

# Distribution of Depression and Suicidality in a Psoriasis Clinical Trial Population

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## SYNOPSIS

- Patients with psoriasis have an increased risk of depression and suicidal ideation and behavior (SIB)<sup>1,2</sup>
- Brodalumab is a fully human anti-interleukin-17 receptor A monoclonal antibody that antagonizes the action of specific inflammatory cytokines involved in psoriasis<sup>3</sup>
- 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<sup>3,5</sup>
- 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) in the United States, Canada, Europe, Australia, and Russia were assessed at baseline and throughout the trials

## RESULTS

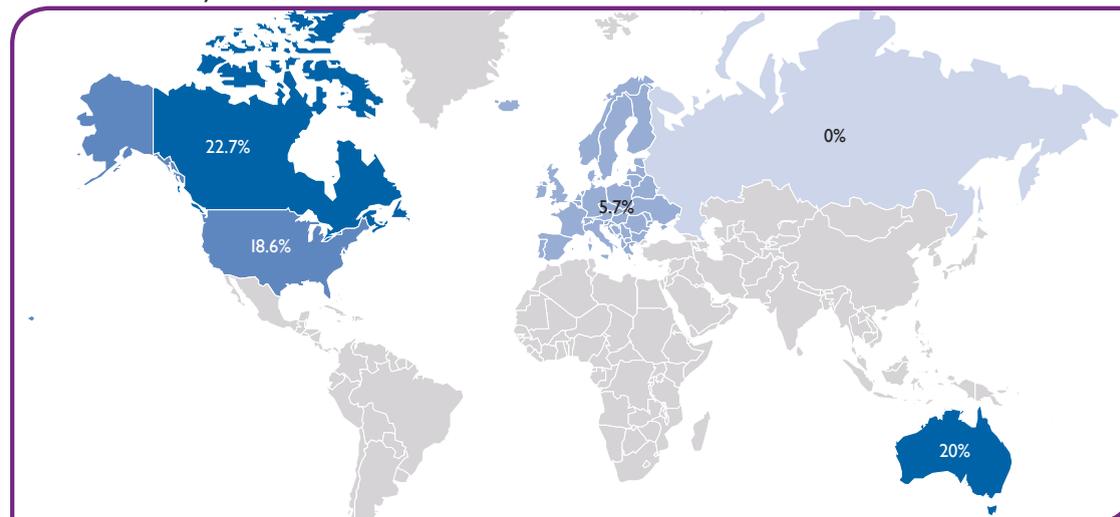
### Patient demographics and baseline disease characteristics

- 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)

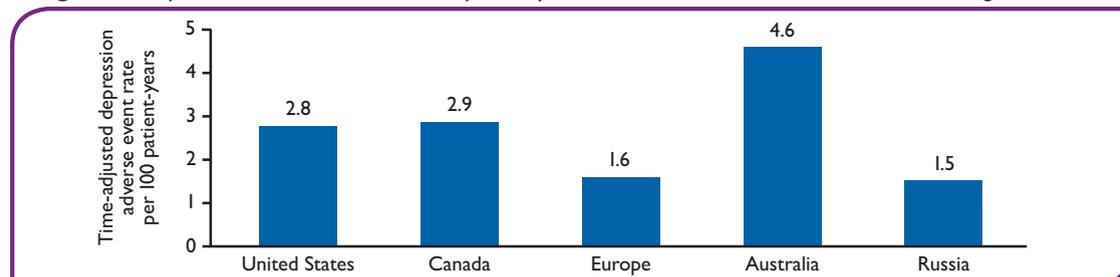
**Figure 1.** Incidence of depression at baseline across geographic regions in patients who received any dose of brodalumab in any of the 4 trials.



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

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

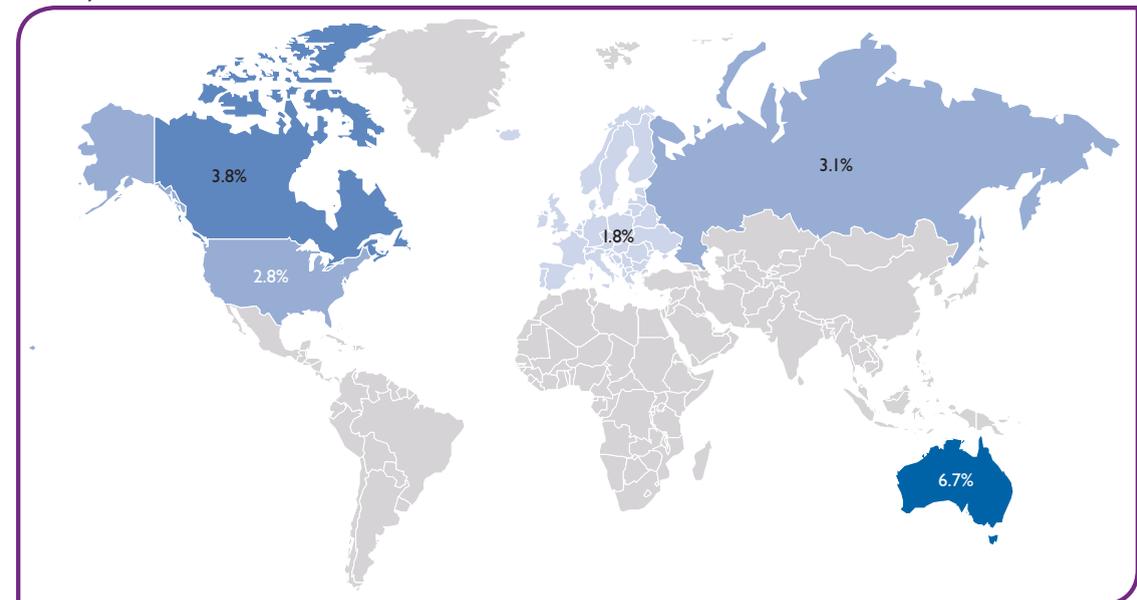
**Figure 2.** Depression adverse event rate in patient-years from the first dose of brodalumab through end of study.



Total patient-year exposure for each region: United States, 3680.9; Canada, 1473.5; Europe, 3496.3; Australia, 388.9; and Russia, 134.4.

- SIB was observed at baseline across all countries involved in the 4 trials (Figure 3)

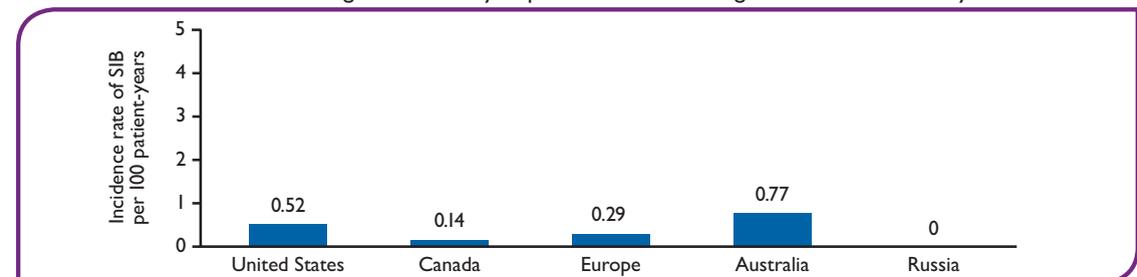
**Figure 3.** Incidence of baseline SIB across geographic regions in patients who received any dose of brodalumab in any of the 4 trials.



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.

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

**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 in patients from the long-term extension of any of the 4 trials.



SIB, suicidal ideation and behavior. Total patient-year exposure for each region: United States, 3672.6; Canada, 1473.4; Europe, 3492.7; Australia, 388.8; and Russia, 134.4.

## 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<sup>2</sup>
- 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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