ADS051, AN ORAL, GUT-RESTRICTED, SMALL MOLECULE NEUTROPHIL MODULATOR IN PATIENTS WITH MODERATE-TO-SEVERE ULCERATIVE COLITIS RECEIVING MULTIPLE ASCENDING DOSES

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Phase 1B study of ADS051, a novel oral gut-restricted neutrophil modulator, demonstrated favorable safety and tolerability with signals of efficacy in 24 patients with moderate to severe ulcerative colitis.

KEY POINTS

- ADS051 is a gut-restricted small molecule derived from cyclosporine A that inhibits MRP2-driven neutrophil migration and FPR1-mediated neutrophil activation without blocking T-cell activation.
- In the randomized, placebo-controlled study, 16.7% of ADS051-treated patients versus 66.7% of placebo patients experienced treatment-emergent adverse events, with no serious adverse events and no discontinuations due to adverse events.
- Clinical remission at Day 28 was achieved in 22% of pooled ADS051 patients versus 0% of placebo patients, and endoscopic response in 50% versus 17%.
- Pharmacokinetic data showed high stool concentrations exceeding the IC50 for target receptors at all dose levels with minimal systemic exposure, with less than 1% of the dose excreted in urine.
- The findings support further investigation of ADS051 in larger studies for patients with ulcerative colitis.

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