2014. Etrolizumab-UC

RCT/Etrolizumab/ UC/Induction

Etrolizumab as induction therapy for ulcerative colitis: a randomised, controlled, phase 2 trial

Double-blind, placebo-controlled, multicentre phase 2 trial.
Patients with moderately-severely active UC with disease extension over 25 cm were randomised to subcutaneous etrolizumab (100mg w0,4 and 8 with placebo at w2; or 420 loading dose at w0 and then 300mg w2,4,8) or matching placebo.

Primary endpoint: Clinical remission at week 10 (Mayo score ≤2)

Results: N=124
- Clinical remission at w10: 21% ETRO100, 10% ETRO420-300 and 0% placebo.
- Clinical response at w10; 33% ETRO100, 31%ETRO420-300, 29%placebo, p=ns

Conclusion:
Etrolizumab was more likely to lead to clinical remission at week 10 than was placebo.

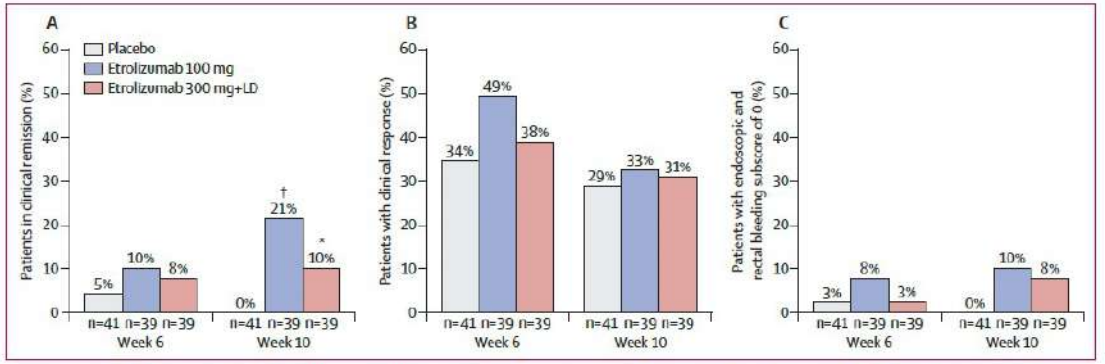

Figure 2: **Proportion of patients with clinical remission, clinical response, and endoscopic remission/rectal bleeding score of 0 in the mITT population**
(A) Clinical remission at week 6 and week 10. (B) Clinical response (3-point decrease and 30% reduction in Mayo Clinic Score and 1-point decrease or more in rectal bleeding subscore or absolute rectal bleeding subscore of 0 or 1) at week 6 and week 10. (C) Endoscopic and rectal bleeding subscores of 0 at week 6 and week 10. LD=loading dose. mITT=modified intention-to-treat. *p<0·05 (*vs* placebo). †p<0·01 (vs placebo).

* Etrolizumab acts blocking α4β7 and αEβ7

Vermeire S et al. Lancet 2014; 384: 309–18