Long-term Efficacy and Safety of Brodalumab in Patients With or Without History of Psoriatic Arthritis: Analysis of Two Phase 3 Psoriasis Studies

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Background: Psoriatic arthritis (PsA) is an inflammatory arthritis associated with psoriasis. Brodalumab is a fully human anti–interleukin-17 receptor A monoclonal antibody approved for treatment of moderate-to-severe plaque psoriasis (AMAGINE-2/-3; Figure 1) with or without a history of psoriatic arthritis.

METHODS

In AMAGINE-2/-3, 3625 patients received brodalumab, of whom 703 (19%) had a self-reported history of PsA at baseline and 2922 (80.6%) did not. Patients were initially randomized to brodalumab 140 or 210 mg every 2 weeks (Q2W), ustekinumab, or placebo. At week 52, all patients entered a long-term extension and received brodalumab. This analysis included patients who received any dose of brodalumab through week 120 and patients receiving brodalumab 210 mg Q2W after ustekinumab.

Skin clearance efficacy was measured by static physician’s global assessment (sPGA) and psoriasis area and severity index (PASI).

Psoriasis symptom inventory (PSI) and dermatology life quality index (DLQI) were also used.

RESULTS

Efficacy

In an observed analysis at week 120, 74.8% of patients receiving any dose of brodalumab with a history of PsA (n=1501) and 79.1% without a history of PsA (n=1501) had an sPGA score of 0 or 1.

• 75% improvement in PASI from baseline (PASI 75; Figure 2A), PASI 90 (Figure 2B), and PASI 100 (Figure 2C) responses were maintained from week 52 through week 120 in those receiving any dose of brodalumab with and without a history of PsA.

• At week 120, PASI 75 rates were 87.2% and 90.0%, PASI 90 rates were 76.0% and 78.7%, and PASI 100 rates were 57.8% and 58.0% in patients with and without a history of PsA, respectively.

• Skin clearance was also maintained at similar levels in patients with (n=105) and without (n=462) a history of PsA who received brodalumab 210 mg Q2W after ustekinumab.

• At week 120, PASI 75 rates were 86.2% and 91.3%, PASI 90 rates were 72.4% and 83.1%, and PASI 100 rates were 60.3% and 63.1% in patients with and without a history of PsA, respectively.

PSI and DLQI responses

• The rates of PSI and DLQI score of 0 or 1 responses were robust among brodalumab-treated patients at week 52 (the last observation time point).

• The rates of PSI response were 73.5% and 79.3% in patients with and without a history of PsA, respectively (Figure 3A).

• The rates of DLQI score of 0 or 1 were 67.2% and 72.4% in patients with and without a history of PsA, respectively (Figure 3B).

Safety

• Across all study years, TEAE rates in patients receiving any dose of brodalumab with and without a history of PsA were 331.9 and 292.8 per 100 patient-years, respectively (Table 1).

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

<table>
<thead>
<tr>
<th>Category</th>
<th>No history of PsA</th>
<th>History of PsA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEAEs</td>
<td>326.9 (312.2)</td>
<td>293.9 (282.3)</td>
</tr>
<tr>
<td>Serious AEs</td>
<td>83.6 (79.3)</td>
<td>72.5 (67.8)</td>
</tr>
<tr>
<td>Fatal AEs</td>
<td>1 (0.1)</td>
<td>1 (0.2)</td>
</tr>
</tbody>
</table>

• Skin clearance rates were maintained through week 120 in patients regardless of PsA history.

• The data presented here suggest that brodalumab is efficacious and well tolerated in patients with and without history of PsA.

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