

FAECALIBACTERIUM PRAUSNITZII - EXL01 IN CROHN'S DISEASE: FROM PRECLINICAL DISCOVERY TO FIRST-IN-HUMAN CLINICAL TRIAL IN PATIENTS WITH MILD TO MODERATE CROHN'S DISEASE

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UEG Week Berlin 2025

Presentation

Gut Microbiota

IBD

October 7, 2025

First-in-human study of *Faecalibacterium prausnitzii* strain EXL01 in Crohn's disease demonstrated safety and tolerability over 24 weeks with evidence of biological activity through changes in ileal gene expression.

KEY POINTS

- EXL01 (10¹⁰ cells/day orally for 24 weeks) was well tolerated with no treatment-related serious adverse events or safety signals in 8 patients with mild to moderate ileal Crohn's disease following corticosteroid-induced remission or response.
- Six of 8 patients (75%) completed the 24-week treatment; two discontinued due to disease flare.
- Patients who flared during the study showed higher baseline systemic inflammation markers (CRP, neutrophils, platelets) and innate immunity gene expression with limited corticosteroid response compared to those who remained in remission.
- Transcriptomic analyses revealed distinct changes in ileal gene expression following EXL01 treatment, notably modulation of immune-related genes and upregulation of energy metabolism pathways.
- Gut microbiota composition remained largely stable during treatment.
- This is the first administration of *F. prausnitzii* to humans; a phase 2 randomized controlled trial is ongoing to further assess efficacy.

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