Randomized, double-blind, double-dummy, parallel-group study. Etrolizumab vs Infliximab in moderate to severe UC patients naïve to antiTNF. Randomly assigned to etrolizumab SC 105 mg q4w or IFX 5mg/kg (0,2,6) and q8w thereafter for 52 w.

<u>Primary endpoint</u>: clinical response at week 10 and 54 <u>Secondary endpoints w54</u>: clinical remission, endoscopic remission/ improvement, steroid free remission.

Results:

- Clinical response w10 and clinical remission w54: 19.7% IFX vs 18.6% ETR, p=0.81
- No differences in the secondary endpoints between IFX vs ETR.

Conclusions:

ETR not met primary endpoint for superiority against IFX in clinical response w10 &clinical remission w 54.

Nominal significance not observed in the secondary endpoints.



