CLINICAL PROOF OF PRINCIPLE AND FAVORABLE TOLERABILITY PROFILE SHOWN WITH ORALLY DOSED MORF-057 AS INDUCTION THERAPY FOR MODERATELY TO SEVERELY ACTIVE UC: PHASE 2A EMERALD-1 STUDY RESULTS

Yujun Wu

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Phase 2a open-label study of MORF-057, an oral α4β7 integrin inhibitor dosed at 100 mg twice daily, met its primary histologic endpoint with statistically significant improvement in moderately to severely active ulcerative colitis patients over 12 weeks.

KEY POINTS

- The primary endpoint was met with a mean reduction in Robarts Histopathology Index score of -6.4 (SD=11.2, p=0.0019) at week 12 in 35 patients, 89% of whom completed induction.
- Secondary clinical outcomes included 25.7% achieving modified Mayo Clinic score clinical remission, 45.7% achieving clinical response, and 25.7% achieving endoscopic improvement, with a mean mMCS change of -2.3 points.
- The study enrolled a difficult-to-treat population with mean baseline RHI of 22.7, modified Mayo score of 6.7, and 40% having prior advanced therapy experience; approximately half had Mayo endoscopic sub-score of 3.
- Pharmacodynamic analysis showed median α4β7 receptor occupancy >99% at trough with selective increases in circulating ITGb7+ lymphocyte subsets without rise in total lymphocyte counts.
- Treatment-emergent adverse events were low with no safety signals identified; the most common events were UC exacerbation (11.4%) and anemia (8.6%).

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