Efficacy and safety of up to two years of tralokinumab treatment in adults of different racial subgroups with moderate-to-severe atopic dermatitis

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Introduction
- Atopic dermatitis (AD) is a chronic skin disease which may impact patients throughout their lifetime, requiring effective long-term treatment options with acceptable safety profiles.
- Although AD is highly prevalent in patients with skin of color, data on the efficacy of AD therapies in these patients is limited since most clinical trials enroll predominantly White patients.

Several standard measures, including IGA, can underrepresent AD severity in diverse populations.
- Tralokinumab is a specific, high-affinity interleukin-31 inhibitor, is approved in Europe, Canada, and the United States for the treatment of adults with moderate-to-severe AD.
- ECZTEND-ICT130978R5 is an ongoing open-label extension trial assessing the safety and efficacy of tralokinumab over 5 years after the completion of parent trial PT3.

Objective
To evaluate the efficacy and safety of up to 2 years of tralokinumab treatment by self-identified racial subgroup (Black, White in adults with moderate-to-severe AD).

Materials and Methods

Patients and treatment
- In ECZTEND, patients who completed PT3 of tralokinumab received open-label tralokinumab 300 mg every two weeks (Q2W), home use of topical corticosteroids (mNRI i/c/oc 23–50), and optional topical corticosteroids (mNRI i/c/oc 5–23) or topical calcineurin inhibitors with visits every 8 weeks.
- All patients who completed PT3 at sites with ECZTEND were eligible to enroll in ECZTEND, regardless of prior treatment or response.
- For key inclusion and exclusion criteria, please see Blauvelt et al2.
- All patients were evaluated in the post hoc analysis of the efficacy and safety of tralokinumab treatment in ECZTEND by the data cutoff 30/03/2022 (Figure 1).

Responders, %

| Responders, % | Wors... | Evidence of AD improvement (EASI-75, -90, -95)

| Responders, % | DLQI ≤5 | EASI-75, -90, -95

| Responders, % | IG... | 0/1

Values are presented as mean (SD) unless otherwise stated.

Table 1. Baseline demographic and disease characteristics of patients by racial subgroup

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Asian</th>
<th>Hispanic or Latino</th>
<th>Native American or Alaska Native</th>
<th>Caucasian</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>37.4 (10.3)</td>
<td>37.1 (10.8)</td>
<td>36.6 (10.7)</td>
<td>37.0 (10.5)</td>
</tr>
<tr>
<td>Gender</td>
<td>47% male</td>
<td>52% male</td>
<td>54% male</td>
<td>49% male</td>
</tr>
<tr>
<td>Residence</td>
<td>United States, 52% (214)</td>
<td>United States, 57% (293)</td>
<td>United States, 77% (139)</td>
<td>United States, 79% (205)</td>
</tr>
<tr>
<td>Age at AD onset (years)</td>
<td>9.2 (10.7)</td>
<td>9.2 (7.9)</td>
<td>8.9 (11.7)</td>
<td>8.7 (7.2)</td>
</tr>
<tr>
<td>AD duration (years)</td>
<td>10.6 (7.2)</td>
<td>10.6 (7.3)</td>
<td>10.6 (7.2)</td>
<td>10.6 (7.2)</td>
</tr>
</tbody>
</table>

Adjusting for differences in baseline characteristics and country between subgroups impacts estimated response proportions.
- Adjusted for race and country as main effects, EASI-75 was achieved in 86% of Asian patients, 89% of Black patients, and 87% (67/79) of White patients, as observed (Figure 2).
- Similar patterns of response were observed for EASI-40, EASI-70, IGA 0/1, and DLQI ≤5, and when using LiCI or LiKRC to account for missing data (Figure 3 and 4).

Conclusions
- Improvements in disease severity, itch, and quality of life were comparable across different racial subgroups following up to two years of tralokinumab treatment in adults with AD.
- Limited the analysis included the total of pokalololarm in ECZTEND, disparate country data across races (especially non-White populations) and the lower response rates observed for the Asian subgroup relative to other racial groups, which could be potentially explained, by adjusting for country.

Abbreviations
- AD: atopic dermatitis.
- A: Asian.
- Adj: adjusted
- C: Caucasian.
- EASI: Eczema Area and Severity Index.
- ECZTEND: ECZema Treatment and Efficacy with Tralokinumab Dosing in Daily Practice.
- IQ: investigator.
- IGA: Investigator’s Global Assessment.
- LiCI: linear mixed-effects imputation with country-specific thresholds.
- LiKRC: linear mixed-effects imputation with country-specific cutoffs.
- M: male.
- N: number.
- Of: of.
- P: percentage.
- R: racial.
- SD: standard deviation.
- W: White.
- Wh: White.

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Disclosures
The authors declare no competing interests.

Supporting Information
- Figure S1. Schematic of ECZTEND interim analysis of adult patients and 30 patient disposition at parent trial completion, ECZTEND baseline, and at April 30, 2021 data cutoff.
- Table S1. Baseline demographic and disease characteristics of patients by racial subgroup.
- Table S2. Summary of all AD by EASI for racial subgroups.