Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by recurrence of itching and dry skin, accompanied by scaling and swelling, among other symptoms. AD is one of the most common inflammatory skin diseases of childhood and adolescence. 

Translating a fully human monoclonal antibody that specifically neutralizes interleukin-13 (IL-13), a cytokine of the chronic type 2 inflammation underlying AD, is correspondingly a rewarding and non-toxic target. 

**ECZTRA 3 (NCT03363854)** was a Phase 3, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of tralokinumab 300 mg q2w in combination with topical corticosteroids (TCS) in adults with moderate-to-severe AD. 

Methods

Study design and patients

**ECZTRA 3** was a randomized, double-blind, placebo-controlled, 32-week trial in adult patients with moderate-to-severe AD. 

Eligible patients were 18 years of age, with a confirmed diagnosis of AD for ≥12 months at screening and ≤18 years of age, with a confirmed diagnosis of AD for ≥6 months at screening. 

Patients were enrolled from Europe, Australia, the United States, Canada, South America, and Japan. 

Eligible patients were randomized 2:1 to receive tralokinumab q2w or placebo q2w, both in combination with TCS. 

The primary endpoint was the proportion of patients achieving Investigator’s Global Assessment (IGA) of 0/1 with no rescue medication prior to week 16 or with missing data. 

Safety assessments

Adverse events were collected from the first trial-related activity after patients provided informed consent, and were considered non-responders. 

Endpoints

Primary endpoints were defined as IGA 0/1 and EASI 75 at week 16. 

Key secondary endpoints included reduction of worst daily pruritus Numerical Rating Scale (NRS) (weekly average) from baseline to week 16, and change in Dermatology Life Quality Index (DLQI) score from baseline to week 16. 

Statistical analysis

For key secondary endpoints, the difference in the proportion of patients achieving IGA 0/1 and EASI 75 at week 16 was analyzed using the Cochran-Mantel-Haenszel test. 

Conclusions

Overall, the North American and primary study populations had similar baseline demographics, although there was slight variation in the baseline disease characteristics. 

Patient characteristics: 

- In total, 380 patients were randomized in ECZTRA 3, with 372 patients 65% of whom patients had moderate-to-severe AD. 

Endpoints: 

- At week 16, patients with moderate-severe AD had similar baseline demographics and disease characteristics in the North American population as compared to the primary study population. 

Results

**Patient characteristics**

In total, 380 patients were randomized in ECZTRA 3, with 372 patients 65% of whom patients had moderate-to-severe AD. 

**Endpoints**

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Safety

The overall incidence of adverse events was similar between treatment groups. 

Disclosures

The authors have no conflicts of interest to disclose.

Acknowledgments

The authors thank the patients who participated in ECZTRA 3, the ECZTRA 3 investigators, and the North American and primary study populations. 

References