Long-term Efficacy and Safety of Brodalumab in Patients With Psoriasis Disease Duration <10 and ≥10 Years: Analysis of Two Phase 3 Studies

Benjamin Ehst,¹ George Han,² Scott Guenther,¹ Kimberly Eads,¹ Abby Jacobson³
¹Oregon Medical Research Center, Portland, OR; ²Icahn School of Medicine at Mount Sinai, New York, NY; ³The Dermatology Center of Indiana, Plainfield, IN; ⁴Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NJ

INTRODUCTION

• Brodalumab is a fully human anti-interleukin-17 receptor A monoclonal antibody that is efficacious in treating moderate-to-severe plaque psoriasis.
• Evidence from studies of other biologics indicates that shorter disease duration may predict higher skin clearance rates.

OBJECTIVE

To characterize the relationship between psoriasis duration and brodalumab efficacy and safety.

METHODS

• Data were derived from two phase 3, multicenter, randomized clinical trials (AMAGINE-2/3).
• In both studies, patients with moderate-to-severe plaque psoriasis were initially randomized to brodalumab every 2 weeks (Q2W), ustekinumab, or placebo.
• At week 52, all patients entered the long-term extension and received brodalumab.
• In this post hoc analysis, skin clearance was assessed by 75% and 100% improvement in psoriasis area and severity index (PASI 75 and PASI 100, respectively) for patients who received any dose of brodalumab during the study and those who received continuous brodalumab 210 mg Q2W through week 120.

RESULTS

• Overall, 72.8% of patients receiving any dose of brodalumab had disease duration ≥10 years.
• In an observed analysis at week 52, for patients receiving any dose of brodalumab, 91.6% with disease duration ≥10 years and 92.4% with disease duration <10 years achieved PASI 75 (Figure 1A).
• PASI 75 response rates for patients receiving continuous brodalumab 210 mg Q2W were similar (≥10 years, 93.5%; <10 years, 94.4%; Figure 1B).
• At 120 weeks, patients receiving any dose of brodalumab and those receiving continuous brodalumab 210 mg Q2W achieved similar response rates of PASI 75 response regardless of disease duration (Figure 1).

• Observed PASI 100 responses at week 52 for patients with disease duration ≥10 years and <10 years were 54.0% and 54.4%, respectively, for patients receiving any dose of brodalumab and 62.7% and 65.2%, respectively, for patients receiving continuous brodalumab 210 mg Q2W (Figure 2).
• At week 120, 58.3% of patients receiving any dose of brodalumab with disease duration ≥10 years and 57.3% of patients with disease duration <10 years achieved PASI 100 (Figure 2).
• PASI 100 response rates for patients receiving continuous brodalumab 210 mg Q2W were similar at week 120 (disease duration ≥10 years, 63.4%; disease duration <10 years, 52.0%) (Figure 2).

Table 1. Exposure-Adjusted Rates of TEAEs in Patients Who Received ≥1 Dose of Brodalumab

<table>
<thead>
<tr>
<th>Preferred term, n</th>
<th>&lt;10 years (N=984; 1742.5 PY)</th>
<th>≥10 years (N=2640; 4787.0 PY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All TEAEs</td>
<td>4836 (277.5)</td>
<td>5888 (1157.3)</td>
</tr>
<tr>
<td>Grade ≥2</td>
<td>2558 (146.8)</td>
<td>2610 (52.7)</td>
</tr>
<tr>
<td>Grade ≥3</td>
<td>2100 (123.3)</td>
<td>610 (12.7)</td>
</tr>
<tr>
<td>Serious AEs</td>
<td>110 (6.3)</td>
<td>371 (7.8)</td>
</tr>
<tr>
<td>Fatal AEs</td>
<td>1 (0.1)</td>
<td>2 (0.1)</td>
</tr>
</tbody>
</table>

Safety

• For all study years, slightly higher rates of TEAEs were observed in those with disease duration ≥10 years compared with disease duration <10 years (Table 1).
• The rate of serious adverse events was similar between subgroups.

CONCLUSION

• Brodalumab is efficacious and well tolerated in patients with moderate-to-severe psoriasis regardless of disease duration.

Acknowledgments:
This study was sponsored by Ortho Dermatologics. Medical writing support was provided by MedThink SciCom and funded by Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

References:

© 2019 All Rights Reserved