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# Brodalumab in psoriatic arthritis (PsA): 24-week results from the phase III AMVISON-1 and -2 trials

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**Background:**

The IL-17 receptor blocker brodalumab (BRO) was investigated in PsA in two double-blind, placebo (PBO)-controlled, Phase III trials. Although terminated early by sponsor decision, sufficient patients were recruited to allow a meaningful evaluation of efficacy and safety.

**Methods:**

AMVISION-1 (NCT02029495) and -2 (NCT02024646) enrolled adult patients with active PsA (≥3 swollen and ≥3 tender joints) despite prior DMARD therapy (including biologics in AMVISION-2). Randomization (1:1:1) was to PBO, BRO 140 mg or BRO 210 mg Q2W (with additional dose at Wk 1). PBO patients were switched to BRO 210 mg at Wk 24 with early escape possible from Wk 16. Primary endpoints (Wk 16 ACR20 response) were reported previously [1, 2]. ACR20/50/70 and PASI responses were evaluated through 24 wks in this pooled analysis. Response rates were calculated using a generalised estimating equation model with non-responder imputation for discontinuation for reasons other than trial termination (including inadequate response at Wk 16 or later). Intermittent missing data and missing data due to trial termination were analysed as missing completely at random. Safety was also evaluated.

**Results:**

962 patients (BRO 140 mg: n=318; BRO 210 mg: n=322; PBO: n=322) were randomized across both trials. Baseline characteristics were balanced across treatment groups for sex, age (trial mean ±SD: 48.3 ±12.5 y) and swollen/tender joint counts (mean ±SD: 12 ±9.2/21 ±14.6, respectively).

At Wk 24, significantly more patients treated with BRO achieved ACR20 (210 mg: 55% [95% CI: 48–61%]; 140 mg: 51% [95% CI: 45–57%]) vs PBO (24% [95% CI: 19–30%]; both $p<0.0001$). ACR50 response rates were higher with BRO (210 mg: 37% [95% CI: 31–43%]; 140 mg: 30% [95% CI: 24–36%]) than PBO (11% [95% CI: 7–15%]; both $p<0.0001$); ACR70 response rates were also higher with BRO (210 mg: 21% [95% CI: 17–27%]; 140 mg: 14% [95% CI: 11–20%]) than PBO (5% [95% CI: 3–8%]; 210 mg $p<0.0001$, 140 mg $p=0.0003$). As expected, highly significant improvements in PASI scores were observed with BRO compared with PBO.

Through Wk 24 or treatment switch, adverse-event (AE) rates/100 patient-years for PBO vs combined BRO-treated groups were 477.6 vs 386.8, serious AEs were 13.0 vs 9.0, and discontinuations due to AEs were 5.6 vs 3.7. There were no deaths.

**Conclusions:**

BRO delivers consistent, dose-dependent, and clinically meaningful improvements in PsA at Wk 24.

**References:**


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