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Summary

RELATIONSHIP BETWEEN CLINICAL AND HISTOLOGIC FINDINGS WITH TULISOKIBART INDUCTION AT WEEK 12 AND MAINTENANCE DOSING AT WEEK 50 IN THE PHASE 2 RANDOMIZED CONTROLLED ARTEMIS-UC STUDY IN PARTICIPANTS WITH ULCERATIVE COLITIS

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UEG Week Berlin 2025 Poster

IBD

October 6, 2025

Analysis of the ARTEMIS-UC phase 2 trial found strong correlations between clinical remission or endoscopic improvement and histologic endpoints in ulcerative colitis patients treated with tulisokibart, a TL1A monoclonal antibody, at 12 and 50 weeks.

KEY POINTS

- Tulisokibart demonstrated significantly higher rates of clinical remission, endoscopic improvement, and histologic improvement versus placebo in participants with moderately to severely active ulcerative colitis in the ARTEMIS-UC trial.
- At week 12 post-induction, correlations between endoscopic improvement and histologic-endoscopic mucosal improvement (HEMI) or mucosal healing, and between clinical remission and HEMI or mucosal healing, were greater than 0.8.
- At week 50 after maintenance therapy in induction responders, the same correlations increased to greater than 0.9, and fecal calprotectin normalization showed strong correlation with histologic endpoints (greater than 0.7).
- The analysis examined 65 participants at week 12 and 34 participants at week 50 from the Histology Analysis Set, assessing 15 pairwise relationships using the Phi correlation coefficient.
- Authors suggest these findings may inform the use of clinical and endoscopic measures to estimate histologic treatment efficacy in routine care, where histologic assessment is inconsistently performed.

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