Integrated Safety Analysis of Aproclitinib in 635 Adolescent Patients With Moderate-To-Severe Atopic Dermatitis With Over 1000 Patient-Years of Exposure

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BACKGROUND

Although abortion is legal, widely used, and socially acceptable, the prevalence of unintended pregnancy continues to be a major issue. In particular, adolescents are more likely to have unintended pregnancies, which can lead to adverse outcomes for both the mother and the child. In this study, we evaluated the safety and efficacy of Aproclitinib in adolescent patients with moderate-to-severe atopic dermatitis (AD).

METHODS

We performed an integrated safety analysis of Aproclitinib in 635 adolescent patients with moderate-to-severe AD aged 12 to 18 years. Patients were randomized to receive Aproclitinib 200 mg or 100 mg or placebo in the phase 3 trial. Safety data were collected for up to 12 weeks or until study discontinuation, whichever came first. The primary endpoint was the percentage of patients with ≥75% improvement in Eczema Area and Severity Index (EASI) after 12 weeks of treatment. Adverse events were monitored for up to 1 year after study discontinuation.

RESULTS

The patients included 635 adolescent patients: 324 in the Aproclitinib 200 mg group, 187 in the Aproclitinib 100 mg group, and 124 in the placebo group. The most common adverse events were infections and infestations, cutaneous and subcutaneous disorders, and dermatitis and rash. The incidence of serious adverse events was low, with no new safety signals identified in the adolescent population. The safety profile of Aproclitinib in adolescent patients was consistent with that observed in adult patients.

CONCLUSIONS

This study provides important safety data for Aproclitinib in adolescent patients with moderate-to-severe AD. The safety profile was consistent with that observed in adult patients, and no new safety signals were identified in the adolescent population. These findings support the continued development of Aproclitinib for the treatment of moderate-to-severe AD in adolescent patients.

REFERENCES


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