Introduction

- Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with significant disease burden.
- Although AD is highly prevalent in patients with skin of color, data on the efficacy and safety of AD therapies in these patients is limited since most clinical trials enroll predominantly White patients.
- Several standard measures, including EASI, can underestimate AD severity in dark skin.

- Tralokinumab, a specific, high-affinity interleukin-13 inhibitor, is approved in Europe, Canada, and the United States for the treatment of adults with moderate-to-severe AD.
- ECZTRA 1 (NCT03368654), ECZTRA 2 (NCT03676835), and ECZTRA 3 (NCT03753935) were randomized phase 3 trials assessing the safety and efficacy of tralokinumab or placebo + TCS as needed.

Patients and treatment

- ECZTRA 1 and 2 were two identically designed multinational, double-blinded, randomized, placebo-controlled, 52-week trials.
- Patients were randomized 3:1 to subcutaneous tralokinumab 300 mg or placebo every 2 weeks (GW) for an initial 16 weeks following a 600 mg loading dose.
- Patients who achieved IGA 0/1 at EAS-75 at Week 16 with tralokinumab were randomized to tralokinumab GW or every 4 weeks, or placebo, for an additional 52 weeks.
- Rescue treatment could be used at the discretion of the investigator to control intolerable symptoms.
- In ECZTRA 3, patients were randomized 2:1 to subcutaneous tralokinumab 300 mg + TCS as needed or placebo + TCS as needed GW for an initial treatment period of 16 weeks following a 600 mg loading dose.
- Patients who achieved IGA 0/1 at EAS-75 at Week 16 with tralokinumab were randomized to tralokinumab GW or every 4 weeks, or placebo, with TCS as needed, for an additional 16 weeks.
- Patients self-reported their racial subgroup.

Materials and Methods

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- Patients self-reported their racial subgroup.

Table 1. Baseline demographic and disease characteristics of patients by racial subgroup in pooled 1/2/3 trials

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Black</th>
<th>White</th>
<th>Asian</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>35.2 (12.3)</td>
<td>36.0 (11.6)</td>
<td>31.1 (15.8)</td>
<td>35.0 (11.9)</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>44/56</td>
<td>217/343</td>
<td>133/137</td>
<td>584/396</td>
</tr>
<tr>
<td>Sex distribution (%)</td>
<td>48.4</td>
<td>57.4</td>
<td>50.4</td>
<td>54.8</td>
</tr>
<tr>
<td>DLQI (SD)</td>
<td>19.7 (9.7)</td>
<td>17.2 (9.7)</td>
<td>17.2 (9.7)</td>
<td>17.7 (9.7)</td>
</tr>
<tr>
<td>N (%)</td>
<td>99</td>
<td>98</td>
<td>98</td>
<td>98</td>
</tr>
<tr>
<td>Sex distribution (%)</td>
<td>50.0</td>
<td>50.0</td>
<td>51.5</td>
<td>50.5</td>
</tr>
</tbody>
</table>

Results

- This post hoc analysis included 1867 patients (USPI population) across ECZTRA 1, 2, and 3 who self-reported that race as Asian, Black, or White.
- Baseline demographic and disease characteristics were largely balanced between treatment groups and across racial subgroups (Table 1): patients were more in the White subgroup.

Table 2. Summary of AEs through Week 16 in ECZTRA 1/2/3 by racial subgroup

<table>
<thead>
<tr>
<th>Condition</th>
<th>Black</th>
<th>White</th>
<th>Asian</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total AEs</td>
<td>53 (45.7)</td>
<td>42 (36.5)</td>
<td>16 (12.7)</td>
</tr>
<tr>
<td>AEs leading to withdrawal</td>
<td>10 (8.6)</td>
<td>13 (11.4)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>Serious AEs</td>
<td>7 (5.8)</td>
<td>6 (5.2)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Rate (%)</td>
<td>2.8 (2.8)</td>
<td>1.9 (1.9)</td>
<td>1.1 (1.1)</td>
</tr>
<tr>
<td>Rate (%)</td>
<td>2.8 (2.8)</td>
<td>1.9 (1.9)</td>
<td>1.1 (1.1)</td>
</tr>
</tbody>
</table>

Conclusions

- In this post hoc analysis, tralokinumab was well-tolerated and improved the signs and symptoms of moderate-to-severe AD, regardless of race, with further improvements up to 52 weeks of treatment.
- Limitations of this analysis include disparate sample sizes across racial subgroups.

Acknowledgements

[...]

References

[...]

Disclosures

[...]