2022. GALAXI 1

Phase 2/ GUS/ CD/ Induction

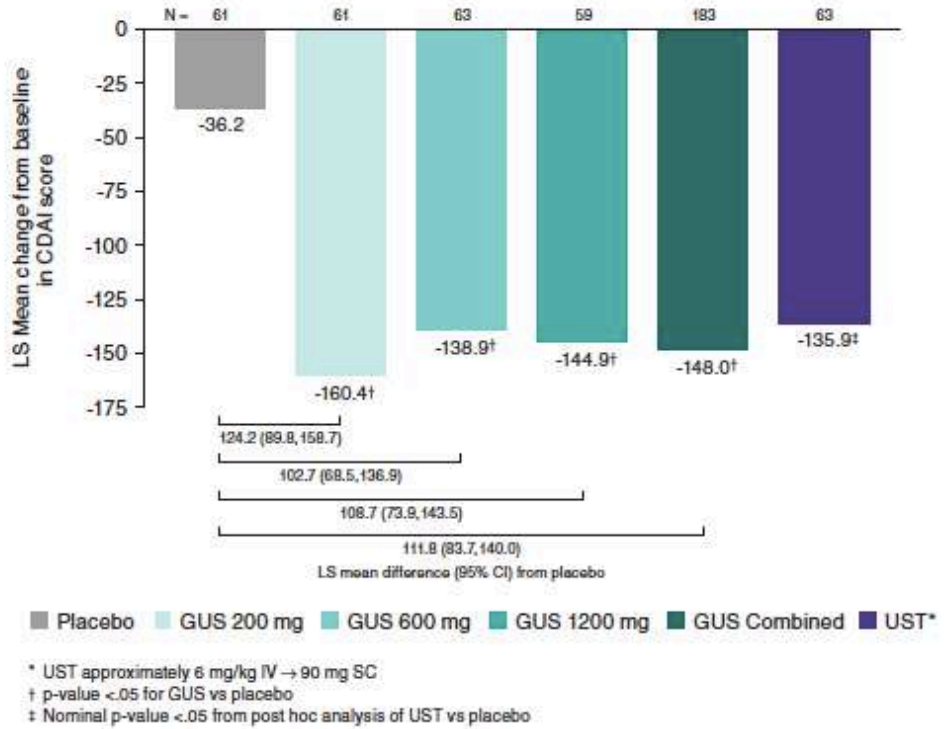
Guselkumab for the Treatment of Crohn's Disease: Induction Results From the Phase 2 GALAXI-1 Study

Phase 2, double-blind, placebo controlled trial.
Patients with moderate to severe CD were randomised to:
Placebo vs GUS 1200mg IV q4w vs GUS 600 mg vs GUS 200 mg vs UST 6mg/kg IV→UST 90mg sc

Primary outcome: Change in CDAI w12.
Secondary: Clinical remission/response/endoscopic remission/ response/biomarker response/PRO remission

Results:
- W12: greater reduction in CDAI in GUS groups vs placebo p<0.05
- Greater clinical remission, clinical response, PRO2 remission, clinical-biomarker response and endoscopic response in GUS vs placebo p<0.05

Conclusions:
At week 12, all 3 dose regimens of guselkumab induced greater clinical and endoscopic improvements vs placebo, with a favorable safety profile.



* UST approximately 6 mg/kg IV → 90 mg SC
† p-value <.05 for GUS vs placebo
‡ Nominal p-value <.05 from post hoc analysis of UST vs placebo

Figure 2. Primary efficacy end point. LSM change from baseline in CDAI score at week 12. CI, confidence interval; GUS, guselkumab; LS, least squares; UST, ustekinumab.

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