The impact of tralokinumab on quality of life in patients aged 12–17 with atopic dermatitis: results from the phase 3 ECZTRA 6 trial

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Introduction:
Adolescents is a fully human monoclonal antibody that blocks with high affinity to interleukin 12, a key driver of atopic dermatitis (AD) pathogenesis.1,2
• AD is a chronic inflammatory skin disease associated with poor quality of life (QoL) and substantial psychosocial impairment.1

The phase 3 ECZTRA 6 trial (NCT03526861) of patients aged 12–17 years with moderate-to-severe AD showed:
• Tralokinumab monotherapy had superior efficacy to placebo for all primary and key secondary endpoints, including change in Children’s Dermatology Life Quality Index (CDLQI) from baseline to Week 16.1

Objective:
To examine the impact of tralokinumab on AD-related QoL and school in adolescents during Weeks 0–16 of the ECZTRA 6 trial (NCT03526861).1

Materials and Methods:
Study design:
Adolescents with moderate-to-severe AD (n=289) received tralokinumab 150 mg or 300 mg or placebo every 2 weeks (Q2W) during the initial trial phase (Weeks 0–16).2 QoL and impact on school were measured using the CDLQI, a 10-item, patient/caregiver-reported questionnaire, at baseline and Weeks 0, 2, 4, 12, and 16. Patients who received rescue medication (topical calcineurin inhibitor (TCI), TCS, systemic treatment) were used if medically necessary.2

Statistical analysis:
Change in CDLQI and reduction of CDLQI ≥6: Weeks 0–16
• At Week 16, adjusted mean change from baseline in CDLQI was significantly greater with tralokinumab 150 mg (n=83) and 300 mg (n=82) vs placebo (n=84) and was similar with both tralokinumab groups (p=0.012; Table 1).
• More patients had ≥6-point reduction (minimal important difference) in adolescents with tralokinumab 150 mg (30.8%) and 300 mg (33.7%) vs placebo (15.9%) (difference* 14.9% and 21.9% respectively) (p=0.0049; Table 1).

Figure 1. Adjusted mean change in CDLQI and reduction of CDLQI ≥6 by week

Data presented as mean (95% CI). CDLQI, Children’s Dermatology Life Quality Index; CI, confidence interval. *Between-arm difference. 1, 2, 4, and 12 weeks. Significance at the 0.05 level. **Between arm difference, p<0.001.

Results:
Change in CDLQI and reduction of CDLQI ≥6: Weeks 0–16
• At Week 16, adjusted mean change from baseline in CDLQI was significantly greater with tralokinumab 150 mg (n=83) and 300 mg (n=82) vs placebo (n=84) and was similar with both tralokinumab groups (p=0.012; Table 1).
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Table 1. Change in CDLQI and reduction of CDLQI ≥6

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Tralokinumab 150 mg</th>
<th>Tralokinumab 300 mg</th>
<th>Placebo</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean change from baseline (95% CI)</td>
<td>-11.6 (-18.3 to -4.8)</td>
<td>-13.2 (-19.6 to -6.8)</td>
<td>-2.8 (-9.2 to 3.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients with CDLQI ≥6-point reduction (%)</td>
<td>30.8 (22.9–39.0)</td>
<td>33.7 (25.2–42.2)</td>
<td>15.9 (10.1–22.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Discussion:
In the ECZTRA 6 trial, tralokinumab significantly improved quality of life and school outcomes in adolescents with moderate-to-severe AD.2

Conclusion:
Tralokinumab improved QoL and school outcomes in adolescents with moderate-to-severe AD.2 The impact of tralokinumab on quality of life and school in patients aged 12–17 with atopic dermatitis: results from the phase 3 ECZTRA 6 trial

References:
1. Becker T. Allergy. 2020;75:54
8. Wobbe, A. J. Presented at 2021 Fall Clinical Conference of the American Academy of Dermatology

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Disclosure:
The authors declare no conflicts of interest.

Appendix E. Figures A-F. Click to download a copy of this poster.