2012. CERTIFI

Phase 2b/UST/CD/Induc/Maintain

Ustekinumab Induction and Maintenance Therapy in Refractory Crohn's Disease

Randomized, double-blind, placebo controlled.
Moderate to severe CD failing to antiTNF were randomized to:
Induction IV ustekinumab (at a dose of 1, 3, or 6 mg per kilogram) or placebo at week 0.
Maintenance phase, patients who had a response to ustekinumab at w6 underwent a second randomization to receive subcutaneous injections of ustekinumab (90 mg) or placebo at w8 and 16.

Primary outcome: The primary end point was a clinical response (≥100 point decrease from the baseline CDAI score) at w6.

Results:
- Clinical response w6: 36.6%, 34.1%, and 39.7% for 1, 3, and 6 mg of ustekinumab per kilogram, as compared with 23.5% placebo (p = 0.005 for the comparison with the 6-mg group).
- Clinical remission w 22: 41.7% UST vs 27.4% placebo, p=0.03
- Clinical response w22: 69.4% UST vs 42.5%, p<0.001

Conclusions:
Patients with moderate-to-severe CD that was resistant to TNF antagonists had an increased rate of response to induction with ustekinumab, as compared with placebo. Patients with an initial response to ustekinumab had significantly increased rates of response and remission with ustekinumab as maintenance therapy.

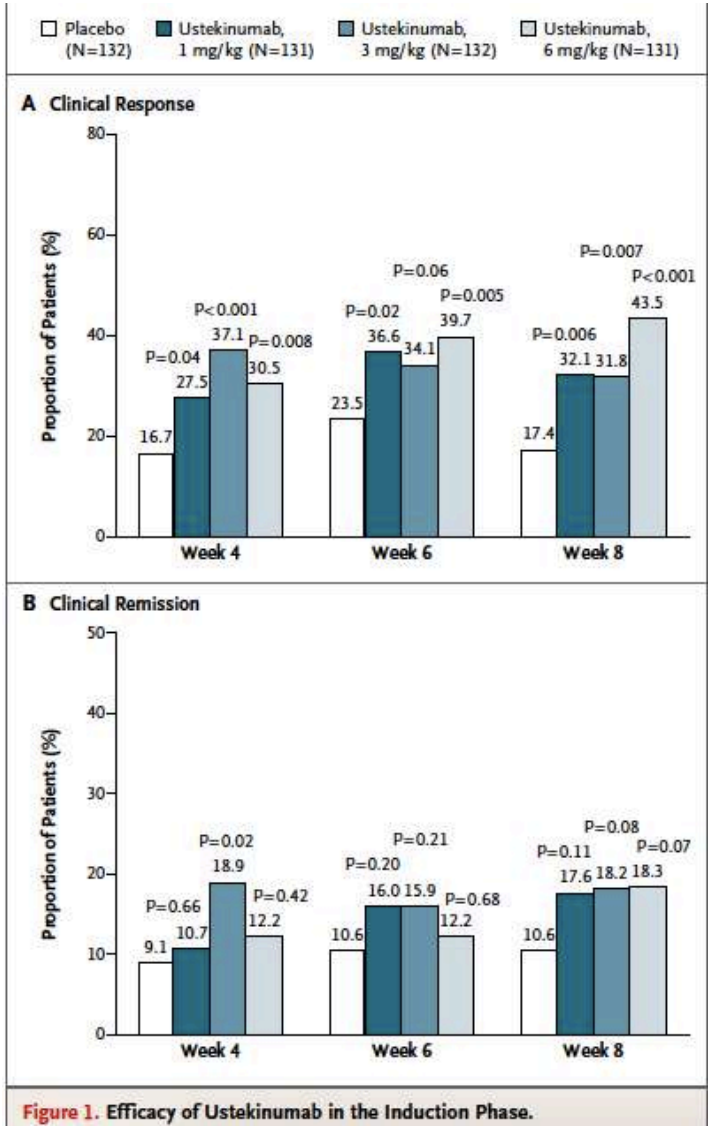

Figure 1. Efficacy of Ustekinumab in the Induction Phase.

Sandborn WJ et al. N Engl J Med. 2012; 367:1519-1528