Efficacy and Safety of Abrocitinib in Adolescents With Moderate-to-Severe Atopic Dermatitis From the JADE Clinical Trial Program

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INTRODUCTION

• Treatment options are limited for patients with moderate-to-severe atopic dermatitis (AD) associated with topical corticosteroids.

• Once-daily oral abrocitinib, a selective Janus kinase 1 inhibitor, as monotherapy or with topical corticosteroids, and/or a phosphodiesterase 4 inhibitor) for 12 weeks

• A separate phase 3 study, JADE TEEN (NCT03796676), was conducted to investigate the efficacy and safety of abrocitinib in adolescents with moderate-to-severe AD in combination with medicated topical therapy in adolescents with moderate-to-severe AD

OBJECTIVE

• To investigate the efficacy and safety of abrocitinib as monotherapy or in combination with topical medication, in adolescents with moderate-to-severe AD phase 2a trial designs

METHODS

Key Patient Eligibility Criteria

• Age 12-17 years: JADE TEEN and 18 years in JADE MONO-1 and JADE MONO-2

• Confirmed AD diagnosis based on Hanifin and Rajka criteria

• Moderate-to-severe AD (affected body surface area ≥10%, Investigator’s Global Assessment [IGA] ≥4, and at least one assessment ≥3 or ≥4; Pruritus Numerical Rating Scale [PP-NRS] ≥3, ≥4, or ≥5, respectively)

• Candidate for systemic therapy for AD or had in the past month had inadequate response to at least 3 consecutive weeks of topical medication

Treatments

• In JADE TEEN, patients were randomly assigned 1:1:1 to receive once-daily oral abrocitinib (200 mg or 100 mg) or placebo in combination with topical corticosteroids or medium potency topical corticosteroids or oral corticosteroids, or a phosphodiesterase 4 inhibitor (twice a week) for 12 weeks

• In JADE MONO-1 and JADE MONO-2, patients were randomly assigned 2:2:2 to receive once-daily oral abrocitinib (200 mg or 100 mg) or placebo as monotherapy

Key Endpoint

• Co-primary endpoints were the proportions of patients who achieved IGA 0/1 with placebo

• A secondary endpoint was the proportion of patients who achieved IGA 0/1 with placebo

RESULTS

Baseline Demographics and Disease Characteristics

• Overall 258 and 104 adolescents were treated in these studies

• A separate phase 3 study, JADE TEEN (NCT03796676), was conducted to investigate the efficacy and safety of abrocitinib in adolescents with moderate-to-severe AD in combination with medicated topical therapy in adolescents with moderate-to-severe AD

A key secondary endpoint was the proportion of patients who achieved PP-NRS4 at week 12; a significant difference was also observed for abrocitinib 200 mg versus placebo at week 4

JADE TEEN Co-primary Endpoints: Clinical Signs of AD

• The coprimary endpoints of the JADE TEEN study were met

JADE MONO-1 and JADE MONO-2 Co-primary Endpoints: Clinical Signs of AD

• JADE MONO-1 and JADE MONO-2 were randomized in a 2:2:2 treatment ratio and included patients with confirmed AD diagnosis based on Hanifin and Rajka criteria

• A key secondary endpoint was the proportion of patients who achieved PP-NRS4 at weeks 4, 8, and 12

• Safety endpoints were assessed for 12 weeks

• Treatment-emergent adverse events (TEAEs)

• Serious and severe TEAEs

• TEAEs leading to discontinuation

JADE MONO-1 and JADE MONO-2 Co-primary Endpoints: Clinical Signs of AD

• As a separate phase 3 study, JADE TEEN (NCT03796676), was conducted to investigate the efficacy and safety of abrocitinib in adolescents with moderate-to-severe AD in combination with medicated topical therapy in adolescents with moderate-to-severe AD

Figure 1. JADE TEEN Co-primary endpoints

Figure 2. JADEC MONO-1 and JADE MONO-2 Co-primary endpoints

CONCLUSIONS

• In JADE TEEN, abrocitinib combined with medicated topical therapy or adolescents who achieved significant improvement in IGA scores (IGA 0/1, EASI-75) and signs (PP-NRS4) compared with placebo

• In the pooled adolescent population from JADE MONO-1 and JADE MONO-2, abrocitinib had significantly greater efficacy than placebo

• The safety of abrocitinib in JADE TEEN was consistent with the safety profile observed in JADE TEEN and JADE MONO-1 and 2 (except for those medications or interventions used as concomitant therapies and the use of oral corticosteroids in JADE TEEN) and the benefit-risk profile

REFERENCES


4. These studies were sponsored by Pfizer Inc.