THE EFFICACY AND SAFETY OF ETRASIMOD IN MILDLY TO MODERATELY ACTIVE ULCERATIVE COLITIS: RESULTS FROM THE GLADIATOR TRIAL

Severine Vermeire

UEG Week Berlin 2025 | Presentation

IBD | Mechanisms & Personalised Medicine

October 7, 2025

GLADIATOR, a proof-of-concept trial of etrasimod 2 mg daily in mildly to moderately active ulcerative colitis (MMS 4–6), did not meet its primary endpoint of clinical remission at week 52 but demonstrated statistically significant superiority over placebo at week 12 for clinical remission, endoscopic improvement, and endoscopic improvement-histologic remission.

KEY POINTS

- At week 52, 26.0% of etrasimod-treated patients versus 18.3% of placebo achieved clinical remission (difference 7.4%, 95% CI -5.2 to 19.9, p=0.2524), failing to meet the primary endpoint.
- At week 12, etrasimod achieved significantly higher rates of clinical remission (28.3% vs 11.7%, p=0.0068), endoscopic improvement (44.1% vs 20.0%, p=0.0007), and endoscopic improvement-histologic remission (29.1% vs 13.3%, p=0.0128) compared with placebo.
- Sustained clinical remission at both weeks 12 and 52 was achieved by 16.5% of etrasimod versus 5.0% of placebo patients (difference 11.2%, 95% CI 2.6–19.8, p=0.0104).
- Etrasimod was generally well tolerated with no new safety signals; findings were consistent with the known safety profile from the ELEVATE UC programme.
- The trial enrolled 187 patients (127 etrasimod, 60 placebo) with MMS 4–6, endoscopic subscore ≥2, and rectal bleeding subscore ≥1; this is the first global randomised controlled trial of an advanced therapy specifically in this mild-to-moderate UC population.

VIEW THIS CONTENT ON GUTFLIX

https://gutflix.eu/search/d/44d3f3fa-a813-11f0-96ec-0242ac140006

AI-generated summary

This summary was generated by an AI large language model based on the content transcript. It is for informational purposes only and should not be considered a substitute for clinical judgment. Always rely on your professional expertise and the full clinical context when making clinical decisions.