2021.TOUCHSTONE-OLE

Phase 2/ OZA/UC/ Efficacy/Safety

Long-Term Efficacy and Safety of Ozanimod in Moderately to Severely Active UC: Results From the Open-Label Extension of the Randomized, Phase 2 TOUCHSTONE Study

Open label extension.
Patients with moderate-to-severe UC with over 4 years of follow-up in the phase 2 TOUCHSTONE OLE.
Placebo or ozanimod HCl 0.5 mg or 1 mg during the double-blind period could enter the OLE (ozanimod HCl 1 mg daily).

Primary endpoint : clinical remission w56.

Results:
- Maintenance w56: Clinical remission 54.7% and clinical response 71.2%.
- Discontinuation rates 28% at year 1 and 15-18% annually through year 4.
- Histological remission w56 and 104, 46.3% and 38.5%
- No new safety signals identified.

Conclusions:
There was a high rate of continued study participation and long-term benefit with ozanimod HCl 1 mg daily based on clinical, histological and biomarker measures in patients with moderately to severely active UC in the TOUCHSTONE OLE.

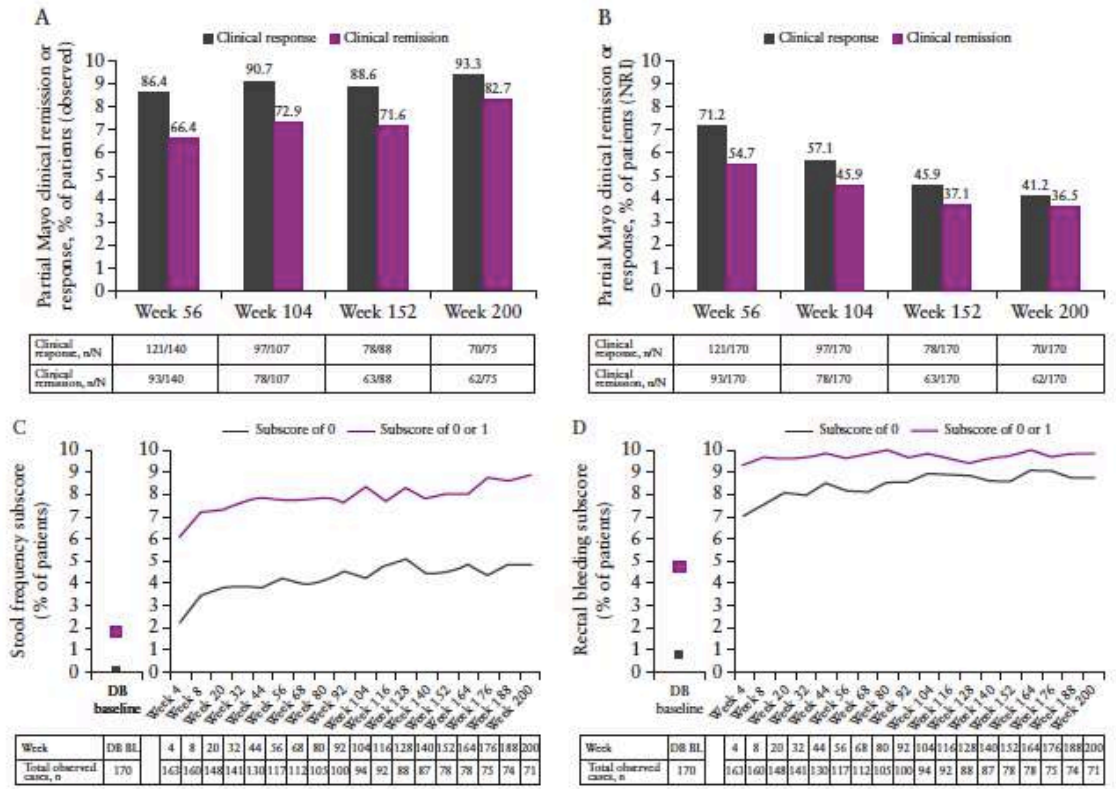

Figure 4. Percentages of patients with partial Mayo clinical response or remission based on observed cases [A] or based on NRI [B], patients with a Mayo stool frequency subscore of 0 or a subscore of 0 or 1 [observed cases] [C], and patients with a Mayo rectal bleeding subscore of 0 or a subscore of 0 or 1 [observed cases] [D] in the OLE phase. BL, baseline; DB, double-blind; NRI, non-responder imputation; OLE, open-label extension.

Sandborn WJ et al. J Crohn Colitis 2021;1-10