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Summary

GUSELKUMAB PHARMACOKINETICS AND EXPOSURE-RESPONSE RELATIONSHIPS ARE CONSISTENT FOLLOWING INTRAVENOUS VERSUS SUBCUTANEOUS INDUCTION IN PARTICIPANTS WITH CROHN'S DISEASE

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Pharmacokinetic and exposure-response analysis of guselkumab in Crohn's disease demonstrates comparable efficacy and safety between intravenous and subcutaneous induction routes despite differences in peak and trough concentrations.

KEY POINTS

- Subcutaneous induction (400 mg) resulted in higher trough concentrations at week 12 (14.7 vs 9.76 µg/mL) and lower peak concentrations (27.7 vs 70.1 µg/mL) compared with intravenous induction (200 mg), but similar average concentrations and area under the curve.
- Week 12 efficacy outcomes were comparable within concentration quartiles after subcutaneous versus intravenous induction, and week 48 outcomes were similar for patients receiving the same maintenance regimen regardless of induction route.
- No positive exposure-response trends were observed between peak concentration and week 12 efficacy endpoints, and the higher peak concentration with intravenous induction did not improve efficacy.
- Incidence of safety events including infections, serious infections, serious adverse events, and abnormal liver function tests was comparable between intravenous and subcutaneous induction regimens across concentration quartiles.
- This analysis supports the use of either intravenous or subcutaneous administration routes for guselkumab induction therapy in patients with Crohn's disease.

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