# 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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## INTRODUCTION

- Psoriatic arthritis (PsA) is an inflammatory arthritis associated with psoriasis[1]
- Brodalumab is a fully human anti–interleukin-17 receptor A monoclonal antibody approved for treatment of moderate-to-severe plaque psoriasis[2]

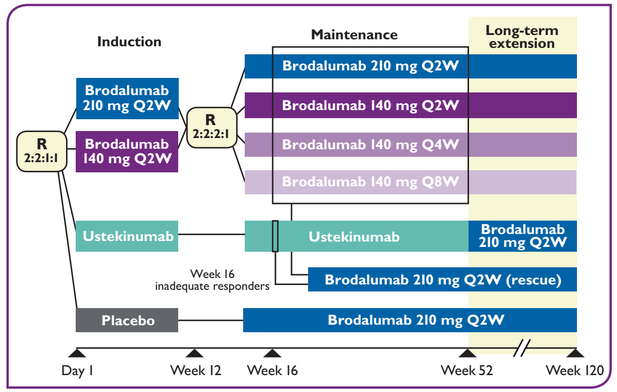
## OBJECTIVE

- To evaluate the efficacy and safety of brodalumab in a post hoc analysis of two phase 3, multicenter, randomized trials of brodalumab in patients with moderate-to-severe plaque psoriasis (AMAGINE-2/-3; Figure 1) with or without a history of psoriatic arthritis[3]

## METHODS

- In AMAGINE-2/-3, 3625 patients received brodalumab, of whom 703 (19.4%) 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[3]
- At week 52, all patients entered a long-term extension and received brodalumab[4]
- 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
  - The PSI measures the severity of 8 signs and symptoms of psoriasis (itch, redness, scaling, burning, stinging, cracking, flaking, and pain) each scored on a scale of 0 (not at all severe) to 4 (very severe), with a total score of up to 32
  - A PSI responder was defined as having a total score ≤8 with no item scores >1
- Safety was summarized via exposure-adjusted rates of treatment-emergent adverse events (TEAEs)

**Figure 1.** AMAGINE-2/-3 study design.




R, randomization; Q2W, every 2 weeks; Q4W, every 4 weeks; Q8W, every 8 weeks.

## RESULTS

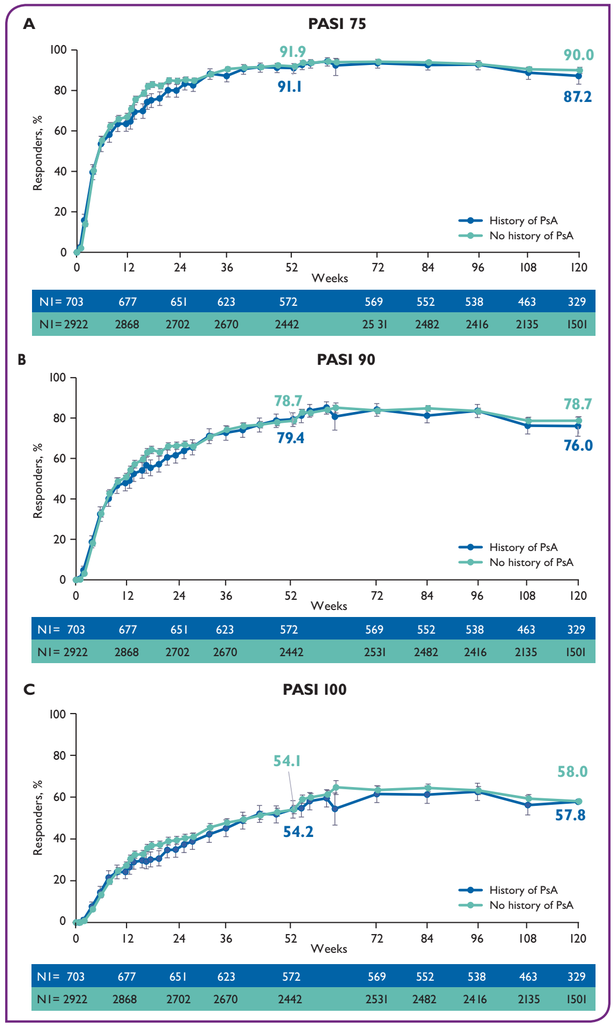
### Efficacy

- In an observed analysis at week 120, 74.8% of patients receiving any dose of brodalumab with a history of PsA (n=329) 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 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 63.2% in patients with and without a history of PsA, respectively

### PSI and DLQI responses

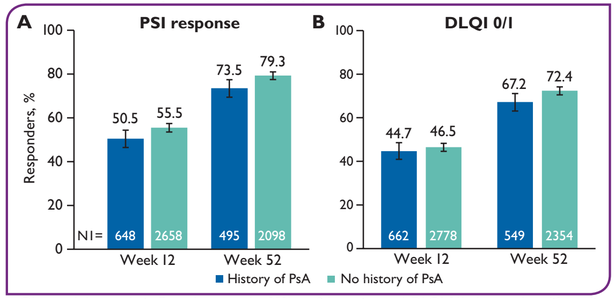
- The rates of PSI and DLQI score of 0 or 1 responses were robust among brodalumab-treated patients at week 52 (the last observation time point)
  - The rates of PSI response were 73.5% and 79.3% in patients with and without a history of PsA, respectively (Figure 3A)
  - The rates of DLQI score of 0 or 1 were 67.2% and 72.4% in patients with and without a history of PsA, respectively (Figure 3B)

**Figure 2.** PASI 75 **(A)**, PASI 90 **(B)**, and PASI 100 **(C)** responses through week 120 in patients who received ≥1 dose of brodalumab by history of PsA subgroups.




Observed data analysis. Error bars are the 95% confidence interval. N1, number of patients who had a valid measurement at the specified week; PASI 75, 90, and 100, psoriasis area and severity index 75%, 90%, and 100% improvement; PsA, psoriatic arthritis; Q2W, every 2 weeks.

**Figure 3.** PSI and DLQI 0/1 response rates in brodalumab-treated patients by history of PsA subgroups.




Observed data analysis. Error bars are the 95% confidence interval. DLQI 0/1, dermatology life quality index score of 0 or 1; PsA, psoriatic arthritis; PSI, psoriasis symptom inventory.

### 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

| | History of PsA (N=703, 1219.2 PY) | No history of PsA (N=2922, 5312.3 PY) |
|---|---|---|
| All TEAEs, n (r) | 4046 (331.9) | 15,556 (292.8) |
| Grade ≥2 | 2202 (180.6) | 8194 (154.2) |
| Grade ≥3 | 181 (14.8) | 639 (12.0) |
| Serious AEs, n (r) | 117 (9.6) | 364 (6.9) |
| Fatal AEs, n (r)[a] | 1 (0.1) | 2 (0.0) |

Observed data analysis. AE, adverse event; CI, confidence interval; n, number of adverse events; N, number of patients; PsA, psoriatic arthritis; PY, total patient-years of exposure through the end of the study; r, exposure-adjusted event rate per 100 patient-years; TEAE, treatment-emergent AE.
[a]The 3 fatal AEs were 1 sudden death (cause undetermined), 1 cardiac arrest (267 days on brodalumab; event occurred 7 days after last dose), and 1 accidental death (motor vehicle accident).

## CONCLUSION

- **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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**References: 1.** Gottlieb et al. *J Am Acad Dermatol.* 2008;58:851-864. **2.** Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America, LLC; 2017. **3.** Lebwohl et al. *N Engl J Med.* 2015;373:1318-1328. **4.** Menter et al. Poster presented at the 2017 Fall Clinical Dermatology Conference; October 12-15, 2017; Las Vegas, NV.