Brodalumab is a fully human anti–interleukin-17 receptor A monoclonal antibody that antagonizes the action of specific inflammatory cytokines involved in psoriasis. One multicenter, randomized, placebo-controlled phase 3 trial (AMAGINE-1), 2 multicenter, randomized, placebo- and active comparator–controlled phase 3 trials (AMAGINE-2/3), and one phase 2 trial demonstrated the efficacy and safety of brodalumab in patients with moderate-to-severe psoriasis. All regions involved in the trials reported baseline rates of depression and SIB. Rates of SIB events were low throughout all trials (range, 0 to 0.77 per 100 patient-years [PY]).

**OBJECTIVE**

This analysis evaluated rates of depression adverse events (AEs) and SIB in patients participating in one phase 2 and three phase 3 clinical trials of brodalumab.

**METHODS**

**Study design**

Pooled data for all trials in patients who received any dose of brodalumab are included. Of note, the brodalumab trials had no exclusions based on the presence or history of psychiatric disorders or substance abuse.

**Endpoints/Assessments**

Rates of depression AEs and SIB (intentional self-injury, suicidal behavior, suicide attempt, and completed suicide) were consistent with those in other studies.

**RESULTS**

**Patient demographics and baseline disease characteristics**

A total of 4464 patients received brodalumab, with cumulative exposure times of 3672.6 PY in the US (n=1937), 1473.4 PY in Canada (n=631), 3492.7 PY in Europe (n=1651), 388.8 PY in Australia (n=180), and 134.4 PY in Russia (n=65).

**Safety**

At baseline, depression was observed across most study regions, which is representative of the psoriasis population (Figure 1).

**Figure 1.** Incidence of depression at baseline across geographic regions in patients who received any dose of brodalumab in any of the 4 trials.

<table>
<thead>
<tr>
<th>Region</th>
<th>Incidence Rate of Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>18.6%</td>
</tr>
<tr>
<td>Canada</td>
<td>18.7%</td>
</tr>
<tr>
<td>Europe</td>
<td>32.7%</td>
</tr>
<tr>
<td>Australia</td>
<td>18.6%</td>
</tr>
<tr>
<td>Russia</td>
<td>11.8%</td>
</tr>
</tbody>
</table>

Depression AE rate in PY from the first dose of brodalumab through end of study was also consistent across regions (Figure 2).

**Figure 2.** Depression adverse event rate in patient-years from the first dose of brodalumab through end of study.

**Figure 3.** Incidence of baseline SIB across geographic regions in patients who received any dose of brodalumab in any of the 4 trials.

SIB, suicidal ideation and behavior. Number of patients who had valid measurements at baseline: United States, 1937; Canada, 631; Europe, 1651; Australia, 180; and Russia, 65.

**Figure 4.** Follow-up observation time-adjusted incidence rates (per 100 patient-years) of SIB events from the first dose of brodalumab through end of study were consistent across regions.

**CONCLUSIONS**

- Clinical trials of brodalumab reflected real-world populations of patients with moderate-to-severe psoriasis.
- The patients in these 4 trials had baseline rates of depression and SIB that were consistent with those in other studies.
- The follow-up observation time-adjusted incidence rates (per 100 PY) of SIB events from the first dose of brodalumab through end of study were consistent across regions.

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