RCT/Guselkumab SC/UC/ Induction

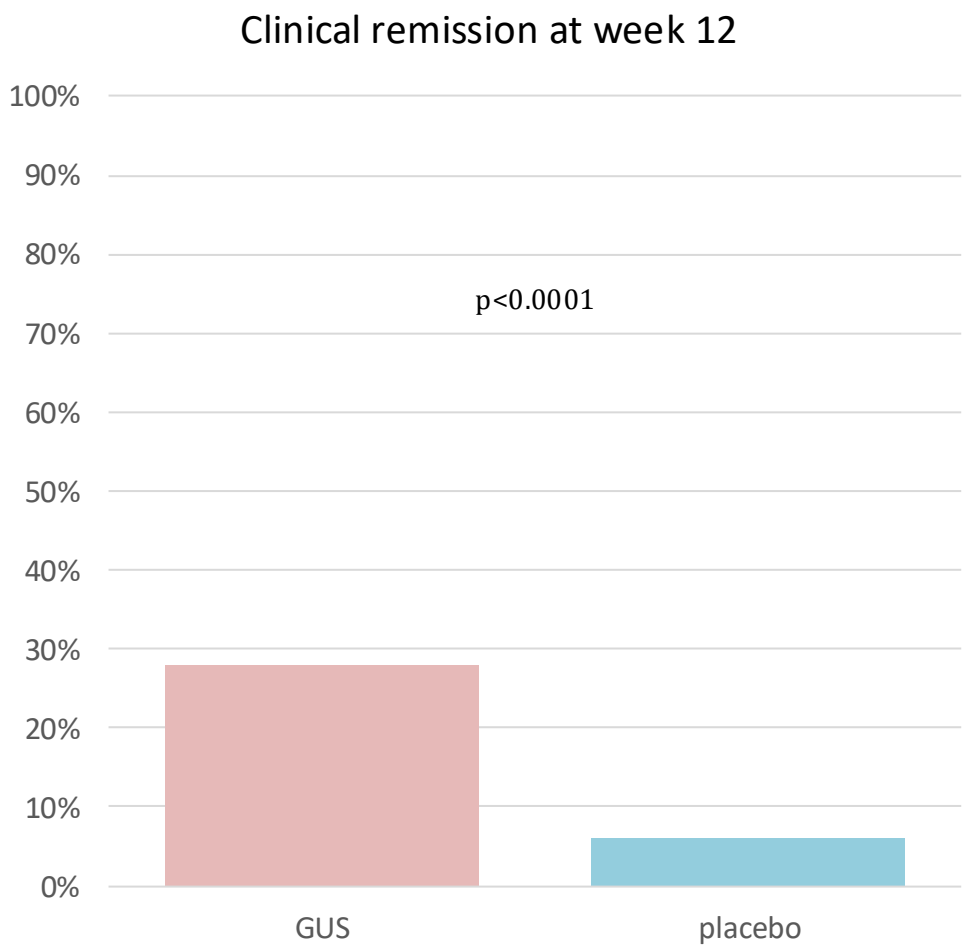
Efficacy and safety of subcutaneous guselkumab induction therapy in participants with moderately to severely active ulcerative colitis (ASTRO): a double-blind, treat-through, randomised, placebo-controlled, phase 3 trial

Double-blind, treat-through, randomised, placebo-controlled pase 3 trial.
Patients with mod-severe UC were randomized to subcutaneous (SC) guselkumab 400mg at weeks 0,4,8 followed by 100mg q8w (400/100); SC guselkumab 400mg 0,4,8 and then 200mg q4w (400/200) or matched placebo.

Primary endpoints: Clinical remission at week 12.

Results: N=418
- Clinical remission at week 12 was: 28% guselkumab vs 6% placebo, p<0.0001.
- At week 24 clinical remission was 35% GUS 400/100 vs 36% GUS 400/200 vs 9% placebo.

Conclusion:
SC guselkumab induction and maintenance was safe and efficacious for 24 weeks in participants with mod-severe UC, establishing a fully SC guselkumab regimen as a treatment option in this patient population.



Long M et al. Lancet Gastroenterol Hepatol. 2026