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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Background: Abrocitinib is a Janus kinase-1-selective inhibitor that was developed for the treatment of moderate-to-severe atopic dermatitis (AD). The short-term efficacy and safety of abrocitinib was demonstrated in multiple phase 3 studies in the JADE clinical trial program.

Objective: JADE EXTEND (NCT03422822) is an ongoing, long-term extension study investigating the safety and efficacy of abrocitinib, with or without concomitant topical treatments, in adult and adolescent patients who previously participated in qualifying JADE clinical trials.

Methods: JADE EXTEND is enrolling participants with moderate-to-severe AD who remain eligible to receive abrocitinib after completing the full treatment period of a qualifying parent study (JADE MONO-1 [NCT03349060], JADE MONO-2 [NCT03575871], JADE REGIMEN [NCT03627767], JADE COMPARE [NCT03720470], JADE TEEN [NCT03796676], JADE DARE [NCT04345367], and JADE MOA [NCT03915496]) or after completing the full open-label run-in period of JADE REGIMEN without meeting the protocol-defined response criteria at week 12, or after completing the full rescue treatment period in that study. Participants enroll in Treatment Period 1 (TP1) of JADE EXTEND directly from the qualifying parent study at the relevant timepoint and do not complete 4-week follow-up in the qualifying parent study. All participants receive abrocitinib 200 mg or 100 mg once daily (QD) in JADE EXTEND. Medicated and nonmedicated topical treatments for AD are permitted, at investigator discretion, throughout JADE EXTEND.

In JADE EXTEND, blinding for some participants is maintained in TP1 if required to conserve blinding in any ongoing qualifying parent study. Participants who received double-blind abrocitinib 200 mg or 100 mg QD in JADE MONO-1, JADE MONO-2, JADE REGIMEN, JADE COMPARE, JADE TEEN, or JADE MOA are initially allocated in a blinded manner to receive the same dose in JADE EXTEND. Participants who received only placebo in JADE MONO-1, JADE MONO-2, JADE TEEN, or JADE MOA and patients who received dupilumab in JADE COMPARE are randomly allocated to receive abrocitinib 200 mg or 100 mg QD in JADE EXTEND in a double-blind manner. Participants who were randomly allocated to placebo in the double-blind treatment period of JADE REGIMEN are randomly allocated to receive abrocitinib 200 mg or 100 mg QD in JADE EXTEND in a double-blind manner. Some participants enter JADE EXTEND and receive a known dose of abrocitinib in TP1. Participants who previously received open-label abrocitinib 200 mg QD in the run-in or rescue treatment period of JADE REGIMEN and then immediately entered JADE EXTEND are allocated to receive the same, known dose in JADE EXTEND. Participants who received abrocitinib 200 mg QD or dupilumab in JADE DARE are allocated to receive known-dose abrocitinib 200 mg QD in JADE EXTEND regardless of their prior treatment allocation in JADE DARE.

Treatment Period 2 (TP2) begins after the week 92 visit for all eligible participants and is an open-label treatment period. Participants receive the same dose that they received in TP1. The maximum total duration of treatment for participants in JADE EXTEND may differ for participants; a participant may continue to receive abrocitinib in JADE EXTEND until commercial product becomes available in their country or until the sponsor terminates the study in that country. Participants will enter a 4-week follow-up period after permanent discontinuation of treatment in JADE EXTEND.

Primary endpoints are the incidence of treatment-emergent adverse events, serious adverse events, adverse events leading to discontinuation, clinical abnormalities, and change from baseline in clinical laboratory values, electrocardiogram measurements, and vital signs. Secondary endpoints include efficacy endpoints, patient-reported outcomes, and biomarker-based endpoints.