2021.ENVISION I

Phase 3/ ADA/pediaUC/ Efficacy/safety

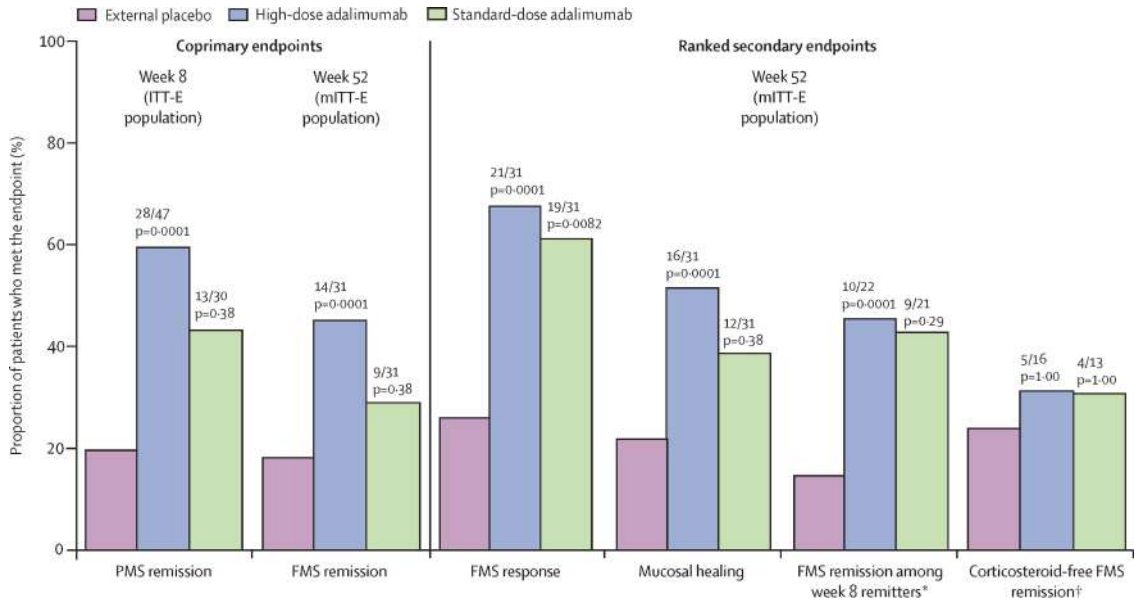
# Efficacy and safety of adalimumab in paediatric patients with moderate-to-severe ulceative colitis (ENVISION I): a randomized, controlled, phase 3 study

Randomized, double-blind. Maintenance placebo controlled trial.
Paediatric moderate-to-severe UC. Patients randomized to: High induction dose(week 0 and 1) or standard dose (week 0 and week 1 placebo) of ADA randomly assigned.
Responders in w8, were randomized to: high dose maintenance 0.6mg/kg weekly or standard 0.6mg/kg eow or placebo up to w52.

Coprimary endpoints : Clinical remission at w8 (ITT analysis) and remission at week 52.

Results:
- At w8 clinical remission, high induction dose 60% vs standard 43% vs 19.8% placebo
- At w52 remission, high maintenance dose 45%, standard dose 29% vs placebo 18.4%

Conclusions:
Clinically meaningful rates of remission and reponse were reported in children who received adalimumab. No new safety signals were observed.




Croft NM et al. Lancet. 2021; 6(8): 616-627