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Summary

EFFICACY AND SAFETY OF MORF-057 THERAPY IN ADULTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS: PHASE 2B EMERALD-2 STUDY RESULTS THROUGH WEEK 12

Silvio Danese

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EMERALD-2 phase 2b trial of oral α4β7 integrin inhibitor MORF-057 in moderate-to-severe ulcerative colitis showed dose-dependent clinical remission rates (17.1% at 100 mg QD to 31.9% at 200 mg BID) that were numerically but not statistically higher than placebo (24.3%) at Week 12.

KEY POINTS

- The primary endpoint of clinical remission at Week 12 was not met: MORF-057 200 mg BID achieved 31.9% vs. 24.3% placebo (not statistically significant), with lower doses at 23.9% (100 mg BID) and 17.1% (100 mg QD).
- MORF-057 demonstrated a favorable safety profile with treatment-emergent adverse events mostly mild or moderate in severity, frequency similar to placebo (36.0% vs. 34.8%), and no cases of progressive multifocal leukoencephalopathy or deaths.
- Higher MORF-057 doses showed numerically greater rates of endoscopic improvement (43.5% at 200 mg BID vs. 31.4% placebo) and histo-endoscopic mucosal improvement (42.0% vs. 25.7%).
- In the advanced-therapy-experienced subgroup (N=87), clinical remission with MORF-057 200 mg BID was 21.1% vs. 13.0% placebo, with lower rates at the other doses (4.3% and 13.6%).
- The study observed a dose-dependent increase in α4β7 receptor occupancy, and the trial is ongoing for maintenance phase evaluation with further development planned.

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