

Randomized, double-blind, placebo-controlled trial.
 Moderate to severe UC patients randomised to:
 10w induction: Cohort 1 received 1mg OZA vs placebo.
 Cohort 2 received OL OZA1mg. Patients with clinical response at w10,
 randomized to OZA vs placebo for maintenance period.

Primary endpoint induction: clinical remission w10. Primary endpoint maintenance: clinical remission w 52.

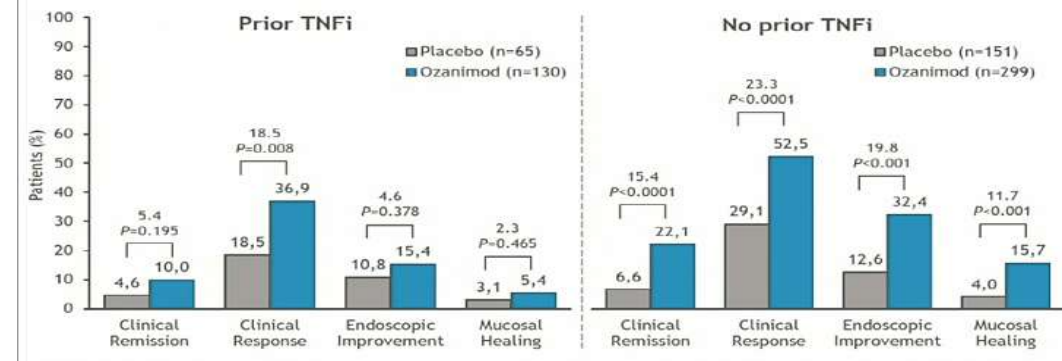
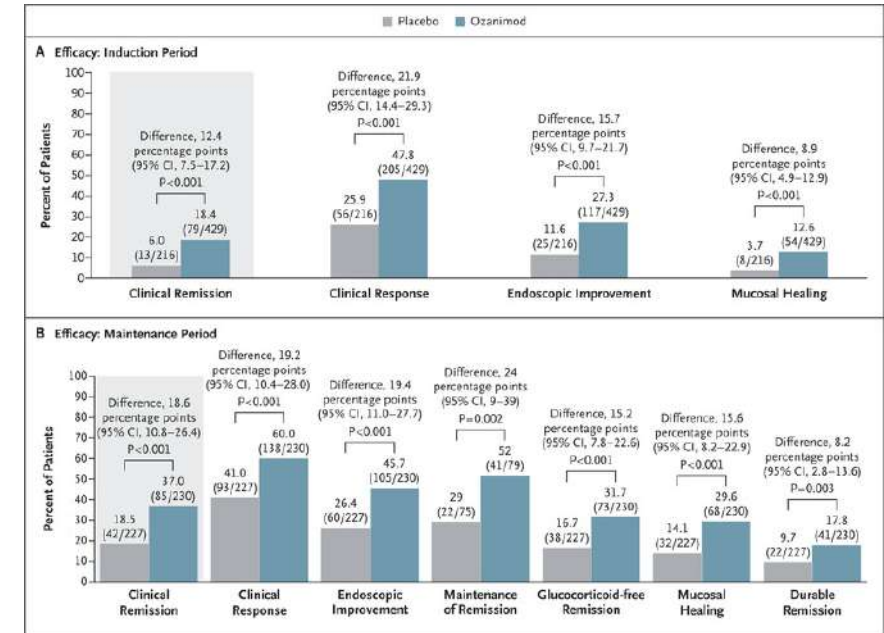
Results:

- Induction w10: Clinical remission 6%pbo vs 18.4%OZA, $p < 0.0001$.
- Clinical remission met for naïve to anti-TNF, but not for anti-TNF exposed.
- Maintenance w52: Clinical remission 18.5% pbo vs 37%OZA, $p < 0.0001$.

Conclusions:

OZA superior than placebo inducing remission and maintenance in UC

Phase 3, double-blind, placebo RCT Ozanimod in UC induction & Maintenance of remission vs placebo.



Data based on all randomized patients who received ≥1 dose of study treatment (intent-to-treat population). Missing data handled using non-responder imputation. P-values refer to odds ratios (not shown) based on 2-sided Cochran-Mantel-Haenszel test.

