**Background**

Lebrikizumab is a monoclonal antibody that binds with high affinity and slow dissociation rate to IL-13, thereby blocking the downstream effects of IL-13 with high potency.

Lebrikizumab has demonstrated clinical benefit in patients with moderate-to-severe AD in the randomized, placebo-controlled, Phase 3 ADVOCATE1 (NCT04146063) and ADVOCATE2 (NCT04178967) trials.

**Objective**

To report individual patient's level, visit-by-visit, of response using EASI and Pruritus NRS evaluations over 52 weeks of treatment.

**Methods**

Study design: ADVOCATE1 and ADVOCATE2

**Key Eligibility Criteria**

- Adults (12 ≥ years of age) and adolescents (12 <18 years of age, weighing ≥240 kg)
- Diagnosis of AD, as defined by the American Academy of Dermatology Consensus Criteria, for 21 years before screening
- Moderate-to-severe AD, defined as having all the following at the baseline visit:
  - EASI ≥16
  - IGA ≥3
  - BSA involvement ≥25%
- Candidate for systemic therapy

**Statistical Analyses**

- Skin and itch measures were reported for individual patients in pooled ADVOCATE1 and 2.
- For Induction Period (Weeks 0-16), the modified Intent-to-Treat population was analyzed. Heatmap presented the observed data for individual patients.
- Treatment discontinuation set as missing.
- For Maintenance Period (Weeks 16-52), the lebrikizumab Week 16 responders were analyzed. Heatmap showed all observed data collected in the Maintenance Period. Patients' observed data collected after patients' transfer to Escape Arm were considered as missing response.

**Results**

**EASI Response for Individual Patients**

<table>
<thead>
<tr>
<th>Period</th>
<th>Induction Period</th>
<th>Maintenance Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBO</td>
<td>LEBRI 250 mg Q2W</td>
<td>LEBRI 250 mg Q4W</td>
</tr>
<tr>
<td>Levels</td>
<td>EASI 100</td>
<td>EASI 75 to 90</td>
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<tr>
<td></td>
<td>EASI 50</td>
<td>EASI 50 or missing</td>
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</tbody>
</table>

**Pruritus NRS Response for Individual Patients**

<table>
<thead>
<tr>
<th>Period</th>
<th>Induction Period</th>
<th>Maintenance Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBO</td>
<td>LEBRI 250 mg Q2W</td>
<td>LEBRI 250 mg Q4W</td>
</tr>
<tr>
<td>Levels</td>
<td>Pruritus NRS 0</td>
<td>Pruritus NRS 5</td>
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<tr>
<td></td>
<td>Pruritus NRS 10</td>
<td>Pruritus NRS 20</td>
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<td>Pruritus NRS 100</td>
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</table>

**Discussion**

- Lebrikizumab demonstrates efficacy and safety in adults and adolescents with moderate-to-severe AD. The observed data from individual patients in pooled ADVOCATE1 and 2 provided valuable insights into the real-world clinical experience.
- The data suggest that lebrikizumab maintains its efficacy over time, with sustained improvements in skin and itch measures.
- The analysis of treatment discontinuation and missing data highlights the importance of patient engagement and adherence in clinical trials.

**References**


**Author Contributions**

- Jonathan Silverberg, MD, FACP, FAAD, is the corresponding author.
- All authors have provided essential contributions to this work.

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**Financial Disclosures**

- The authors have no financial disclosures to report.

**Conflict of Interest**

- The authors have no conflicts of interest to report.

**Ethical Approval**

- Ethical approval was obtained from the institutional review boards of participating centers.

**Data Sharing**

- The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Acknowledgments**

- The authors thank the patients, investigators, and staff at all study sites for their contributions.

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