2007. CLASSIC II

RCT/ ADA/ CD/ Maintain&Safety

Adalimumab for maintenance treatment of Crohn's disease: results of the CLASSIC II trial

Long-term efficacy of safety follow-up of patients in CLASSIC I.
After 2 doses (CLASSIC I trial) patients in clinical remission entered the CLASSIC II trial and were randomized to placebo, ADA eow or ADA ew.

Primary end point: maintenance of remission (CDAI <150) in randomised patients w 56.
Secondary end points: Safety; IBDQ changes; differences in CRP and biochemistry parameters.

Results:

- Remission w56: patients randomized: 79% ADA 40 mg eow vs 83% ADA ew vs 44% placebo, p<0.05
- Rates of remission were similar in patients on combotherapy vs monotherapy.
- Steroid free remission w56: patients in the open-label arm was 57% placebo vs 67% ADA eow vs 88% ADA ew.
- Adalimumab was generally well-tolerated in all patients.

Conclusion:
Adalimumab induced and maintained clinical remission in patients with moderate-severe CD naïve to antiTNF

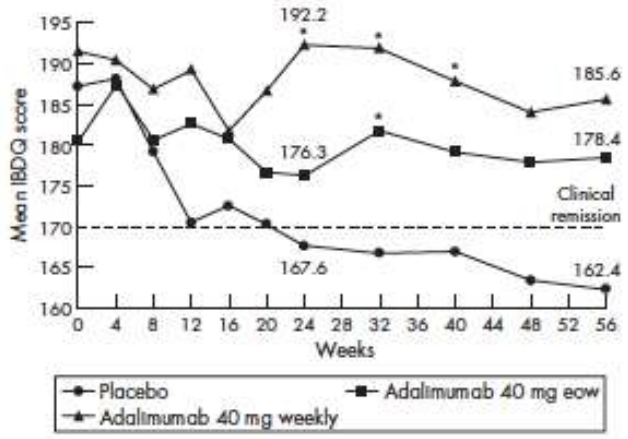

Figure 3 Mean total Inflammatory Bowel Disease Questionnaire (IBDQ) scores by visit: randomised cohort of CLASSIC II. Mean total IBDQ scores in each adalimumab dosage group and the placebo group at weeks 4, 8, 12, 16, 24, 32, 40, 48, and 56. IBDQ values ≥170 correlate with clinical remission. All data are last observation carried forward for the intention-to-treat population, n = 55. *p<0.05 for adalimumab every other week v placebo at week 32; p<0.005 for adalimumab 40 mg weekly v placebo at weeks 24, 32, and 40. eow, every other week.

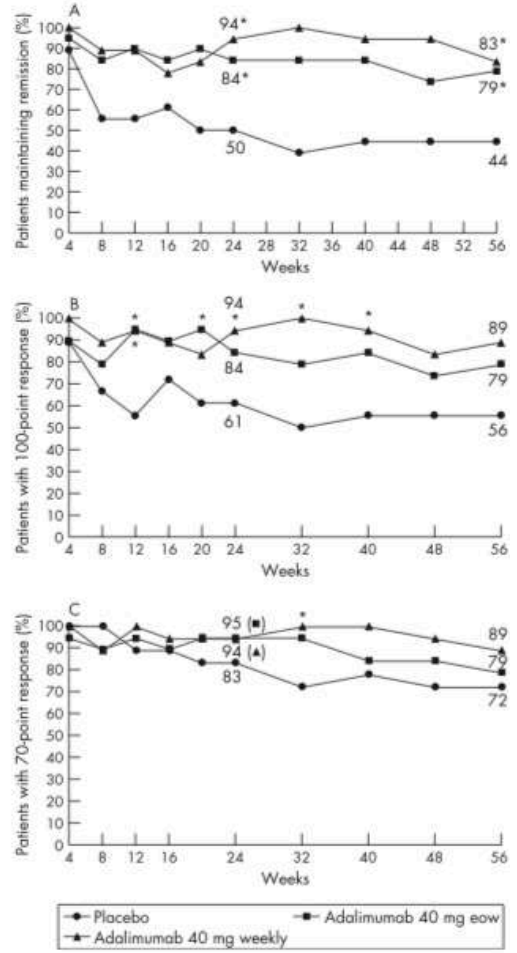

Figure 2 Efficacy of adalimumab as maintenance treatment in Crohn's disease in the randomised cohort. Remission was defined as a decrease in the CDAI score of <150 points; 100-point response was defined as a decrease from CLASSIC I baseline in the CDAI score of ≥100 points; and 70-point response was defined as a decrease from CLASSIC I baseline in the CDAI score of ≥70 points. Significance was assessed v placebo. (A)

Sandborn WJ et al. Gut. 2007; 56:1232-1239