PSORIASIS

LONG-TERM EFFICACY AND SAFETY OF BRODALUMAB BY GEOGRAPHIC REGION

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Introduction: Brodalumab is a fully human anti–interleukin-17 receptor A monoclonal antibody approved for the treatment of moderate-to-severe psoriasis.

Objective: Evaluate 120-week efficacy and safety of brodalumab in 2 multicenter randomized clinical trials (AMAGINE-2/-3) in patients with moderate-to-severe psoriasis from Europe, Canada, and the United States.

Materials and Methods: Patients were initially randomized to brodalumab every 2 weeks, ustekinumab, or placebo. At week 52, all patients received brodalumab. Skin clearance through week 120 was assessed by static physician's global assessment (sPGA), psoriasis area and severity index 75% improvement response (PASI 75), PASI 90, and PASI 100. Other assessments included dermatology life quality index (DLQI) and psoriasis symptom inventory (PSI; responders had a total score ≤8 with no item scores >1) through week 52. Safety was examined via exposure-adjusted rates of treatment-emergent adverse events (TEAEs) per 100 patient-years.

Results: Overall, 3625 patients received brodalumab (Europe: n=1590; Canada: n=406; US: n=1629), totaling 6531.6 patient-years of exposure. At week 120, sPGA score of 0 or 1 responses were 83.3% (Europe), 73.1% (Canada), and 73.7% (US), and PASI 100 rates were 64.0% (Europe), 46.3% (Canada), and 53.9% (US). PASI 75 and PASI 90 rates from week 52 to 120 were similar across regions. At week 52, PSI responses were 77.6% (Europe), 83.2% (Canada), and 77.5% (US), and DLQI score of 0 or 1 responses were 73.7% (Europe), 66.3% (Canada), and 70.0% (US). In the 12-week induction phase, TEAE rates in patients from Europe, Canada, and the United States were 444.9, 545.7, and 463.4 for placebo, respectively; 506.5, 484.1, and 468.5 for ustekinumab, respectively; and 605.2, 728.9, and 540.2 for brodalumab, respectively. Across all years, TEAE rates with brodalumab were 286.6 (Europe), 374.7 (Canada), and 295.3 (US).

Conclusions: Brodalumab was well tolerated and efficacious in patients with moderate-to-severe psoriasis across geographic regions.