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Summary

EFFICACY AND SAFETY OF UPADACITINIB MAINTENANCE TREATMENT IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE: 3-YEAR RESULTS FROM THE U-ENDURE LONG-TERM EXTENSION STUDY

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UEG Week Berlin 2025 | Poster

IBD

October 5, 2025

Long-term extension data from the U-ENDURE study demonstrate sustained efficacy and consistent safety of upadacitinib 15 mg and 30 mg once-daily over 3 years of maintenance therapy in patients with moderately to severely active Crohn's disease.

KEY POINTS

- Clinical remission rates remained stable from long-term extension week 0 to week 96 for both upadacitinib 15 mg (78.3% to 83.1% by stool frequency and abdominal pain score; 81.3% to 83.1% by CDAI) and upadacitinib 30 mg (84.7% to 84.3% by stool frequency and abdominal pain score; 86.1% to 88.6% by CDAI).
- Endoscopic response and remission rates remained stable over 96 weeks, with endoscopic remission rates of 42.4% to 50.8% for upadacitinib 15 mg and 53.0% to 56.7% for upadacitinib 30 mg.
- Inflammatory markers (high-sensitivity C-reactive protein and faecal calprotectin) showed stable mean changes from induction baseline through long-term extension week 96 in both dose groups.
- No new safety signals were identified; the safety profile was consistent with the known profile of upadacitinib in Crohn's disease, with events including serious infections, herpes zoster, gastrointestinal perforations, and rare cases of malignancy, major adverse cardiovascular events, and venous thromboembolism.
- This analysis is most relevant to clinicians managing patients with moderately to severely active Crohn's disease considering long-term upadacitinib maintenance therapy.

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