Specifically targeting interleukin-13 with tralokinumab improved sleep in two Phase 3, randomized, double-blind, placebo-controlled trials in patients with atopic dermatitis

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Introduction

Eczema affects a considerable fraction of the general population and is associated with a number of comorbidities, including worse sleep quality. Given the connection between improved sleep and other eczema outcomes, we examined the impact of tralokinumab, a monoclonal antibody for IL-13, on sleep in two large Phase 3 trials of patients with atopic dermatitis. These trials were identical in design, randomized, double-blind, placebo-controlled, multinational, 52-week trials of tralokinumab 300 mg given subcutaneously every 2 weeks (q2w) in patients with moderate-to-severe atopic dermatitis (ECZTRA 1 [n=802] and ECZTRA 2 [n=794]; Figure 1). Each trial consisted of a 16-week initial treatment period followed by an open-label extension period of 36 weeks with all patients receiving tralokinumab 300 mg q2w.

Methods

Study design and patients

- **SCORAD** and **POEM** sleep scores were assessed in patients with moderate-to-severe atopic dermatitis in the initial 16-week treatment period of ECZTRA 1 and 2. The percentage of patients in each of the five POEM sleep score categories was assessed at baseline and week 16. The percentage of patients with 3 or more nights of sleep disturbance was calculated. Several measures of sleep were assessed in ECZTRA 1 and 2 during the initial 16-week treatment period
- **Worst daily pruritus NRS weekly average score**
- **IGA score**
- **Mean SCORAD sleep score**
- **Mean visual analog scale of average sleeplessness**
- **Mean sleep efficiency**

Table 1. Patient-reported sleep measures assessed during the initial 16-week treatment period

<table>
<thead>
<tr>
<th>Measure</th>
<th>Scale</th>
<th>Ecztra 1 (n=802)</th>
<th>Ecztra 2 (n=794)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst daily pruritus NRS weekly average score</td>
<td>Daily residential chronicity symptoms</td>
<td>36 (5.8)</td>
<td>36 (5.8)</td>
</tr>
<tr>
<td>IGA score</td>
<td>0.0 to 100/0.0</td>
<td>32.9 (2.2)</td>
<td>32.2 (2.2)</td>
</tr>
<tr>
<td>Mean SCORAD sleep score</td>
<td>0.0 to 100/0.0</td>
<td>6.4 (2.1)</td>
<td>6.5 (2.1)</td>
</tr>
<tr>
<td>Mean visual analog scale of average sleeplessness</td>
<td>0.0 to 100/0.0</td>
<td>51.3 (6.9)</td>
<td>50.6 (6.9)</td>
</tr>
<tr>
<td>Mean sleep efficiency</td>
<td>0.0 to 1.0</td>
<td>97.8 (2.6)</td>
<td>97.5 (2.6)</td>
</tr>
</tbody>
</table>

Conclusions

- Tralokinumab monotherapy 300 mg every 2 weeks demonstrated improvements compared with placebo in all three sleep measures (NRS for eczema-related sleep interference, SCORAD sleep score, and POEM sleep score) during the initial 16-week treatment period
- Improvement in sleep measures was consistent across two large Phase 3 trials, ECZTRA 1 and ECZTRA 2
- A greater proportion of tralokinumab-treated patients reported either "no days" or "1–2 days" of sleep disturbance
- Early improvement in sleep measures as early as week 1 with tralokinumab is consistent with its effects on the signs and troublesome symptoms of atopic dermatitis, including pruritus

References