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Summary

PALI-2108, A NEW GI-ACTIVATED PDE4 INHIBITOR PROMOTES CLINICAL RESPONSE IN ULCERATIVE COLITIS PATIENTS WITHIN ONE WEEK OF TREATMENT

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UEG Week Barcelona 2026 Poster

IBD

October 20, 2026

PALI-2108, a microbiome-activated oral PDE4 inhibitor prodrug, demonstrated sustained ileocolonic exposure with minimal systemic levels and was associated with rapid clinical improvement in patients with moderate-to-severe ulcerative colitis after one week of treatment.

KEY POINTS

- All five UC patients achieved clinical response with mean 62.8% reduction in modified Mayo score after 7 days, and two of five met criteria for clinical remission.
- Histologic improvement was observed across all indices with reductions of 58% (Nancy), 56% (Robarts), and 36% (Geboes), along with structural changes consistent with early mucosal healing.
- Pharmacodynamic analyses showed tissue PDE4B expression decreased approximately 71%, tissue lymphocyte content decreased approximately 40%, and fecal calprotectin decreased approximately 70.3%.
- PALI-2108 demonstrated sustained ileocolonic drug presence with systemic peak concentrations above IC90 at 8-9 hours, supporting once-daily dosing with minimal systemic exposure.
- Treatment was well tolerated with no serious adverse events reported; a Phase 2 program is planned to evaluate safety and efficacy out to 48 weeks in ulcerative colitis and Crohn's disease.

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