2020. VISIBLE 1

Phase 3/VDZ SC/UC/Maintain

Efficacy and Safety of Vedolizumab Subcutaneous Formulation in a Randomized Trial of Patients With Ulcerative Colitis

Randomized, placebo-controlled trial.
Patients with moderate to severe UC.
IV induction (0,2), patients with clinical response at w6 were randomized to maintenance with vedolizumab SC (108 mg vedolizumab SC q2w along with IV placebo q8w), vedolizumab IV (300 mg q8w along with SC placebo q2w), or placebo (SC placebo q2w and IV q8w).

Primary endpoint: Clinical remission, defined as a total Mayo score of 2 and no individual subscore >1 at week 52.

Results:

- Clinical remission at w52 was achieved by 46.2%, 42.6%, and 14.3% of patients in the SC vedolizumab, IV vedolizumab, & placebo groups, respectively (subcutaneous vedolizumab vs placebo: p< .001).
- SC VDZ group also had greater endoscopic improvement and durable clinical response at w52 compared with placebo (both p <.001).

Conclusion:
Subcutaneous vedolizumab is effective as maintenance therapy in patients with moderately to severely active UC who had a clinical response to IV induction therapy. It has a favorable safety and tolerability profile.

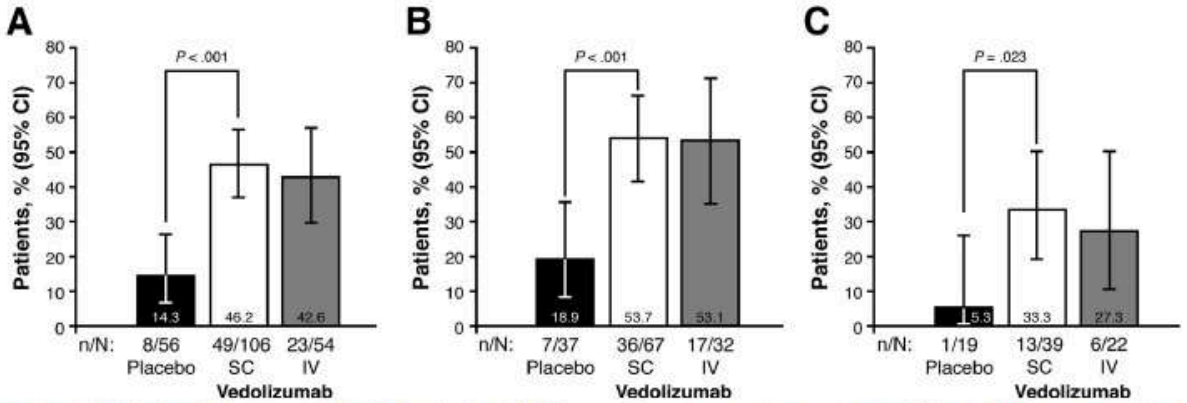

Figure 2. Clinical remission at week 52 (full analysis set) in (*A*) overall treatment groups, n = 216; (*B*) in anti-TNF–naïve patients, n = 136; and (*C*) in patients with prior anti-TNF treatment, n = 80. Clinical remission: Total Mayo score of ≤2 and no individual subscore >1.

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