Efficacy of Baricitinib in Patients With Atopic Dermatitis and Atopic Comorbidities: Results of Pooled Data From 2 Phase 3 Monotherapy Randomized, Double-blind, Placebo-Controlled 16-Week Trials (BREEZE-AD1 and BREEZE-AD2)

Andreas Wollenberg, 1 Mark Boguniewicz, 2 Jeffrey B. Travers, 2 Jacob P. Thysen, 2 Orin Goldblum, 6 Susan G. Ball, 5 Luna Sun, 5 Sherry Chen, 4 Jonathan I. Silverberg 2

1 Ludwig Maximilian University, Munich, Germany; 2 National Jewish Health, Denver, USA; 3 Wake Forest State University, Winston-Salem, NC, USA; 4 University of Copenhagen, Herlev and Gentofte Hospital Department of Dermatology and Allergy, Hellerup, Denmark; 5 Eli Lilly and Company, Indianapolis, USA; 6 Syneos Health, Morrisville, USA; 7 Northwestern University, School of Medicine, Evanston, USA

BACKGROUND

Atopic dermatitis (AD) is a chronic inflammatory skin disease that may affect up to 20% of the global population. Baricitinib (BARI) is an oral Janus kinase (JAK) inhibitor approved for the treatment of moderate-to-severe AD in adults. The objective of this analysis was to evaluate the efficacy and safety of baricitinib in patients with AD and atopic comorbidities.

OBJECTIVE

To assess the efficacy and safety of baricitinib in patients with AD and atopic comorbidities in two Phase 3 monotherapy randomized, double-blind, placebo-controlled 16-week trials (BREEZE-AD1 and BREEZE-AD2) in a pooled analysis.

METHODS

Study Design, BREEZE-AD1 and BREEZE-AD2

Key Eligibility Criteria

- Age ≥18 years
- Moderate-to-severe AD at screening
- IGA of 0 or 1c

Assessments

- EASI50
- PASI
- Itch NRS
- NRS=Numeric Rating Scale; PBO=placebo; QD=once daily; EASI50=Eczema Area and Severity Index 50% improvement;
- LSC=Least-Squares Change
- Baseline demographics and disease activity were similar in patients with or without atopic comorbidity

Statistical Analysis

- Population: pooled data from BREEZE-AD1 and BREEZE-AD2 clinical trials
- Efficacy analyses: intent-to-treat population
- Safety analyses: all randomized patients
- For continuous efficacy endpoints: analysis of covariance was used to evaluate differences between treatment groups at each time point. For dichotomous efficacy endpoints: analysis of variance was used to evaluate differences between groups
- For continuous safety variables: t tests were used to evaluate differences between groups
- For dichotomous safety variables: chi-square tests were used to evaluate differences between groups

RESULTS

Baseline Characteristics and Disease Activity

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>Moderate-to-severe AD at screening</th>
<th>IGA, n (%)</th>
<th>Itch NRS ≥4, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BARI 1-mg</td>
<td>357</td>
<td>100</td>
<td>78 (57.4)</td>
<td>26.7</td>
</tr>
<tr>
<td>BARI 2-mg</td>
<td>246</td>
<td>100</td>
<td>78 (57.4)</td>
<td>30.2</td>
</tr>
<tr>
<td>BARI 4-mg</td>
<td>248</td>
<td>100</td>
<td>78 (57.4)</td>
<td>33.8</td>
</tr>
<tr>
<td>PBO</td>
<td>493</td>
<td>100</td>
<td>78 (57.4)</td>
<td>39.5</td>
</tr>
</tbody>
</table>

Responders (%) at Week 16

- BARI 1-mg: 45.8%
- BARI 2-mg: 46.7%
- BARI 4-mg: 47.6%
- PBO: 36.2%

Conclusions

- There were no significant differences in the efficacy and safety of baricitinib across patients with and without atopic comorbidities.
- Baricitinib was well tolerated in patients with AD and atopic comorbidities.

Note: Figures and tables are not included in this brief summary for the sake of brevity. Full details are available in the full manuscript.