Lebrikizumab Demonstrates Consistent Efficacy at 16 Weeks in Patients With Moderate-to-Severe Atopic Dermatitis Regardless of Baseline Disease Severity

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BACKGROUND

Lebrikizumab is a monoclonal antibody that binds with high affinity and slow dissociation rate to IL-13 with high potency.1

Lebrikizumab has demonstrated clinical benefit in patients with moderate-to-severe AD in the randomized, placebo-controlled, Phase 3 Advocate1 (NCT04463633) and Advocate2 (NCT04178967) trials.1,2

OBJECTIVE

To assess efficacy of lebrikizumab in the Advocate1 and Advocate2 trials within subgroups of patients with moderate (IGA=3) vs. severe (IGA=4) AD at baseline

CONCLUSION

Regardless of baseline disease severity, lebrikizumab 250 mg Q2W demonstrated consistent and robust efficacy on skin and itch in patients with moderate or severe AD at Week 16

METHODS

Study Design: Advocate1 and Advocate2

RESULTS

Baseline Demographics

<table>
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<tr>
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<th>Overall</th>
<th>Moderate AD (Baseline IGA=3)</th>
<th>Severe AD (Baseline IGA=4)</th>
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</thead>
<tbody>
<tr>
<td>Age, years, n (%)</td>
<td>30.7 (7.6)</td>
<td>26.0 (6.9)</td>
<td>38.5 (13.2)</td>
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<tr>
<td>Gender, n (%)</td>
<td>148 (51.6)</td>
<td>74 (54.5)</td>
<td>74 (46.8)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>109 (38.0)</td>
<td>70 (52.2)</td>
<td>39 (25.0)</td>
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Key Efficacy Criteria

- Adults (≥18 years of age) and adolescents (12 to <18 years of age, weighing ≥40 kg)
- Diagnosis of AD, as defined by the American Academy of Dermatology Consensus Criteria, for ≥1 year before screening
- Moderate-to-severe AD, defined as having all the following at the baseline visit:
  - IGA ≥3
  - BSA involvement ≥10%
- Candidate for systemic therapy
- Outcome
- Treatment difference for lebrikizumab vs. placebo between the baseline AD subgroups, moderate AD (IGA=3) vs. severe AD (IGA=4), was calculated at Week 16 for:
  - IGA 0/1 with ≥2-point improvement
  - IGA 75%
- DISCUSSIONS
- The pooled modified ITT population excluded 18 patients in the Advocate2 study (from a single study site), whose eligibility could not be confirmed
- The Pruritus NRS is a patient-reported, single-item, 11-point scale that is used daily by participants to rate their worst itch severity over the past 24 hours (0 indicating “no improvement”)
- At Week 16, the treatment effect of lebrikizumab was consistent regardless of baseline disease severity

REFERENCES

3 Galderma, Janssen, LEO Pharma, Novartis, Sanofi, and UCB Pharma; Valeant Pharmaceuticals; Sun Pharma, and UCB Pharma

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At Week 16, the treatment effect of lebrikizumab was consistent regardless of baseline disease severity

| Treatment | PBO | Lebrikizumab 250 mg Q2W
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<tr>
<td>EASI 90b</td>
<td>23.6 (16.3-30.9)</td>
<td>27.9 (20.4-35.4)</td>
</tr>
<tr>
<td>Pruritus NRS ≥4-Point Improvementbc</td>
<td>28.2 (20.4-36.0)</td>
<td>34.2 (25.3-43.1)</td>
</tr>
</tbody>
</table>

Note: Data are mean (SD) unless stated otherwise

- The pooled modified ITT population included 345 patients (219 treated with PBO and 126 treated with LEBRI)
- IGA (0,1) with ≥2-point improvement
- Logistic regression analysis was used to test the interaction of treatment by baseline severity subgroup
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- Pooled modified ITT; a Includes multiple, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, other, and not reported
- EMA-European Medicines Agency; FDA-US Food and Drug Administration; IGA-Investigator’s Global Assessment; N=564; PBO-placebo; Pooled modified ITT; b Includes multiple, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, other, and not reported