Safety of tralokinumab for the treatment of atopic dermatitis in patients with up to 4.5 years of treatment: an updated integrated analysis of eight clinical trials

**Background**

The safety of tralokinumab for the treatment of atopic dermatitis (AD) in patients with up to 4.5 years of treatment is evaluated in an updated integrated analysis of eight clinical trials.

**Objective**

To evaluate the long-term safety of tralokinumab in an integrated analysis of seven placebo-controlled phase 3 patient trials up to 52 weeks' duration, and the ongoing, up to 5-year extension study (CTICDIN).

**Results**

**Treatments Exposure and Discontinuations**

- In the ALL-TIROL-005 Safety Set, 2031 patients (72 years) received tralokinumab for up to 235.6 weeks (4.5 years) with a median duration of AD 27.8 weeks (range 15.4-72.0). Most patients discontinued due to AE (n=1939; PYE=587.2).

**AEs and Incidence Rates of Select Treatment-Emergent AEs**

- Incidence rates were calculated as weighted average using Cochran-Mantel-Haenszel method.

**Overall Summary of TEAEs**

- Safety data were analyzed as two datasets: PBO-CTRL Safety Set (Week 0-16) and Tralokinumab Safety Set (Week 0-52).

**Most Frequently Reported AEs**

- The most frequently reported AEs occurring more frequently than the known safety profile of tralokinumab were: nasopharyngitis, upper respiratory tract infection, conjunctivitis, injection site reaction, conjunctival allergy, and injection site pain.

**Conclusions**

- Long-term use of tralokinumab up to 4.5 years was well-tolerated in patients (72 years).

**Abbreviations**

- AE: adverse event
- ADR: adverse drug reaction
- AD: atopic dermatitis
- AESI: AE of special interest
- BMI: body mass index
- EASI: Eczema Area and Severity Index
- HLT: high level term
- IGA: Investigator's Global Assessment
- IL-13: interleukin-13
- IR: Incidence rate
- JP: Japan
- MedDRA: Medical Dictionary for Regulatory Activities
- PT: patient treated
- PYE: patient years of exposure
- RCT: randomized controlled trial
- TEAE: treatment-emergent adverse event
- TCS: topical corticosteroids
- TDS: total drug exposure
- TCD: target condition duration
- TIV: total investigator visits
- TIV-E: total investigator evaluations
- TIV-Q: total investigator questionnaires
- TIV-R: total investigator reviews
- TIV-S: total investigator visits
- TIV-Q: total investigator questionnaires
- TIV-R: total investigator reviews
- TIV-S: total investigator visits

**Methods**

- Cases were analyzed:
  - A placebo-controlled (PBO-CTRL) safety analysis set included patients treated with tralokinumab compared with placebo in the initial 16-week period of seven phase 3 trials.
  - An active-controlled (ALL-TIROL) safety analysis set combined the patient data from the subsequent CTICDIN trial including patients from tralokinumab and etrolizumab in trilium exposure or the CTICDIN extension study (CTICDIN 30th-2021).

- Incidence rates were calculated as weighted average using Cochran-Mantel-Haenszel method.

- AE of special interest (AESI) included: eye disorders, skin infections requiring systemic treatment, eczema herpeticum, and malignancies were observed in the PBO-CTRL Safety Set and or/all in the ALL-TIROL Safety Set, or for both datasets.

**Baseline Demographics and Characteristics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>PBO-CTRL Safety Set</th>
<th>Tralokinumab Safety Set</th>
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</thead>
<tbody>
<tr>
<td>Age group, n (%)</td>
<td></td>
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<tr>
<td>&lt;2 years</td>
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<td>279 (60.1)</td>
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<tr>
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<td>12 years and over</td>
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</tr>
<tr>
<td>Male, n (%)</td>
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<tr>
<td>Female, n (%)</td>
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<td>Female, n (%)</td>
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</tr>
</tbody>
</table>

**Incidence Rates of Select Treatment-Emergent AEs**

- Incidence rates were calculated as weighted average using Cochran-Mantel-Haenszel method.

**Other Safety Areas of Clinical Interest**

- The findings are consistent with the known safety profile of tralokinumab. There were no new safety signals detected.