2007. PRECiSE II

RCT/ Certolizumab/ CD/ Maintain

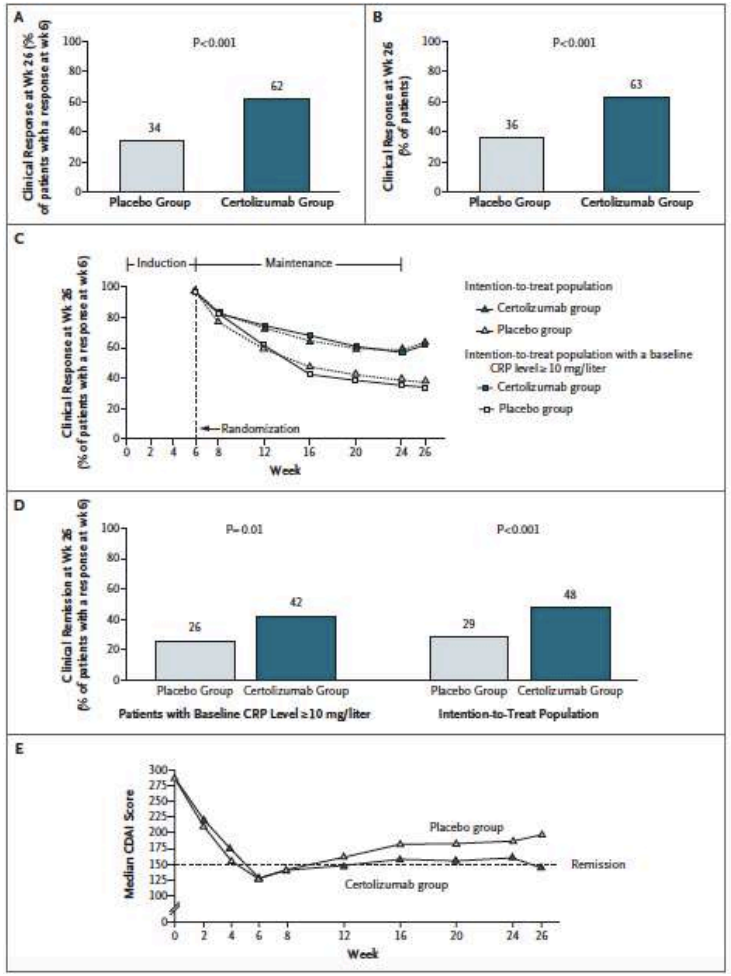
Maintenance Therapy with Certolizumab pegol for Crohn's Disease

Randomized, double-blind, placebo controlled trial.
Patients with clinical response (reduction of >100 CDAI) at w6 were stratified according to their baseline CRP to 400 mg of certolizumab pegol or placebo q4w through w24, follow-up through w26.

Primary outcome:
Clinical response at w26 in patients with CRP >10 mg/L.
Secondary end points included response at w26, remission at w 26 in the ITT, and remission in the group with a baseline CRP >10mg/L

Results:
- Among patients with a response to induction the response was maintained through w26 in 62% certolizumab (patients with CRP >10 mg/L)vs. 34% placebo, p<0.001.
- Remission at w26 was achieved in 48% certolizumab group and 29% of placebo (P<0.001).

Conclusion:
Patients with moderate-to-severe CD who had a response to induction therapy with 400 mg of certolizumab pegol were more likely to have a maintained response and a remission at w26 with continued certolizumab pegol treatment than with a switch to placebo.



Schreiber S etl al. N Engl J Med 2007;357:239-50.