

THE EFFICACY OF MAINTENANCE TREATMENT WITH GUSELKUMAB IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS: PHASE 3 QUASAR MAINTENANCE STUDY RESULTS AT WEEK 44 BY BIOLOGIC/JANUS KINASE INHIBITOR HISTORY

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The Phase 3 QUASAR Maintenance Study demonstrated that subcutaneous guselkumab maintenance therapy achieved clinical remission in 40% of ulcerative colitis patients with prior biologic/JAK inhibitor failure and 58% of biologic-naïve patients at Week 44, both significantly superior to placebo withdrawal.

KEY POINTS

- Among 568 patients who responded to guselkumab IV induction, 42.3% had prior inadequate response or intolerance to biologics/JAK inhibitors (87.9% anti-TNFs, 49.2% vedolizumab, 20.0% tofacitinib), with 48.3% having failed two or more such therapies.
- Clinical remission at Week 44 was achieved by 40.0% of guselkumab 200mg q4w-treated patients versus 8.0% placebo in the biologic/JAK inhibitor-experienced group ($p<0.001$), and by 58.3% versus 25.9% placebo in biologic-naïve patients ($p<0.001$).
- Endoscopic improvement (Mayo endoscopy subscore 0 or 1 with no friability) was achieved by 42.0% of guselkumab-treated patients versus 8.0% placebo in the biologic-experienced group, and by 59.4% versus 25.9% placebo in biologic-naïve patients (all $p<0.001$).
- Histo-endoscopic mucosal improvement (histologic improvement per Geboes grading plus endoscopic improvement) was achieved by 38.6% of guselkumab-treated patients versus 8.0% placebo in the biologic-experienced group, and by 56.3% versus 23.1% placebo in biologic-naïve patients (all $p<0.001$).

- Treatment differences versus placebo were generally greater in patients with prior biologic/JAK inhibitor inadequate response or intolerance, despite overall response rates being higher in biologic-naïve patients.
- No new safety concerns were identified through Week 44, with adverse events consistent across subpopulations and comparable to the known safety profile of guselkumab.

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