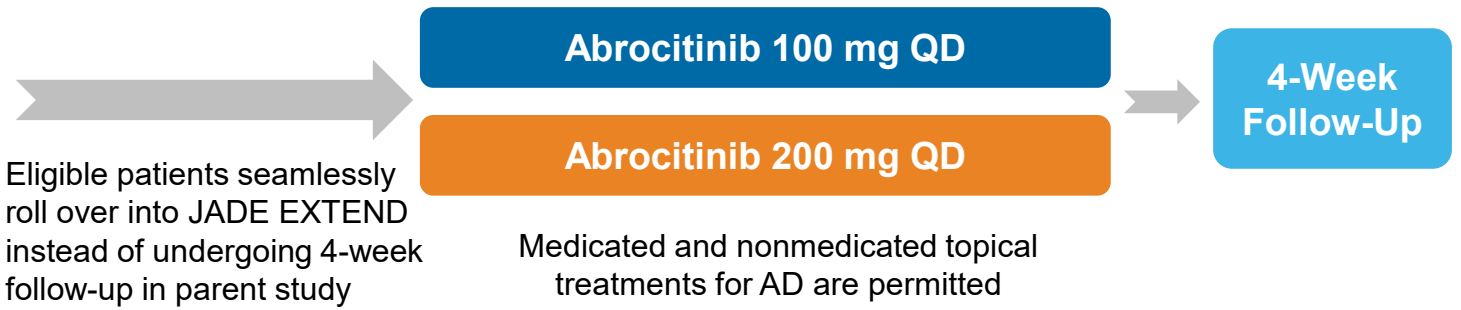
JADE EXTEND (NCT03422822) is investigating the long-term safety and efficacy of abrocitinib, with or without concomitant topical treatments, in adult and adolescent patients who previously participated in a qualifying parent study

Study Design

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

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

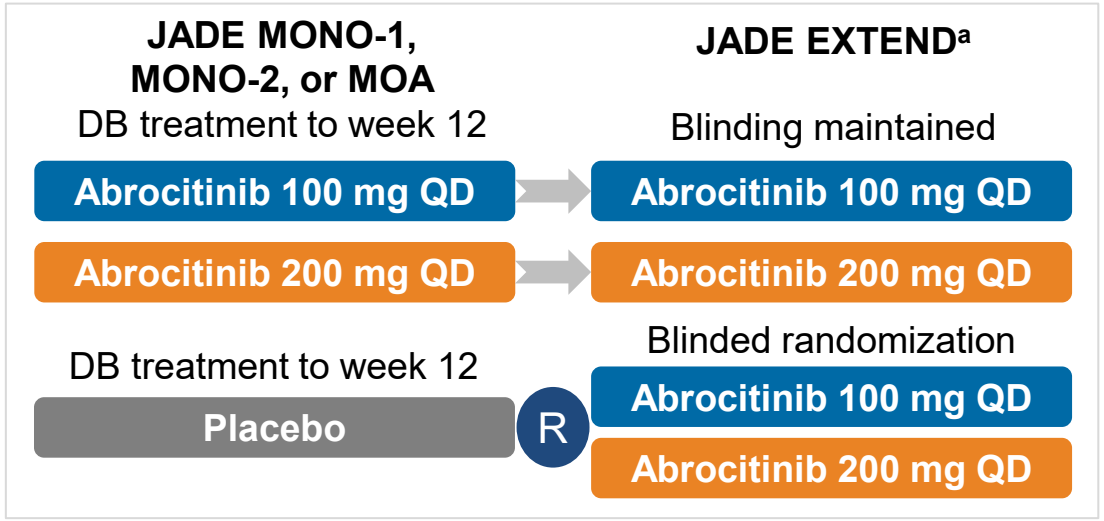


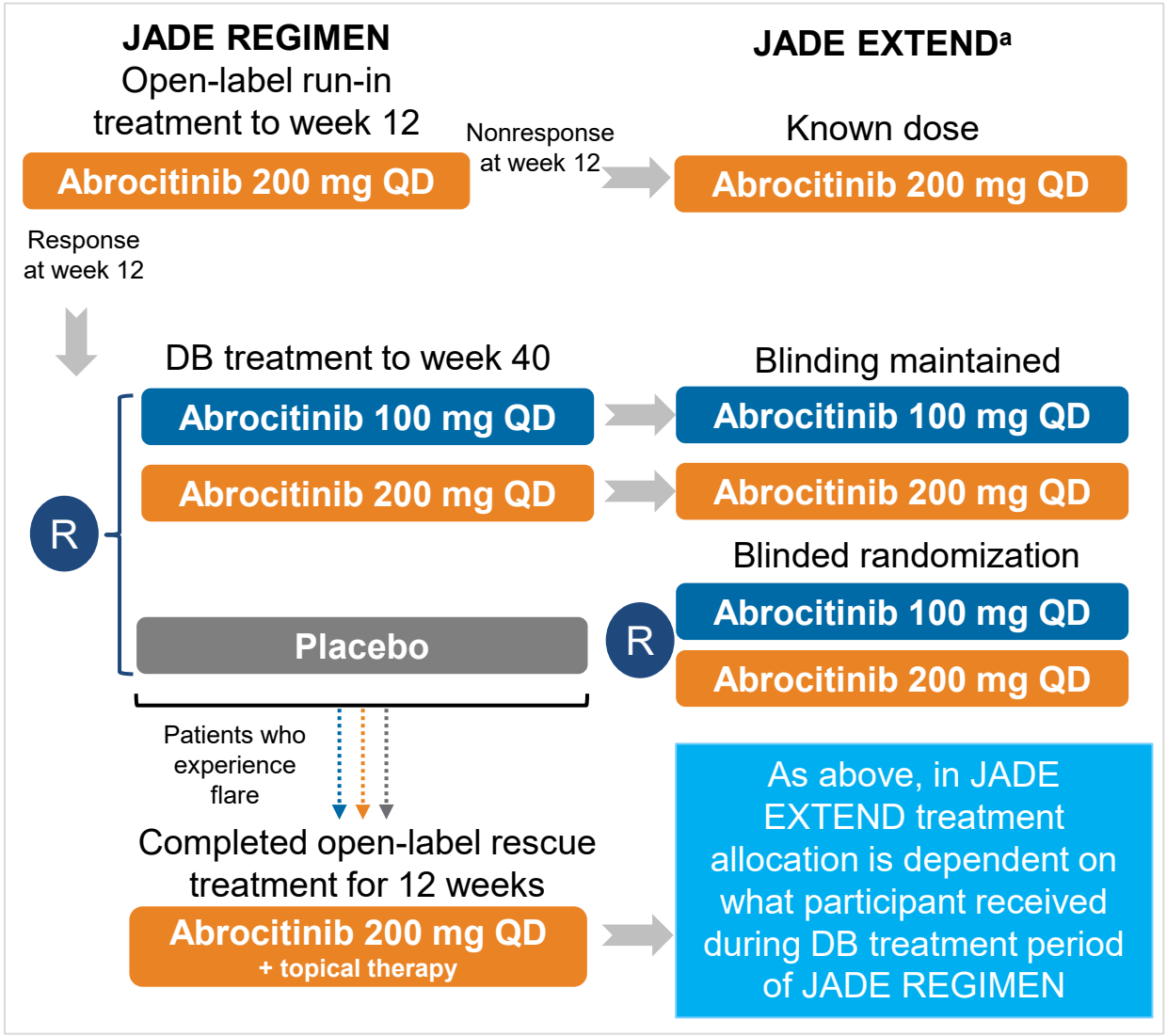
- **Treatment period 1:** 92 weeks of treatment; blinding may be maintained if relevant to conserve the blinding of an active qualifying parent study
- **Treatment period 2:** patients may continue to receive treatment until commercial availability or until the sponsor terminates the study; treatment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

AD, atopic dermatitis; JAK, Janus kinase; QD, once daily.

1. https://www.pfizer.com/news/press-release/press-release-detail/uks-mhra-grants-marketing-authorisation-pfizers-cibinqor 2. https://www.medicines.org.uk/emc/product/12873/smpc 3. https://www.pfizer.com/news/press-release/press-release-detail/japans-mhlw-approves-pfizers-cibingor-abrocitinib-adults 4. Simpson EL et al. *Lancet.* 2020;396:255-266. 5. Silverberg JI et al. *JAMA Dermatol.* 2020;156:863-873. 6. Bieber T et al. *N Engl J Med.* 2021;384:1101-1112. 7. Blauvelt A et al. *J Am Acad Dermatol.* 2021;Aug 17:S0190-9622(21)02343-4. 8. Eichenfield LF et al. *JAMA Dermatol.* 2021;157:1165-1173.

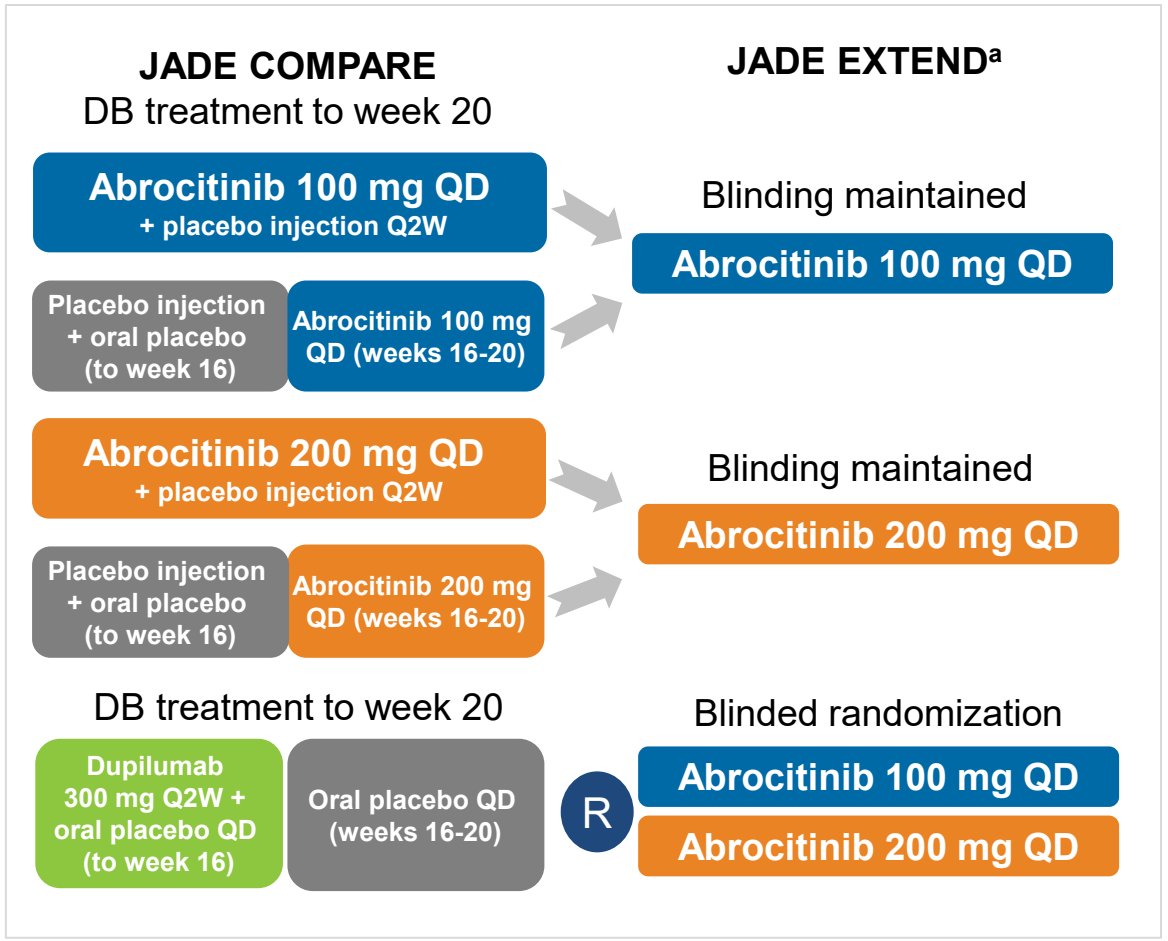
Dose Allocation in Treatment Period 1: Monotherapy Parent Trials

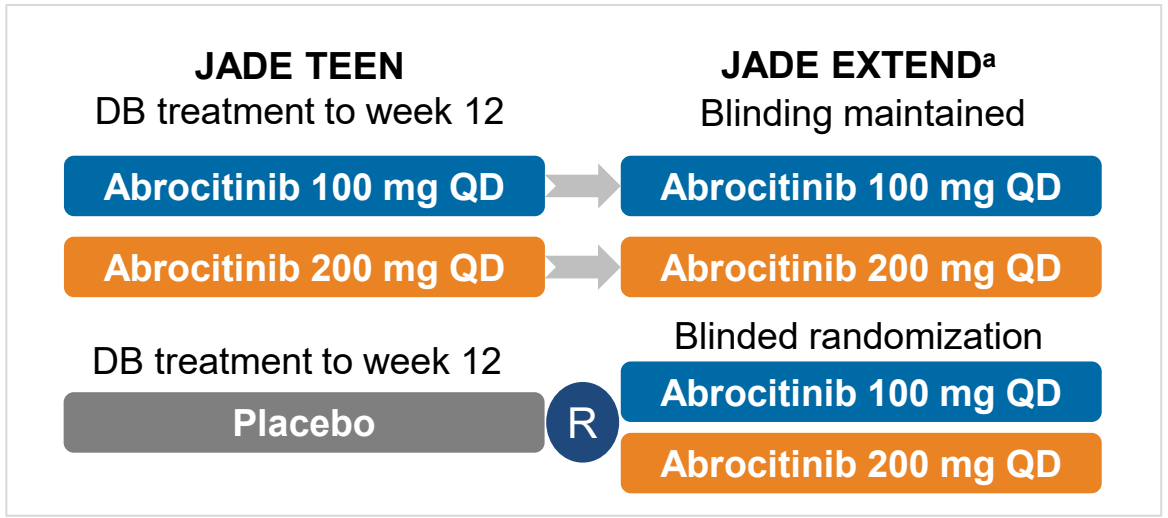


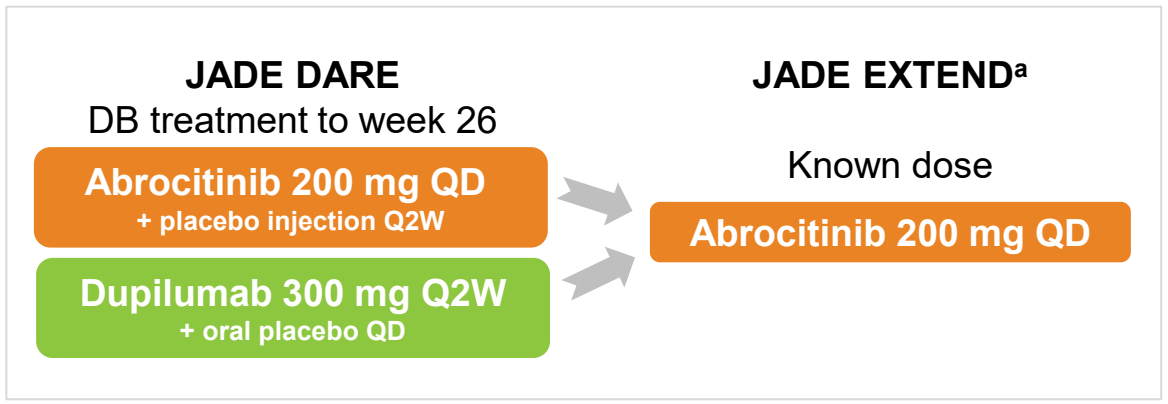


DB, double-blinded; R, randomization.
[a]Medicated and nonmedicated topical treatments for AD are permitted in JADE EXTEND.

Dose Allocation in Treatment Period 1: Concomitant Topical Parent Trials







[a]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

AE, adverse event; EASI, Eczema Area and Severity Index; ECG, electrocardiogram; hsCRP, high-sensitivity C-reactive protein; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; SAE, serious adverse event; TEAE, treatment-emergent adverse event.