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Summary

PHARMACOKINETICS AND EXPOSURE-RESPONSE RELATIONSHIPS OF SUBCUTANEOUS GUSELKUMAB MAINTENANCE IN PARTICIPANTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS

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Population pharmacokinetic and exposure-response analysis of subcutaneous guselkumab maintenance in ulcerative colitis showed that higher serum concentrations were associated with greater efficacy at week 44, with patients with extensive disease deriving greater benefit from the 200 mg every 4 weeks dose compared to 100 mg every 8 weeks.

KEY POINTS

- Higher serum guselkumab concentrations were associated with greater efficacy at maintenance week 44 across all outcomes: clinical remission rates by trough concentration quartile ranged from 29.5% in the lowest to 65.3% in the highest quartile, endoscopic improvement from 32.6% to 65.3%, and histologic-endoscopic mucosal improvement from 28.4% to 61.1%.
- In patients with extensive ulcerative colitis at induction baseline, the 200 mg every 4 weeks maintenance dose achieved clinical remission in 63.0% compared to 40.2% with 100 mg every 8 weeks, and endoscopic improvement in 55.0% versus 45.8%, representing a greater treatment effect than observed in patients with limited disease.
- Covariates including higher body weight, lower serum albumin, higher C-reactive protein, and prior biologic or JAK inhibitor failure were associated with increased guselkumab clearance, but these effects were not clinically meaningful and support the use of fixed-dose maintenance regimens.
- No associations were found between guselkumab concentrations and infections, serious infections, serious adverse events, or abnormal liver function tests.

– Immunosuppressant use did not impact guselkumab concentrations, and the incidence of anti-drug antibodies and neutralizing antibodies was low and not associated with guselkumab pharmacokinetics, efficacy, or safety.

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