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Summary

SAFETY AND EFFICACY OF OD-001, A FIRST-IN-CLASS ORAL RIPK2 SCAFFOLDING INHIBITOR, IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS: RESULTS FROM A PHASE 2A TRIAL (NCT06850727)

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OD-001, a first-in-class oral RIPK2 scaffolding inhibitor, achieved 27% clinical remission at week 12 in patients with moderately to severely active ulcerative colitis who had inadequate response or intolerance to conventional and/or advanced therapies.

KEY POINTS

- The combined change in modified Mayo Clinic Score from baseline to week 12 was -2.6 ($p < 0.001$), with Part 1 (10 mg BID) achieving -3.1 ($p = 0.004$) and Part 2 (20 mg BID regimens) achieving -2.5 ($p < 0.001$).
- The 27% clinical remission rate was significantly higher than the 10% historical placebo rate in recent UC trials (17% difference, $p < 0.05$), with similar efficacy in advanced therapy experienced (25%) and naïve (27%) patients.
- OD-001 was well tolerated with drug-related adverse events in only 4% of patients, all grade 1, and no serious adverse events, serious infections, or discontinuations due to adverse events.
- Combined symptomatic remission was achieved in 47% of patients and endoscopic improvement in 33%.
- The study enrolled 53 participants with mean baseline modified Mayo Score of 6.5, 51% with Mayo endoscopic score 3, 32% advanced therapy experienced, and median baseline fecal calprotectin of 1,785 µg/g.
- Development continues with a phase 2b monotherapy placebo-controlled trial and phase 2a combination trials with standard of care.

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