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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Objectives

- To examine the efficacy of long-term tralokinumab treatment on the head and neck regions through a post hoc analysis of two Phase 3 clinical trials and the ongoing ECZTEND open-label trial

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) regions. In patients treated with tralokinumab for up to a total of 4 years in ECZTRA 1 & 2 and ECZTEND, the median H&N EASI was reduced from 3.0 at parent trial (PT) baseline to 0.2 at Week 152. The proportion of patients with H&N EASI≤1 at baseline (B) was 59.4% (IQR 37.0%; 78.1%) and at Week 152 was 70.6% (IQR 63.0%; 81.4%) (Figure 2).

Results

- In patients treated with tralokinumab for up to a total of 4 years in ECZTRA 1 & 2 and ECZTEND, the median H&N EASI was reduced from 3.0 at parent trial (PT) baseline to 0.2 at Week 152 in ECZTEND. The proportion of patients with H&N EASI≤1 at Week 152 was 70.2%.
- In the most severe subgroup, with IGA 4 and high H&N involvement (H&N EASI>4) at baseline (n=301), the median H&N EASI was reduced from 5.4 at PT baseline to 0.4 at Week 152. The proportion of patients with H&N EASI≤1 at Week 152 was 82.7%.
- The median total EASI (0-72) was improved from 28.2 at PT baseline to 13 at Week 152. The proportion of patients with EASI≤1 at B and EASI≤0.5 at Week 152 was 65.6% and 58.3%, respectively (Figure 3).

Conclusions

- In this post hoc analysis, tralokinumab provided sustained improvements of head and neck regions through continuous tralokinumab treatment for up to 4 years in adults with moderate-to-severe atopic dermatitis.

Analyses

- Overall EASI scores (0–72) were calculated as a composite of the intensity (0–3) and extent of involvement (0–6) of the head and neck regions.
- Head and neck regional scores (H&N EASI; 0–7.2), the intensity of signs (erythema, induration/papulation, excoriation, lichenification) were assessed individually (0–3) and were summarized (0–12) and then multiplied by extent of involvement (0–6). Then the H&N EASI was calculated.

Methods

- Data were obtained from all patients initiated on tralokinumab in ECZTRA 162, identically designed phase 3 monotherapy trials conducted in adults with moderate-to-severe AD.
- Patients on active treatment were followed for up to 52 weeks in parent trials, and patients that then enrolled in the long-term open-label study ECZTEND were followed up to an additional 152 weeks until the April 30, 2022 data cutoff (Figure 4).
- Data from Week 16 responders re-randomized to placebo were not included beyond that timepoint (Figure 4).

Baseline and Disease Characteristics

- Patients generally exhibited substantial disease severity at baseline (Table 1).
- There was a mean EASI 32.2 (19.9) and max 238.5 weeks until the April 30, 2022 data cutoff.
- The most common reasons for discontinuation were Lack of efficacy (11.9 %) and Other reasons (9.8 %).

Table 1. Baseline demographics and characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tr>
<td>Mean age (years)</td>
<td>39.9 (9.4)</td>
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<tr>
<td>Male sex (%)</td>
<td>708 (59.4)</td>
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<tr>
<td>Mean BSA involvement % (years)</td>
<td>52.4 (23.4)</td>
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<tr>
<td>Mean duration of AD years</td>
<td>28.1 (10.2)</td>
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<tr>
<td>IGA 4 (severe), n (%)</td>
<td>579 (49.4)</td>
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<tr>
<td>Mean EASI (SD)</td>
<td>32.2 (9.4)</td>
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<tr>
<td>Mean H&amp;N EASI (SD)</td>
<td>3.1 (1.8)</td>
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Disclosures

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