2023. VIBRATO

RCT/Ritle-Brepocitinib/UC/ Induction

Oral Ritlecitinib and Brepocitinib for Moderate-to-Severe Ulcerative Colitis: Results From a Randomized, Phase 2b Study

Phase 2b, randomized, parallel-arm, double-blind umbrella study.

Adult patients with moderate-severely active UC were randomized to receive 8-week induction threapy with ritlecitinib (20,70, 300mg), brepocitinib (10, 30, 60mg) or placebo once daily for 8 weeks.

Primary endpoint: Total Mayo score (TMS) at week 8.

Results: N=319

- TMS decrease at week 8 was significantly different for all doses of ritlecitinib and brepocitinib vs placebo with ritlecitinib 200mg showing the largest decline.
- The placebo-adjusted mean TMSs (90% CI) at week 8 were 2.0 (3.2 to 0.9), 3.9 (5.0 to 2.7), and 4.6 (5.8 to 3.5) points for ritlecitinib 20, 70, and 200 mg (p 0.003, p < .001, and p < .001), respectively, and 1.8 (2.9 to 0.7), 2.3 (3.4 to 1.1), and 3.2 (4.3 to 2.1) points for brepocitinib 10, 30, and 60 mg (p 0.009, p 0.001, and p <.001), respectively.
- Serious adverse events comparable between groups.

Conclusion:
Ritlecitinib and brepocitinib induction therapies were more effective than placebo for the treatment of moderate-to-severe active UC, with an acceptable short-term safety profile.

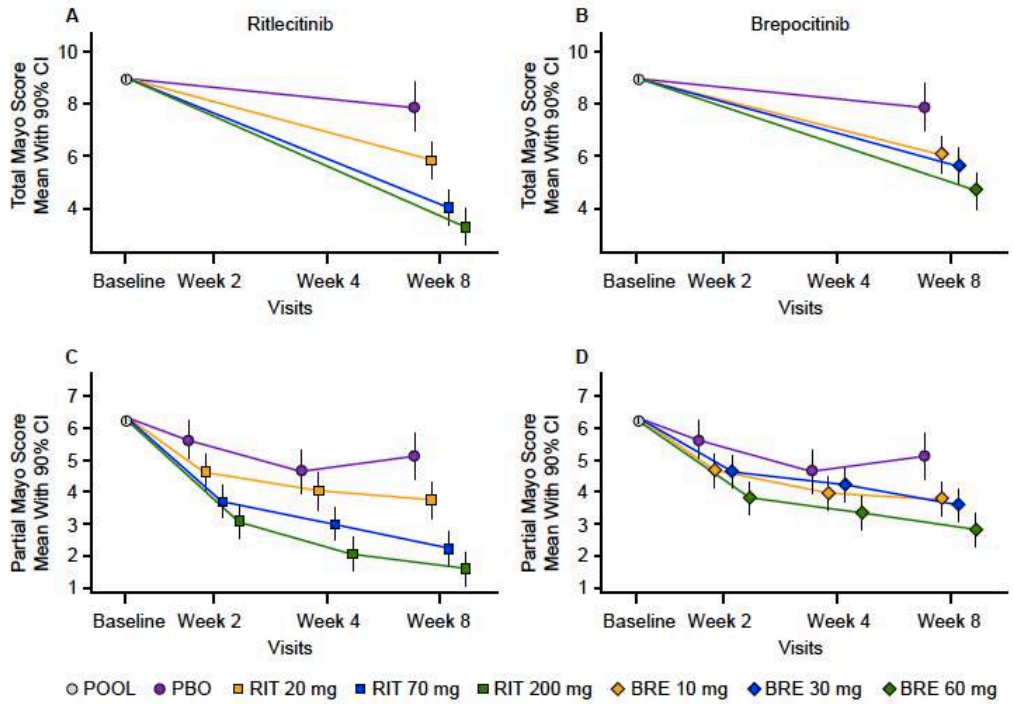

Figure 2. Total and partial Mayo scores. Patients in the 2 placebo treatment arms were pooled. The cLDA method produces estimates of mean at the baseline pooled over all treatment assignments (POOL).

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