Early changes in patient-relevant endpoints in three tralokinumab pivotal Phase 3 trials (ECZTRA 1–3) in adult patients with moderate-to-severe atopic dermatitis

Introduction

- Elevated eosinophils and IL-4 are pivotal in atopic dermatitis (AD) pathogenesis
- IL-13 is a key type 2 cytokine, with IL-4 and IL-13 acting synergistically to drive AD pathogenesis
- Eczema-related sleep interference is particularly relevant for quality of life in patients with AD

Methods

- Tralokinumab is a fully human monoclonal antibody which specifically neutralizes IL-13
- In the 16-week period, the overall safety of tralokinumab was comparable to placebo

Results

- Throughout the 16-week period, the majority of adverse events were mild or moderate in severity

Conclusions

- Tralokinumab, with or without concomitant TCS, led to early improvement in patient-relevant endpoints compared to placebo across the three trials
- AD severity improved, and the quality of life of patients with AD improved with tralokinumab
- These findings support the previously demonstrated superiority of tralokinumab 300 mg every 4 weeks compared to placebo, over 16 weeks of treatment across multiple outcome measures, reflecting the signs and symptoms of AD

Safety

- Adverse events were assessed at baseline and at each subsequent visit

Statistical analysis

- The changes in weekly pruritus NRS were assessed using a repeated measures ANOVA model
- Interim analyses were performed at weeks 2, 4, and 12
- A final analysis was performed at week 16

Table 1: Demographics and clinical characteristics of confirmed patients at baseline

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ECZTRA 1</th>
<th>ECZTRA 2</th>
<th>ECZTRA 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) (mean ± SD)</td>
<td>46.4 ± 14.6</td>
<td>47.9 ± 13.9</td>
<td>48.0 ± 13.7</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>307/294</td>
<td>150/194</td>
<td>254/232</td>
</tr>
<tr>
<td>Skin type</td>
<td>201/190/28</td>
<td>108/99/27</td>
<td>156/152/12</td>
</tr>
<tr>
<td>Eczema severity (mild/moderate/severe)</td>
<td>172/199/206</td>
<td>94/145/116</td>
<td>156/165/125</td>
</tr>
<tr>
<td>DLQI (mean ± SD)</td>
<td>12.9 ± 4.1</td>
<td>12.8 ± 4.1</td>
<td>12.8 ± 4.1</td>
</tr>
<tr>
<td>SCORAD (mean ± SD)</td>
<td>62.6 ± 20.5</td>
<td>62.6 ± 20.5</td>
<td>62.6 ± 20.5</td>
</tr>
</tbody>
</table>

Figure 1. Schedule of PRO measure assessments in initial 16-week period

Figure 2. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 3. Changes in daily eczema-related sleep NRS in ECZTRA 1, 2, and 3

Figure 4. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 5. Changes in DLQI and SCORAD in ECZTRA 1, 2, and 3

Figure 6. Changes in POEM and ECGS in ECZTRA 1, 2, and 3

Figure 7. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 8. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 9. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 10. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 11. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 12. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 13. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 14. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 15. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 16. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 17. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 18. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 19. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3

Figure 20. Changes in worst daily pruritus NRS in ECZTRA 1, 2, and 3