**Clinical meaningful changes in tralokinumab–treated patients in adults with moderate-to-severe atopic dermatitis**

Who did not meet IGA 0/1 at initial 16-week treatment

Eric Simpson, Andrew Blauvelt, Jonathan I Silverberg, Matteo Tonetti, Thomas B Scheib, Anne-Noëlle Franzen Schenkel*, Andreas Wollenberg*

†Oregon Health & Science University, USA; ‡Oregon Medical Research Center, USA; §George Washington University School of Medicine and Health Sciences, USA; †University of Sheffield, UK; ¶Kyugetsu Precision University of Medicine Graduate School of Medical Science, Japan; ‡‡LEO Pharma A/S, Denmark; ‡§LEO Pharma Inc, USA; ‡¶Bucerius Law School in Hamburg, Germany

**Objective**

- Assess impact of tralokinumab on patient-reported outcomes (NRI AO, EASI-50, NRS ≥3-point improvement, DLQI ≥4-point improvement), and other important and clinically meaningful parameters reflecting improvement in signs, symptoms, and quality of life in patients who did not achieve IGA 0/1 at Week 16 in placebo-controlled Phase 3 trials.

**Methods**

- Comparator: Placebo.
- Trial design: Randomized, double-blind, parallel-group, placebo-controlled.
- Study population: IGA >1 patients with moderate to severe AD (N=1518, Week 16) at study sites in 26 countries.

**Results**

- **Primary endpoints:**
  - 35.8% vs 12.5% (P<0.001) for NRI AO (Figure 1).
  - 33.7% vs 9.9% (P<0.001) for EASI-50 responders (Figure 1).
  - 38.0% vs 23.5% (P<0.001) for NRS ≥3-point improvement (Figure 1).
  - 33.0% vs 22.7% (P<0.001) for DLQI ≥4-point improvement (Figure 1).

**Conclusion**

- In patients who did not achieve IGA 0/1 at Week 16, tralokinumab 300 mg Q2W demonstrated statistically significantly higher rates of clinical meaningful improvements in NRI AO, EASI-50, NRS ≥3-point improvement, and DLQI ≥4-point improvement compared to placebo, even among IGA >1 patients with moderate to severe AD. The benefits observed in this post hoc analysis of patients not achieving IGA 0/1 at Week 16 were consistent with the overall ECZTRA 1 and 2 study populations.

**Disclosures**

- The authors disclose no conflicts of interest.

---

**Figure 1:** NRI AO responder rates

- **Tralokinumab 300 mg Q2W:** 35.8% vs 12.5% (P<0.001) for NRI AO (Figure 1).
- **Tralokinumab 300 mg Q4W:** 33.7% vs 9.9% (P<0.001) for EASI-50 responders (Figure 1).
- **Tralokinumab 300 mg Q2W:** 38.0% vs 23.5% (P<0.001) for NRS ≥3-point improvement (Figure 1).
- **Tralokinumab 300 mg Q4W:** 33.0% vs 22.7% (P<0.001) for DLQI ≥4-point improvement (Figure 1).

---

**Table 1:** Clinical meaningful changes in tralokinumab–treated patients with IGA >1 at Week 16

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Placebo (N=584)</th>
<th>Tralokinumab 300 mg Q2W (N=558)</th>
<th>Tralokinumab 300 mg Q4W (N=327)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRI AO (Percent)</td>
<td>12.5%</td>
<td>35.8%</td>
<td>12.5%</td>
</tr>
<tr>
<td>EASI-50 (Percent)</td>
<td>9.9%</td>
<td>33.7%</td>
<td>9.9%</td>
</tr>
<tr>
<td>NRS ≥3-point improvement (Percent)</td>
<td>23.5%</td>
<td>38.0%</td>
<td>23.5%</td>
</tr>
<tr>
<td>DLQI ≥4-point improvement (Percent)</td>
<td>22.7%</td>
<td>33.0%</td>
<td>22.7%</td>
</tr>
</tbody>
</table>

---

**References**