Assessing Long-term Maintenance of Efficacy With Tralokinumab Monotherapy in Patients With Moderate-to-severe Atopic Dermatitis: Combined Results From Two Phase 3, Randomized, Double-blind, Placebo-controlled Trials (ECZTRA 1 and 2)

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterized by intense and pruritic skin inflammation that results in impaired quality of life for patients of all ages.

Tralokinumab is a fully human, immunoglobulin G4 monoclonal antibody that specifically targets interleukin-31 (IL-31), a cytokine that plays a critical role in allergic skin inflammation.

Objectives

- To assess the safety and efficacy of tralokinumab 300 mg every 2 weeks (q2w) for up to 52 weeks in adult patients with moderate-to-severe AD.
- To evaluate the maintenance of efficacy over time with tralokinumab q2w.

Methods

Study Design and Patients

- A double-blind, placebo-controlled, randomized, double-blind, placebo-controlled trial (120 mg q4w vs placebo)
- Patients were randomized to receive tralokinumab 300 mg q2w or placebo for 16 weeks, followed by open-label tralokinumab q2w to 52 weeks.
- The primary endpoint was the proportion of patients achieving Investigator’s Global Assessment (IGA) 0 or 1 and 75% reduction in Eczema Area and Severity Index (EASI) from baseline at week 16.

Results

- Patients achieving IGA 0/1 at Week 16 were re-randomized to receive either tralokinumab q2w, tralokinumab q4w, or placebo until Week 52.
- At Week 52, tralokinumab q2w patients maintained IGA 0/1 and EASI-75 response compared to placebo.
- Safety

- No unexpected safety concerns were reported.

Conclusions

- Tralokinumab 300 mg q2w for up to 52 weeks was well tolerated and maintained efficacy in patients with moderate-to-severe AD.

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References


Table 2. Summary of AEIs in the initial and maintenance treatment periods (420 patients total)

<table>
<thead>
<tr>
<th>Period</th>
<th>AEIs</th>
<th>Placebo</th>
<th>Tralokinumab q2w</th>
<th>Tralokinumab q4w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial treatment period</td>
<td></td>
<td>1591</td>
<td>1651</td>
<td>166</td>
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<tr>
<td>Maintenance period</td>
<td>420</td>
<td>1168</td>
<td>1203</td>
<td>120</td>
</tr>
</tbody>
</table>

AEIs: adverse events; IGA: Investigator’s Global Assessment; q2w: every 2 weeks; q4w: every 4 weeks.