2021. HICKORY

Phase 3/ ETR/ UC/ Induct/Maintain

Etrolizumab vs placebo, phase 3 RCT for mod-sev UC in induction and maintenance of remission.

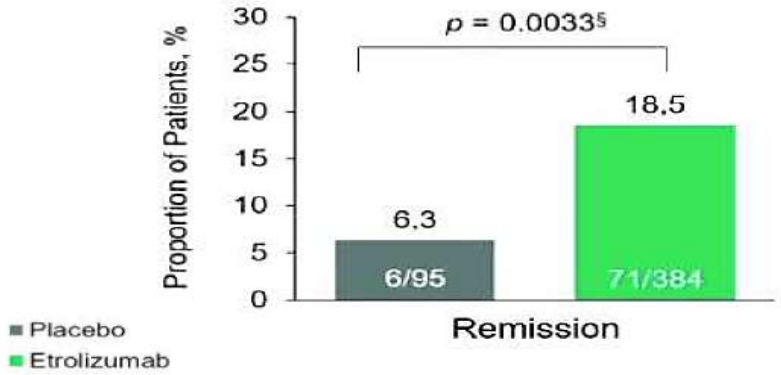
Phase 3, double-blind, placebo controlled trial.
Patients with moderate-severe UC previously expossed to antiTNF were randomised to:
-Cohort 1: OL etrolizumab SC 105 mg q4w for 14w
-Cohort 2: etrolizumab SC 105mg or placebo q4w for 14w

Primary endpoint for induction: Clinical remission w14.
Secondary endpoints induction: Clinical response, endoscopic improvement and response, change in rectal bleeding and Stool frec.
Primary endpoints for maintenance: clinical remission w 66
Secondary endpoints maintenance: endoscopic improvement, steroid free remission, histologic and endoscopic remission

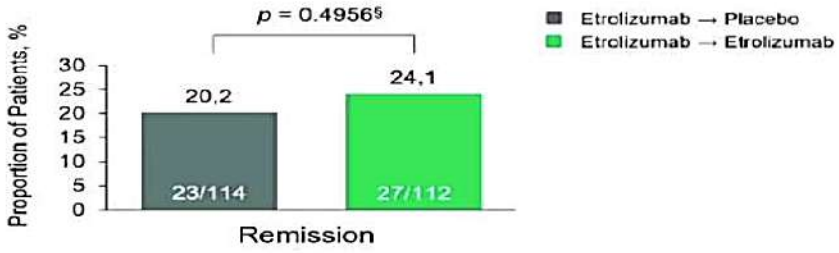
Results:
- Induction clinical remission 6.3%pbo vs 18.5% ETR; p=0.003
- Maintenance 20.2%pbo vs 24.1%ETR; p=0.5

Conclusions:
ETR met induction primary endpoint but not maintenance endpoint in patients with mod-severe UC previously expossed to antiTNF.

INDUCTION w14



MAINTENANCE w66



Remission: MCS ≤ 2, with individual subscores ≤ 1 and RB subscore of 0
Clinical Response: MCS with ≥3 point decrease and 30% reduction from baseline, as well as ≥ 1-point decrease in RB subscore or an absolute RB score of 0 or 1.
§ p value based on analysis adjusting for multiplicity and stratification factors.

Peyrin-Biroulet L et al. Lancet. 2021.7(2):128140