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

Moderate to severe UC. Randomized placebo controlled trial. Randomly assigned to groups given IV placebo, mirikizumab 50 mg or 200 mg with exposure-based dosing, or mirikizumab 600 mg with fixed dosing at weeks 0, 4, and 8.

Clinical responders at w12 who had received mirikizumab were randomly assigned to groups that received maintenance with mirikizumab 200 mg SC every 4w or every 12w.

Primary endpoint: clinical remission w12.

Results:

- Clinical remission w12: 50mg dose 15.9% (p=0.066); 200mg dose 22.6% (p=0.004) and 600mg dose 11.5% (p=0.142) vs 4.8% placebo.
- Clinical remission w52, 46.8% SC MIRI 200mg q4w vs 37% SC MIRI 200mg q12w, p=0.332

Conclusions:
Mirikizumab was effective in inducing a clinical response after 12 weeks. Additional studies are required to determine the optimal dose for induction of remission. Mirikizumab showed durable efficacy throughout the maintenance period.

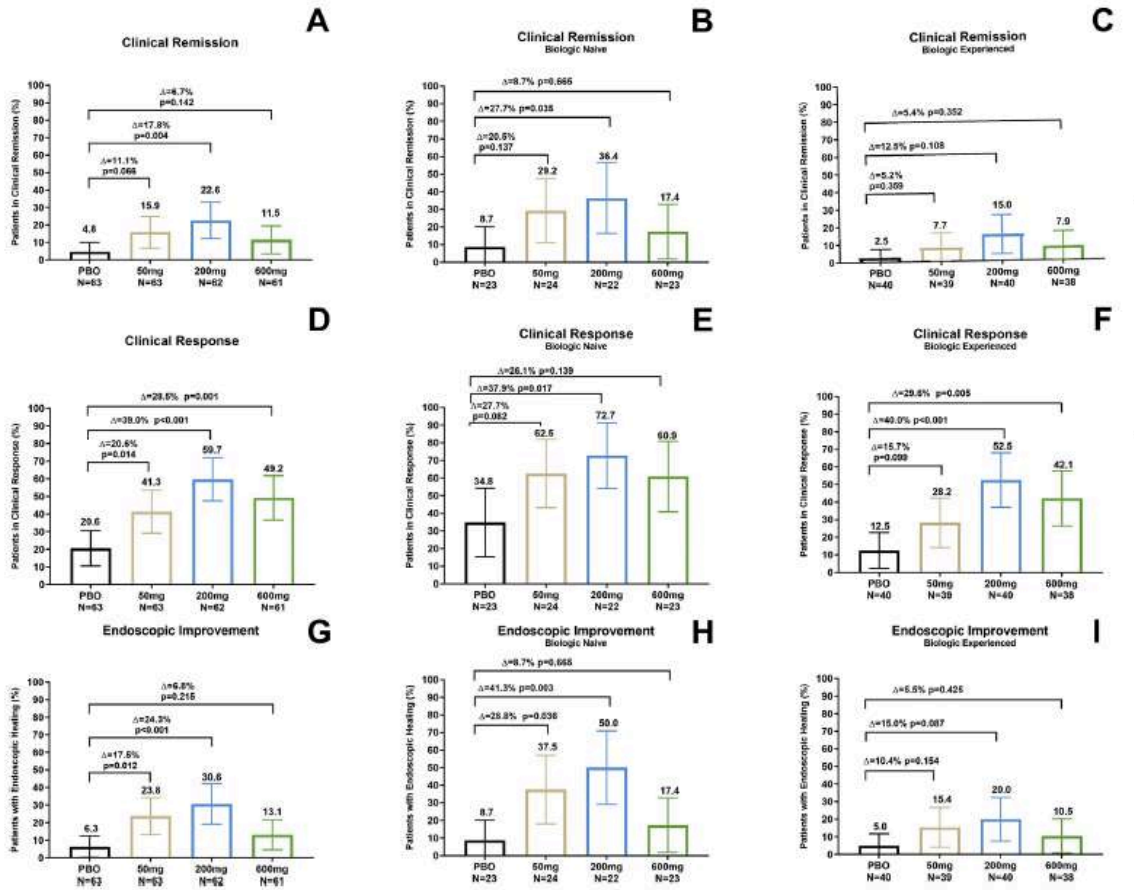

Figure 2. Clinical remission, clinical response, and endoscopic improvement in all, biologic-naive, and biologic-experienced patients at 12 weeks.

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