Improvement of the head and neck regions with continuous tralokinumab treatment for up to 4 years in adults with moderate-to-severe atopic dermatitis

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Introduction/Background: Atopic dermatitis (AD) is a chronic, inflammatory disease that can affect multiple regions of the body, but can be particularly burdensome on exposed areas of skin, such as the head and neck (H&N). Tralokinumab, a high-affinity monoclonal antibody that specifically neutralizes interleukin-13, is approved in multiple countries for adults with moderate-to-severe AD. Phase 3 trials showed tralokinumab provided significant improvements in AD severity and was well-tolerated up to 52 weeks of treatment. The ongoing open-label, 5-year extension trial, ECZTEND (NCT03587805), assesses the safety and efficacy of tralokinumab after the completion of parent trials (PT).

Objectives: To assess tralokinumab efficacy in the H&N region.

Methods: This post hoc analysis included adult patients with moderate-to-severe AD initially randomized to tralokinumab 300mg Q2W in the phase 3 PTs ECZTRA 1 (NCT03131648) or ECZTRA 2 (NCT03160885). Patients on active tralokinumab treatment were followed for up to 52 weeks in PTs and for up to 152 weeks in ECZTEND as of data cutoff April 30, 2022. Patients
re-randomized to placebo at Week (Wk) 16 were not included beyond that timepoint. For this analysis, overall EASI and H&N regional EASI (H&N EASI) were evaluated. H&N EASI (0-7.2) was calculated based on the severity of erythema, induration/papulation, excoriation, lichenification and area of involvement. All data were analyzed and presented as observed.

**Results:** At baseline, 87.8% (1047/1192) of patients had H&N involvement (H&N EASI>1), and 49.9% (591/1192) of patients exhibited severe AD (IGA 4). Baseline median H&N EASI for the pooled PTs was 3.0 (IQR 1.8; 4.5). In the pooled PTs, 48.2% (542/1125) and 71.2% (558/784) of patients achieved H&N EASI≤1, at Wk16 and Wk52, respectively. After 3 years additional treatment (Wk152 in ECZTEND), the proportion of patients with H&N EASI≤1 was 87.2% (232/266) and the median H&N EASI was 0.2 (IQR 0.0; 0.5). In the subgroup of patients (n=301) with severe AD (IGA 4) and high H&N involvement (H&N EASI≥4), median H&N EASI improved from 5.4 at baseline to 2.4 and 0.8 at Wk16 and Wk52, respectively, and 0.4 at Wk152. Improvements in H&N region were comparable to overall EASI improvement.

**Conclusions:** Tralokinumab provided sustained improvements in the H&N regions in patients with moderate-to-severe AD for up to 4 years. Sustained improvements were also seen in patients with severe disease and substantial H&N involvement at baseline.

**Keywords:** atopic dermatitis, tralokinumab, IL-13, head and neck

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