Efficacy and Safety of Lebrikizumab Is Maintained to Two Years in Patients With Moderate-to-Severe Atopic Dermatitis


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SUMMARY OF KEY FINDINGS

Efficacy Outcomes Were Maintained Through 2 Years of Treatment With Lebrikizumab

<table>
<thead>
<tr>
<th>Outcome</th>
<th>%</th>
<th>LEBRI 250 mg Q4W (N=99)</th>
<th>LEBRI 250 mg Q2W (N=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGA (0,1)</td>
<td>76.4</td>
<td>76.8</td>
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<tr>
<td>EASI 75</td>
<td>98.3</td>
<td>98.6</td>
<td></td>
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<tr>
<td>EAST 90</td>
<td>82.5</td>
<td>72.0</td>
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<tr>
<td>Pruritus NRS 24-point improvement</td>
<td>89.7</td>
<td>90.0</td>
<td></td>
</tr>
</tbody>
</table>

*Data were reported through 16 weeks only from Pruritus NRS 24-point improvement (N=104 [101 responder, 3 weeks])

1. Okragly AJ, et al. Parent Study (ADvocate 1&2 or ADhere) were defined as those patients who achieved either EASI 75 or IGA (0,1) following 16 weeks of LEBRI 250mg Q2W treatment without use of rescue therapy

METHODS

Study Design

Lebrikizumab (with or without TCS) was efficacious in providing clinically meaningful improvements in the signs and symptoms of AD through Week 52 among adult and adolescent patients with moderate-to-severe AD.

OUTCOMES

Outcomes were assessed during the Maintenance Period of ADvocate 1&2 (Week 16-104) and then for 52 weeks in ADjoin (Week 105-128). Patients were randomized to LEBRI 250 mg Q4W or LEBRI 250 mg Q2W. Efficacy was assessed up to 88 weeks in ADjoin (Week 16-104).

ADjoin - Long-Term Extension

- Patients were included if they completed the study treatments and had no flare of AD prior to screening.
- Patients were excluded if in the parent trial they: did not have a true AD diagnosis; were not allergic to AD; and had a history of significant allergy or asthma.
- Conditions in the previous parent study were consistent with protocol-defined criteria for permanent study drug discontinuation.
- All adverse events (AE) were recorded.

RESULTS

- Efficacy analysis: as observed analyses used all collected data regardless of rescue medication use; response rates were reported as descriptive.
- Adverse events were assessed during the Maintenance Period of ADvocate 1&2 (Week 16-52) and then for 52 weeks in ADjoin (Week 105-128).
- Safety data were reported from ADjoin enrollment up the data cutoff April 14, 2023.

CONCLUSIONS

- Lebrikizumab provided durable efficacy in skin and itch outcomes through 2 years of treatment with both monthly and 2-week dosing.

- No new safety signals were noted.

REFERENCES

1. Okragly AJ, et al. Parent Study (ADvocate 1&2 or ADhere) were defined as those patients who achieved either EASI 75 or IGA (0,1) following 16 weeks of LEBRI 250mg Q2W treatment without use of rescue therapy

ABBRIVIATIONS

AD = atopic dermatitis; AE = adverse event; BSA = body surface area; EASI = Eczema Area and Severity Index; IGA = Investigator’s Global Assessment; IGA (0,1) = IGA response of clear or almost clear; IL = interleukin; LD = loading dose; PBO = placebo; RCT = randomized controlled trial; TCS = topical corticosteroids; WRT = withdrawal rate tolerance.