2013. **GEMINI II**

Phase 3/ VEDO/CD/ Induct/Maintain

Randomized double-blind, placebo controlled trial.

Induction: VDZ 300mg IV w0 and w2 or placebo, disease evaluation w6 Maintenance: responders w6 randomised to continue VDZ q8w or q4w or placebo for up to 52w.

Primary outcome for induction therapy: clinical response w6

Secondary outcomes: mean change in CRP w6.

Primary outcome for maintenance: remission w52

Secondary outcome for maintenance: CDAI-100 response, steroid free remission and durable remission w52.

Results:

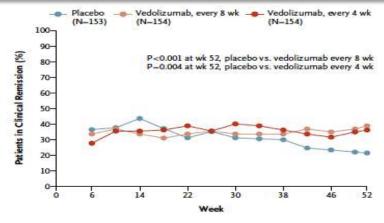
- Remission w6: 14.5%VDZ vs 6.8%pbo; p=0.02
- CDAI response: 31.4% VDZ vs 25.7% pbo
- Remission w52: 39%VDZq8 vs 36.4% VDZq4 vs 21.6%pbo; p=0.001 & p=0.004

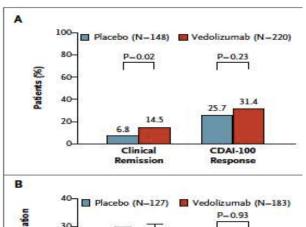
Conclusions:

VDZ-treated patients with CD more likely to achieve remission than those on placebo, but CDAI-100 response at w6 show no differences.

Patients who responded to induction, and continued on VDZ more likely to be in remission w52.

Vedolizumab as Induction and Maintenance Therapy for Crohn's Disease





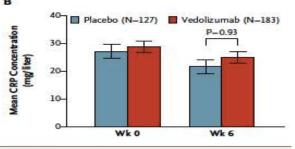


Figure 1. Primary End Points in the Trial of Induction Therapy.

