2023. GALAXI-1

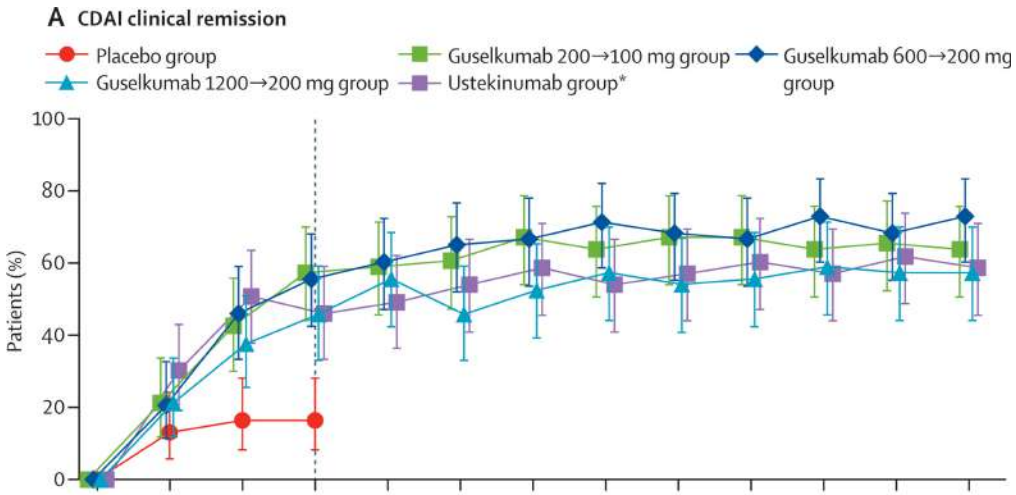
RCT/Guselkumab/ CD/ Maintenance

Efficacy and safety of 48 weeks of guselkumab for patients with Crohn's disease: maintenance results from the phase 2, randomised, double-blind GALAXI-1 trial

Phase 2, multicenter, double blind, placebo controlled trial.
Adult patients with mod-severe CD were randomized to IV induction phase (0,4,8) with subcut maintenance at week 12:

- Guselkumab (GUS) 200 IV→100mg SC
- GUS 600 IV→200mg SC
- GUS 1200 IV→ 200mg SC
- Ustekinumab (UST) 6mg/kg week 0→ 90mg SC q8w
- Placebo induction and for maintenance responders remained on placebo and non-responders were given ustekinumab

<u>Primary endpoint:</u> CDAI remission (<150) at week 48



<u>Results: N=309</u>

- At week 48, DAI remission was 64% GUS200-100, 73% GUS600-200, 57% GUS 1200-200, 59% UST
- CDAI remission w12 in placebo was 15/61 (24.6%) and continued on placebo, of these 9/15 (60%) were in clinical remission at w48with the rest starting UST, of these 59% were in clinical remission at w48.

<u>Conclusion:</u>
Patients receiving guselkumab intravenous induction and subcut maintenance treatment achieved high rates of clinical and endoscopic efficacy up to week 48. No new safety concerns were identified.

Danese S et al. Lancet Gastroenterol Hepatol. 2023