Improvements in itch and sleep disturbance are maintained to Week 48 with nemolizumab\(^b\) plus TCS/TCI treatment in patients with moderate-to-severe atopic dermatitis: results from two global phase 3 pivotal studies (ARCADIA 1 and ARCADIA 2)

**ARCADIA 1:** NCT03985943;
**ARCADIA 2:** NCT03989349

**OBJECTIVE**
- To evaluate the efficacy of nemolizumab\(^b\) in maintaining itch and sleep responses during double-blind, placebo-controlled, phase 3 studies (ARCADIA 1 and ARCADIA 2).

**SUMMARY OF STUDY FINDINGS**
- Based on data from the ARCADIA 48-week maintenance study of nemolizumab\(^b\) in patients with atopic dermatitis.
- Nemolizumab\(^b\) plus TCS/TCI maintained rates of improvements in itch and sleep through Week 48 in patients who achieved clinical response at Week 16.
- The QWIB dosing regimen was similar to the QWIB dosing regimen in terms of maintenance of efficacy over time and sleep disturbance.
- Nemolizumab\(^b\) was well tolerated up to Week 48.

**RESULTS**
- The proportion of patients achieving clinical response at Week 16 presented in Table 2.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Clinical response at Week 16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nemolizumab(^b) Q4W</td>
<td>78.9%</td>
</tr>
<tr>
<td>Placebo</td>
<td>43.8%</td>
</tr>
</tbody>
</table>

**Efficacy**
- At Week 48, response rates for 4-point improvement in SCORAD VAS Pruritus were maintained in the nemolizumab\(^b\)-Q4W (78.9%, P<0.0001) and nemolizumab\(^b\)-Q8W (69.9%, P<0.0001) vs placebo (49.1%); group response rates for ≥4-point improvement in weekly average Peak Pruritus NRS were also maintained in the nemolizumab\(^b\)-Q4W (72.5%, P<0.0001) and nemolizumab\(^b\)-Q8W (67.7%, P<0.0001) vs placebo (51.0%); group response rates for ≥4-point improvement in weekly average Peak Pruritus NRS (ITT, NRI analysis).

**Safety**
- Adverse events were consistent with the initial treatment period.

**INTRODUCTION**
- Atopic dermatitis is a common, chronic, and flaring inflammatory skin disease requiring long-term treatment.
- Interleukin-31 (IL-31) is a key neuropeptide cytokine in the pathophysiology of AD. Signals through the IL-31 receptor complex encoded by尘埃 AD receptor beta subunit (DARC) and the intercellular adhesion receptor alpha (IL-31RA), triggering itch, skin barrier disruption, and exacerbation of inflammation.\(^1\)
- Nemolizumab\(^b\) is a humanized IgG1 monoclonal antibody that inhibits the binding of IL-31 to its receptor.
- Nemolizumab\(^b\) plus topical corticosteroids (TCS) and/or topical calcineurin inhibitors (TCI) achieved improvements in itch and sleep (measured using Peak Pruritus Numerical Rating Scale and Sleep Disturbance Numerical Rating Scale) at Week 0/16 and maintained them up to Week 48 in patients with moderate-to-severe AD.\(^2\)

**METHODS**
- **Study Design**
  - We conducted a 12-week maintenance data pooled from two double-blind, placebo-controlled, phase 3 studies (ARCADIA 1 and ARCADIA 2).

**REFERENCE**

**Figure 4.** (A) ≥4-point improvement in SCORAD VAS Pruritus (ITT, NRI analysis). (B) ≥4-point improvement in weekly average Peak Pruritus NRS (ITT, NRI analysis).

**Figure 4. (A)** ≥4-point improvement in SCORAD VAS Pruritus (ITT, NRI analysis). (B) ≥4-point improvement in weekly average Peak Pruritus NRS (ITT, NRI analysis).