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Summary

EFFICACY AND SAFETY OF ETRASIMOD IN PATIENTS WITH MODERATE TO SEVERE ISOLATED PROCTITIS RELATIVE TO THOSE WITH MORE EXTENSIVE COLITIS: RESULTS FROM THE PHASE 3 ELEVATE UC 52 AND ELEVATE UC 12 TRIALS

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Post hoc analysis of the phase 3 ELEVATE UC trials demonstrates that etrasimod, an investigational oral selective S1P receptor modulator, achieved similar efficacy and safety in patients with isolated proctitis compared to those with more extensive ulcerative colitis.

KEY POINTS

- The analysis included 64 patients with isolated proctitis (less than 10 cm rectal involvement) at week 12 and 36 at week 52, compared to 397 and 326 patients with more extensive colitis from ELEVATE UC 52 and UC 12 trials.
- At week 12, patients with isolated proctitis receiving etrasimod 2 mg once daily achieved clinical remission at 42.9% versus 13.6% for placebo (percentage difference 45.5, p less than 0.001), with similar proportions achieving predefined efficacy endpoints compared to those with more extensive colitis.
- At week 52, etrasimod-treated patients with isolated proctitis achieved corticosteroid-free clinical remission at 44.4% versus 11.1% for placebo (percentage difference 44.4, p less than 0.001) and sustained clinical remission at 29.6% versus 11.1% (percentage difference 35.7, p less than 0.001).
- Improvements in bowel urgency numeric rating scale scores were similar between isolated proctitis and more extensive colitis subgroups (mean change from baseline at week 12: -2.8 vs -2.9; at week 52: -5.0 vs -4.1).
- Safety in patients with isolated proctitis was generally similar to the overall trial population, though the authors note that prospective confirmation in larger cohorts with isolated proctitis is necessary.

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