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Summary

EFFICACY AND SAFETY OF AC-101, A FIRST-IN-CLASS ORAL SELECTIVE RIPK2 INHIBITOR, AS INDUCTION THERAPY FOR MODERATE-TO-SEVERE ULCERATIVE COLITIS: WEEK 12 RESULTS FROM A PHASE 1B/2A PROOF-OF-CONCEPT STUDY

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A phase 1b/2a study in Chinese patients with moderate-to-severe ulcerative colitis evaluated AC-101, a first-in-class oral RIPK2 inhibitor, showing clinical remission in 45.5% of patients receiving 100 mg twice daily at 12 weeks.

KEY POINTS

- At Week 12, the 100 mg twice-daily regimen achieved clinical remission in 45.5% of patients versus 30.8% with 200 mg once daily, with higher rates of clinical response (81.8% vs 61.5%) and statistically significant improvement in symptomatic remission (81.8% vs 38.5%, $p<0.05$).
- The study enrolled 24 Chinese adults with modified Mayo Score 5–9 and endoscopic subscore 2–3 who had inadequate response to conventional or advanced therapies; 41.7% had prior advanced therapy exposure.
- AC-101 targets the upstream NOD/RIPK2 pathway, a driver of proinflammatory cytokines including TNF-α and IL-23, offering a novel mechanism distinct from downstream-targeting therapies.
- Adverse events occurred in 40% of patients, were predominantly grade 1–2, mostly resolved without intervention, and included no serious infections or clinically meaningful safety signals.
- Authors note the efficacy compares favorably to historical East Asian placebo remission rates of 4.2–5.5% and suggest the data support future large-scale trials.

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