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Summary

HEPATIC IMPACT OF ETRASIMOD FOR TREATMENT OF MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS: AN INTEGRATED SAFETY SUMMARY FROM THE ETRASIMOD ULCERATIVE COLITIS CLINICAL PROGRAMME

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Analysis of the etrasimod ulcerative colitis clinical programme found generally low incidence of liver-related treatment-emergent adverse events and sponsor-designated events of interest in both etrasimod-treated and placebo-treated patients, with infrequent treatment discontinuations.

KEY POINTS

- In the Pivotal UC cohort (etrasimod N=527, placebo N=260), liver-related treatment-emergent adverse events occurred at similar rates between etrasimod (exposure-adjusted incidence rate ≤0.04) and placebo (exposure-adjusted incidence rate ≤0.03), affecting ≤3.3% and ≤1.2% of patients respectively.
- Sponsor-designated events of interest related to liver injury occurred in 1.3% of etrasimod-treated patients and 0.8% of placebo-treated patients in the Pivotal UC cohort, with exposure-adjusted incidence rates of ≤0.03 and ≤0.02 per patient-year respectively.
- In the All UC cohort (etrasimod N=942, total exposure 757.9 patient-years across phase 2, phase 3, and open-label extension studies), only three patients discontinued etrasimod due to liver-related adverse events (abnormal liver function test, increased blood alkaline phosphatase, and increased alanine aminotransferase).
- Most common liver-related laboratory abnormalities in etrasimod-treated patients were increased gamma-glutamyl transferase (3.3% in All UC cohort) and increased alanine aminotransferase (2.9% in All UC cohort), both with exposure-adjusted incidence rates of 0.04 per patient-year.

– This analysis would be relevant to clinicians evaluating the hepatic safety profile of etrasimod as a selective S1P receptor modulator for moderately to severely active ulcerative colitis.

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