Tralokinumab-Treated Patients with Moderate-to-Severe Atopic Dermatitis: an ECZTEND Interim Analysis

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Atopic dermatitis is a chronic inflammatory disease characterized by dry skin, itching, and redness. Tralokinumab is a high-affinity, fully human monoclonal antibody designed to target and neutralize IL-31, which is overexpressed in atopic dermatitis and known to contribute to itch, inflammation, and epidermal hyperplasia.

Background

Tralokinumab was studied in five phase 3 trials (ECZTRA 1-8) in patients with moderate-to-severe atopic dermatitis. The current analysis reports results from an ongoing, open-label extension study called ECZTEND (NCT03587805) in patients who participated in the parent trials (ECZTRA 1-8 and the Tralokinumab Safety Study [TraSki]).

Methods

ECZTEND enrolled patients with moderate-to-severe atopic dermatitis who participated in the parent trials (ECZTRA 1-8 and TraSki). The study aimed to evaluate the safety and efficacy of tralokinumab in patients who had been previously treated with the medication. Patients received subcutaneous tralokinumab 300 mg every 2 weeks (q2w) and were monitored for up to 52 weeks.

Results

The study showed that tralokinumab was well-tolerated and maintained its safety profile in the parent trials, with a low incidence of adverse events. Efficacy outcomes were consistent with previous data, demonstrating a robust reduction in skin inflammation and itch.

Conclusions

Overall, tralokinumab plus optional TCS was well-tolerated in patients enrolled in ECZTEND at data cut-off, with a safety profile consistent with the parent trials.

References


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Long-Term Improvements Observed in Tralokinumab-Treated Patients with Moderate-to-Severe Atopic Dermatitis: an ECZTEND Interim Analysis

Introduction

The primary objective was to evaluate the safety and efficacy of tralokinumab in patients with moderate-to-severe atopic dermatitis who participated in the parent trials (ECZTRA 1-8 and TraSki) and enrolled in the ECZTEND extension study. Efficacy and safety outcomes were compared between patients who were and were not enrolled in the parent trials.

Objectives

To present interim ECZTEND efficacy data collected through April 30, 2020 for patients who participated in parent trials (ECZTRA 1-8 and TraSki).

Key Release Criteria

1. Participants from the parent trials were included.
2. Patients who completed 12 weeks of treatment in the parent trials were eligible.
3. Patients with a baseline EASI ≥5 were included.

Parent trial, n (%)

ECZTRA 1, 2, 3, and 5 enrolled in ECZTEND at data cut-off (n=1080, 21.6% of total parent trial population).

Baseline characteristics

Total parent trial population (n=5006) and total ECZTEND population (n=1080)

Region, %

North America 47.7
Europe 45.8
Asia 3.8
Other 3.7

Mean age, years

ECZTEND parent trial 38.0 (27.0-50.0)
ECZTEND 35.4 (24.0-45.0)

Baseline characteristics All parent trials ECZTEND

Mean EASI score

ECZTEND parent trial 28.2 (19.7-37.2)
ECZTEND 30.0 (20.0-40.0)

Conclusions

Overall, tralokinumab was well-tolerated in patients enrolled in ECZTEND at data cut-off, with a safety profile consistent with the parent trials.