2012. EXTEND

Phase 3/ADA/CD/Induct+Maintain

Adalimumab Induces and Maintains Mucosal Healing in Patients With Crohn's Disease: Data From the EXTEND Trial

Moderate to severe ileocolonic CD and mucosal ulceration.
All patients received ADA induction 160/80. At w4, patients randomised o 40 mg or placebo eow until w52.

Primary endpoint: mucosal healing w12 in the ITT population.
Secondary endpoints: mucosal healing w52, CDEIS remission w12&52, CDAI remission.

Results:

- Mucosal healing w12: 27% ADA vs 13%placebo; p>0,05
- Clinical remission w12: 52%vs 28%; p=0.021
- Mucosal healing w52: 24% vs 0%; p<0.001
- Clinical remission w 52: 28% vs 3%; p=0.001

Conclusions:

Following induction therapy with ADA, patients with moderate-severe active CD who continue with ADA are more likely to achieve mucosal healing than those given placebo.

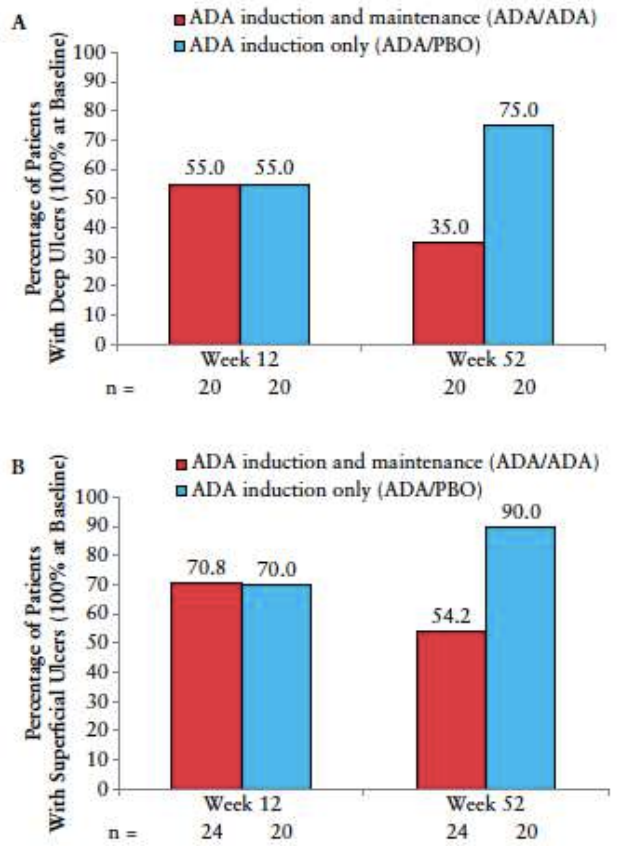

Figure 1. Percentage of patients with [A] deep and [B] superficial ulcers per CDEIS at Weeks 12 and 52. Patients were from the ITT population and had at least one [A] deep or [B] superficial ulcer per CDEIS at baseline and also had data at Week 12 and Week 52 [including data imputed when moving to open-label therapy after Week 12]. ADA, adalimumab; CDEIS, Crohn's Disease Endoscopic Index of Severity; ITT, intent to treat; PBO, placebo.

Rutgeerts P et al. Gastroenterology 2012; 142: 1102-1111