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Summary

MUFEMILAST (ORAL PDE4B SELECTIVE EXPRESSION INHIBITOR) FOR ULCERATIVE COLITIS: OPEN-LABEL EXTENSION RESULTS AT 24 WEEKS FROM A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PARALLEL GROUP INDUCTION PHASE II CLINICAL TRIAL

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UEG Week Barcelona 2026 | Presentation

Histopathology | Mechanisms & Personalised Medicine | IBD

October 20, 2026

Mufemilast, an oral PDE4b-selective inhibitor with gut-selective distribution, achieved 57% clinical remission at 12 weeks in moderate-to-severe ulcerative colitis, with response rates of 80% and 67% endoscopic improvement in the 60mg twice-daily group.

KEY POINTS

- In the phase 2 trial (n=92), mufemilast 60mg twice daily achieved clinical remission in 57% of patients at 12 weeks versus 13% with placebo, with clinical response in 80% and endoscopic improvement in 67%.
- At 24 weeks in the open-label extension, clinical remission increased to 75% in placebo-switched patients and 62% in those escalated from 45mg to 60mg, with endoscopic improvement rates of 75% and 66% respectively.
- Efficacy appeared similar in biologic-naïve and biologic-experienced patients, and locally and centrally read endoscopy data showed consistent results across endpoints.
- Safety was favorable over 24 weeks with one serious adverse event (pre-existing thrombophlebitis), two treatment discontinuations for adverse events (headache, extremity pain), and most adverse events mild or moderate with no clinically relevant changes in vital signs or laboratory parameters.
- Patients with positive Quantiferon tests were included in the trial, and the drug was well tolerated in this subgroup.

– The findings support initiation of a phase 3 trial in patients with moderate-to-severe ulcerative colitis.

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