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Summary

EFFICACY AND SAFETY OF UPADACITINIB MAINTENANCE THERAPY IN MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE: 144-WEEK RESULTS FROM THE U-ENDURE LONG-TERM EXTENSION STUDY

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In the U-ENDURE long-term extension, upadacitinib 15 mg and 30 mg once daily maintained clinical and endoscopic remission through 144 weeks (4 years) in patients with moderately to severely active Crohn's disease, with no new safety signals identified.

KEY POINTS

- At 144 weeks, as-observed clinical remission per stool frequency and abdominal pain score remained stable: 78.9% with upadacitinib 15 mg and 86.6% with upadacitinib 30 mg.
- As-observed endoscopic remission at 144 weeks was maintained at 47.1% with upadacitinib 15 mg and 64.2% with upadacitinib 30 mg.
- Mean reductions from induction baseline in high-sensitivity CRP and faecal calprotectin were sustained at 144 weeks in both dose groups.
- In the cumulative maintenance population, serious infections occurred at 3.0 events per 100 patient-years with upadacitinib 15 mg and 3.8 with 30 mg; herpes zoster occurred at 2.1 and 4.7 events per 100 patient-years, respectively.
- One death (suicide, deemed unrelated to study drug), one major adverse cardiovascular event, and two venous thromboembolism events were reported in the upadacitinib 30 mg group; no lymphomas occurred.
- Interpretation of upadacitinib 15 mg outcomes is limited by small patient numbers.

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