Phase 2/ Etrasimod/UC/ Efficacy/Safety

Efficacy and Safety of Etrasimod in a Phase 2 Randomized Trial of Patients With Ulcerative Colitis

Phase 2, proof-of-concept, double-blind, parallel-group study.
Moderate to severe UC randomised to 3 groups:
once-daily etrasimod 1 mg, etrasimod 2 mg, or placebo for 12 weeks.

Primary endpoint : The primary endpoint was an increase in the mean improvement in modified Mayo Clinic score from baseline to week 12.

Results:

- At w12 etrasimod 2 mg met the primary endpoint and all secondary endpoints.
- Endoscopic improvement occurred in 41.8% of patients receiving etrasimod 2 mg vs 17.8% receiving placebo (p 0.003).
- Most adverse events were mild to moderate.

Conclusions:
In patients with moderately to severely active ulcerative colitis, etrasimod 2 mg was more effective than placebo in producing clinical and endoscopic improvements.
Further clinical development is warranted

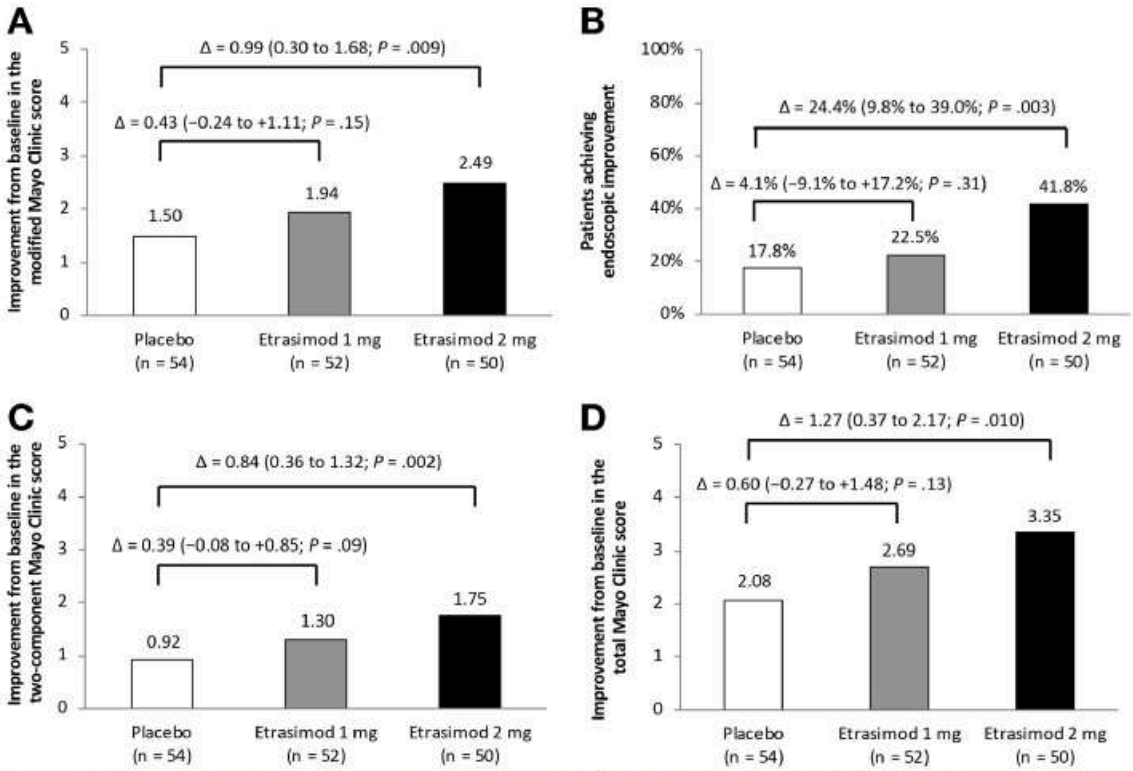

Figure 1. Primary and secondary efficacy endpoints at week 12 (intention-to-treat population). (*A*) LSM improvement from baseline in the modified MCS, which includes stool frequency, rectal bleeding, and endoscopy findings (primary endpoint). (*B*) The proportion of patients who achieved endoscopic improvement, defined as a score of ≤1 point on the Mayo Clinic endoscopic subscore (secondary outcome). (*C*) LSM improvement from baseline in the 2-component MCS, including rectal bleeding and endoscopy findings (secondary outcome). (*D*) LSM improvement from baseline in total MCS (secondary outcome). Values in parentheses indicate 90% confidence intervals. LSM, least squares mean; MCS, Mayo Clinic score.

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