Prolonged off-treatment efficacy of barzolvolimab in chronic spontaneous urticaria

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Introduction: In a Phase 2 study in patients with antihistamine-refractory chronic spontaneous urticaria (NCT05368285), barzolvolimab (anti-KIT mAb) demonstrated significant benefits in urticaria activity/control with complete response (UAS7=0) in up to 41% of patients 7 months after the last dose; barzolvolimab was well-tolerated. Here, we describe post-treatment efficacy among patients who achieved well-controlled disease after 52 weeks.

Methods: In this double-blind, placebo-controlled trial, among 78 patients completing 52 weeks of treatment with either 150 mg Q4W or 300 mg Q8W barzolvolimab, 55 (70.5%) achieved at least well-controlled disease, defined by urticaria activity score over 7 days (UAS7≤6) at Week 52. Forty-eight of these patients with UAS7 scores at Week 76 were further evaluated in an exploratory analysis.

Results: At study entry, 70.9% of these patients had severe disease; mean (SD) UAS7=31.5 (7.4). At Week 52, 87.3% had a complete response (UAS7=0) and 12.7% had well-controlled urticaria. Twenty-eight weeks following the last dose, 81% had mild or no apparent disease, with 50.0% and 18.8% having a complete response and well-controlled disease, respectively. Prolonged, off-treatment efficacy was maintained despite clearance of barzolvolimab and normalization of serum tryptase, a mast cell biomarker. Remarkably, half of these patients had continuous, well-controlled disease with mean (SD) UAS7 0.4 (1.1), mean (SD) Dermatology Life Quality Index (DLQI) 1.17 (3.50), and 83.3% DLQI of 0/1 (no impact of disease on quality of life) at Week 76.

Conclusion: Among patients who achieved at least well-controlled disease after 52 weeks of barzolvolimab, a high degree of prolonged off-treatment efficacy was observed 28 weeks after the last dose, suggesting disease modification.

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