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Summary

TOWARD A SAFER, NON-SYSTEMIC JAK INHIBITOR FOR IBD: A PHASE 2A STUDY TO EVALUATE SAFETY, PHARMACOKINETICS AND PRELIMINAR CLINICAL EFFICACY OF ORAL TREATMENT WITH OST-122 IN PATIENTS WITH ULCERATIVE COLITIS

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Phase 2a trial of OST-122, a GI-targeted JAK3/TYK2 inhibitor, demonstrated favorable safety with no serious adverse events and showed clinical response in 44% of ulcerative colitis patients after 28 days of treatment.

KEY POINTS

- OST-122 400 mg daily for 28 days showed no serious adverse events and no treatment-related discontinuations in 28 patients with active UC, with adverse event rates similar to placebo (71% vs 78%).
- Clinical response was achieved by 44% of OST-122-treated patients versus 11% on placebo, and clinical remission was reached by 22% versus 0% on placebo.
- Pharmacokinetic analysis confirmed gut-restricted profile with minimal plasma exposure (Cmax 0.92 ng/mL) and therapeutically relevant colon tissue levels (15.5 µg/g).
- Rectal bleeding improved in 63% of OST-122 patients versus 33% on placebo, and 48% achieved PRO-2 improvement of ≥2 points versus 11% on placebo.
- OST-122 induced clinical response in both bionaïve and bioexperienced patients, with 16% achieving histological response and remission versus 0% on placebo.
- This Phase 2a trial had a small sample size (n=37) and short duration (28 days); confirmatory studies are planned to determine optimal dosing and statistical significance.

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