2002. ACCENT I

Phase 3 / IFX/ CD/Maintenance

Maintenance infliximab for Crohn's disease: the ACCENT I randomised trial

Patients with moderate-severe CD, CDAI>220 received 5mg/kg 1st dose of IFX.
At w2 after assessment of response randomized to different groups:
Group I: placebo. Group II: IFX 5 mg/kg weeks 2,6 and q8w. Group III: IFX 10mg/kg maintenance q8w.

The prespecified co-primary endpoints:

- Response at w2 & remission (CDAI <150) at w30.
-Time to loss of response up to week 54 in patients who responded.

Analyses of the co-primary endpoints were by intention to treat.

Results:

- w2: **58% responded** to single IFX infusion.
- **w30 remission**: 21% pbo vs 39% IFX5 vs 45% IFX10; p=0.003, p=0.0002.
- Median **time to loss of response** in IFX5 and IFX10 was 38w.

Conclusion:
Induction and maintenance response to IFX q8w better than placebo in CD.

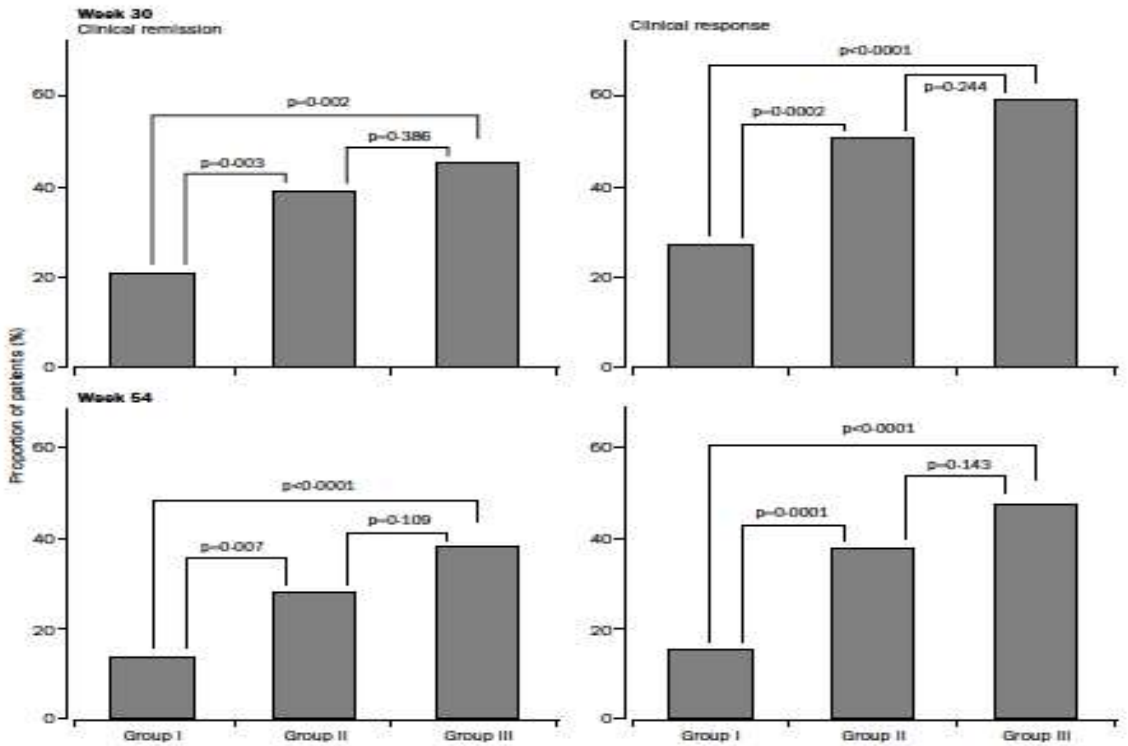

Figure 2: **Clinical response and clinical remission for week-2 responders**
Clinical response=reduction in CDAI to >70 points and >25% from baseline. Clinical remission=CDAI <150 points.

. Hanauer SB et al.Lancet 2002. 359 (9327): 1541-9