2023. BERGAMOT

RCT/Etrolizumab/CD/ Induction

Etrolizumab as induction and maintenance therapy in patients with moderately to severely active Crohn's disease (BERGAMOT): a randomised, placebo-controlled, double-blind, phase 3 trial

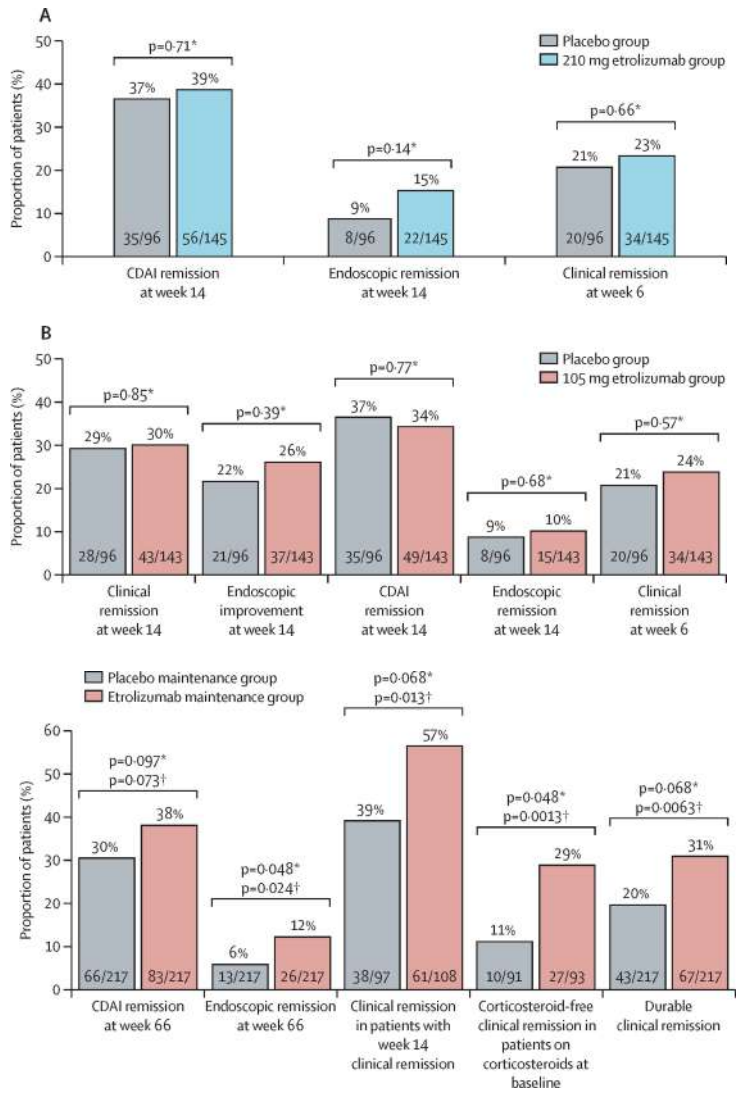
Randomized double-blind, placebo-controlled phase 3 trial.
BERGAMOT consisted of 3 induction cohorts: cohort 1 (placebo controlled, double-blind exploratory cohort), cohort 2 (active treatment cohort without placebo control) & cohort 3 (placebo-controlled, double-blind pivotal cohort) and one maintenance cohort.
In induction cohort 3, patients with moderate-severe CD were randomized to: 105mg etrolizumab SC every 4 weeks, etrolizumab 210mg SC or placebo.
-Week 14 responders were randomized to 105mg etrolizumab or placebo for maintenance up to week 52

<u>Coprimary endpoints induction and maintenance:</u> clinical remission & endoscopic improvement at week 14 and week 66

<u>Results: N=385 cohort 3; Maintenance N=434</u> (response in any induction cohort)

- Clinical remission w14: 33% ETRO210 vs 29% placebo, p=ns.
- Endoscopic improvement w14: 27% ETRO210 vs 22% pbo, p=ns.
- Clinical remission w66: 35% ETRO105 vs 24%pbo, p=0.0088
- Endoscopic improve w66: 24% ETRO105 vs 12%pbo, p=0.0026
- No differences in the rates of adverse events.

<u>Conclusion:</u>
Higher proportion of patients with moderately to severe CD achieved clinical remission and endoscopic improvement with etrolizumab than with placebo during maintenance but not during induction.



Sandborn EJ et al. Lancet Gastroenterol Hepatol. 2023; 8(1):43-55