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Summary

EFFICACY AND SAFETY OF EMVISTEGRAST (FORMERLY GS-1427), AN ORAL A4B7 INTEGRIN INHIBITOR, FOR MODERATE TO SEVERE ULCERATIVE COLITIS: RESULTS OF THE INDUCTION PHASE OF THE PHASE 2 SWIFT TRIAL

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Standards & Guidelines | Paediatrics | Mechanisms & Personalised Medicine | Immunology | IBD | Endoscopy

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Emvistegrast 200 mg, an investigational once-daily oral α4β7 integrin inhibitor, met the primary endpoint and all secondary endpoints in a Phase 2 dose-ranging study of adults with moderately to severely active ulcerative colitis at 12-week induction.

KEY POINTS

- At Week 12, clinical response was achieved by 66% of participants receiving emvistegrast 200 mg versus 37% receiving placebo (treatment difference 30.2%, 95% CI 13.5–46.8; P = 0.0004).
- Clinical remission was achieved in 31% of emvistegrast 200 mg participants versus 8% of placebo participants (treatment difference 22.6%, 95% CI 8.6–36.5; P = 0.0015).
- Emvistegrast 200 mg was significantly superior to placebo for all secondary endpoints including histologic endoscopic mucosal improvement (26% vs 9%, P = 0.0231), mucosal healing (24% vs 9%, P = 0.0395), and endoscopic improvement (39% vs 12%, P = 0.0002).
- The study enrolled 238 participants (78% advanced therapy-naive, 22% with prior failure of ≤2 advanced therapies); 92% completed the 12-week induction phase.
- Adverse events occurred in 36% of emvistegrast participants versus 37% of placebo participants, were largely Grade ≤2, and serious adverse events (2% emvistegrast, 0% placebo) were deemed unrelated to study drug; no cases of progressive multifocal leukoencephalopathy were reported.
- The results support Phase 3 development of emvistegrast 200 mg once daily for inflammatory bowel disease.

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