2020. Mirikizumab-UC

RCT/Mirikizumab/UC/ Induction

Efficacy and Safety of Mirikizumab in a Randomized Phase 2 Study of Patients With Ulcerative Colitis

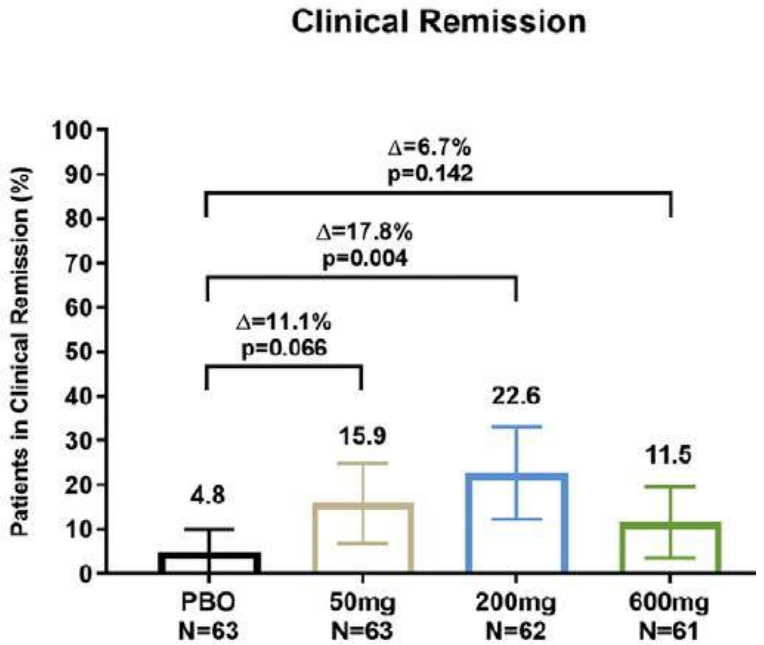
Phase 2, randomised, double-blind controlled trial.
Patients with moderate-severe UC were randomized to mirikizumab 50mg, 200mg, 600mg or placebo at weeks 0,4,8.

Primary endpoint: Clinical remission (Mayo subscores of 0 for rectal bleeding, with 1-point decrease from baseline for stool frequ, and 0 or 1 for endoscopy) at week 12.
A multiple testing procedure was used that began with the 600-mg group, & any nonsignificant comparison result ended the formal statistical testing procedure.

Results:

- The primary endpoint was not significant (comparison to 600 mg, P > .05). Clinical remission w12: 15.9%(P 0.066), 22.6% (P 0 .004), and 11.5% (P 0.142) in the 50-mg, 200-mg, and 600-mg groups, respectively, compared with 4.8% placebo.
- Clinical responses occurred in 41.3% (P 0 .014), 59.7% (P < .001), and 49.2% (P 0 .001) of patients in the 50-mg, 200-mg, and 600-mg groups, respectively, vs 20.6% placebo.
- At w52, 46.8% of patients given SC mirikizumab 200 mg every 4 weeks and 37.0% given 200 mg every 12 weeks were in clinical remission.

Conclusion:
In a randomized trial of patients with UC, mirikizumab was effective in inducing a clinical response after 12 weeks



Sandborn WJ et al. Gastroenterology. 2020; 158: 537-549