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Summary

ORAL MUFEMILAST (A NOVEL SELECTIVE PDE4INHIBITOR) DEMONSTRATES EFFICACY AND SAFETY IN A PHASE II MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED INDUCTION TRIAL IN CHINESE PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

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Phase 2 trial of mufemilast, an oral PDE4 inhibitor, achieved 57% clinical remission at 12 weeks in moderate to severe ulcerative colitis, with a 44% placebo-subtracted benefit (p<0.001) for the 60mg twice-daily dose.

KEY POINTS

- Clinical remission rates were 13% for placebo, 39% for mufemilast 45mg twice daily, and 57% for 60mg twice daily at 12 weeks in 92 patients with moderate to severe UC (modified Mayo score 4-9).
- Mucosal healing was achieved in 67% of patients on 60mg twice daily versus 16% on placebo, with both active doses statistically superior to placebo.
- Clinical response rates were 87% for 45mg and 80% for 60mg versus 42% for placebo.
- Safety profile showed one serious adverse event (thrombophlebitis, pre-existing condition), two discontinuations due to adverse events in the 60mg group, and no clinically relevant changes in vital signs, laboratory values, or ECG parameters.
- Efficacy and safety were similar in biologic-naive and biologic-exposed patients and in Quantiferon-positive and negative patients, though subgroup numbers were small.
- A phase 3 study is planned to confirm these results.

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