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Summary

# EFFICACY AND SAFETY OF GUSELKUMAB MAINTENANCE THERAPY IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE: RESULTS THROUGH WEEK 144 FROM THE PHASE 3 GALAXI 2 & 3 STUDIES

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**Three-year data from pooled GALAXI 2 and 3 trials show that guselkumab maintained clinical and endoscopic efficacy through Week 144 in patients with moderately to severely active Crohn's disease, with no new safety signals.**

## KEY POINTS

- At Week 144, 57.0% of patients on guselkumab 100mg SC q8w and 59.8% on 200mg SC q4w achieved clinical remission (CDAI <150) in the primary efficacy analysis using non-responder imputation.
- Among patients who remained on continuous treatment (As Observed analysis), clinical remission rates at Week 144 were 94.0% for the 100mg q8w dose and 90.7% for the 200mg q4w dose.
- Endoscopic remission (SES-CD ≤4 with ≥2-point reduction and no subscore >1) was achieved by 30.4% of patients on 100mg q8w and 38.2% on 200mg q4w at Week 144 in the primary efficacy analysis.
- Efficacy outcomes were generally similar in bionaïve and biologic-experienced patients, supporting durability irrespective of prior biologic exposure.
- Safety events per 100 patient-years through Week 144 were lower in guselkumab groups than placebo, with rare adverse events of interest including active TB (0.1-0.2), malignancies (0.2-0.3), and MACE (0.0-0.2).
- The treat-through design allowed evaluation of all patients initially randomised to guselkumab induction, with 74% continuing treatment through Week 144.

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