

Two randomized, placebo-controlled, double-blind studies were conducted in mod-severe UC & CD.

All patients received open label CT-P13 IV 5mg/kg at week 0,2,6. At week 10, clinical responders were randomized to CT-P13 SC 120mg or placebo every 2 weeks.

Coprimary endpoint: Clinical remission and endoscopic response in CD and clinical remission UC at w54.

Results: N=396 CD and 548 UC

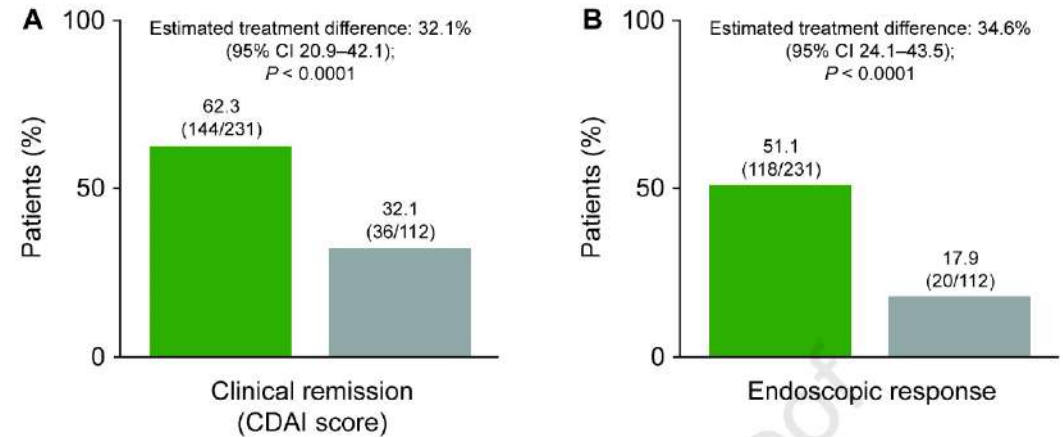
- At week 54 clinical remission CD: IFX SC 62.3% vs placebo 32.1%,  $p < 0.0001$
- At week 54 clinical remission UC: IFX-SC 43.2% vs 20.8% placebo,  $p < 0.0001$
- Immunogenicity: CD study 65.1% IFX-SC and 76.2% placebo developed antibodies. In UC study 63.8% and 91.8% respectively,

Conclusion:

CT-P13 SC was more effective than placebo as maintenance therapy in CD and UC patients who responded to IV induction.

CD

Co-primary endpoints



UC

Primary endpoint

