LONG-TERM SAFETY OF OZANIMOD IN MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS AND RELAPSING MULTIPLE SCLEROSIS

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Long-term safety analysis of ozanimod 0.92 mg/day in 1158 ulcerative colitis patients (mean 28.4 months exposure) and 2494 relapsing multiple sclerosis patients (mean 56.4 months exposure) showed the S1P receptor modulator was generally well tolerated with low rates of serious infections and malignancy.

KEY POINTS

- Treatment-emergent adverse events occurred in 74.6% of UC patients and 88.2% of RMS patients, with serious adverse events in 17.3% and 14.1% respectively, and discontinuation rates of 9.3% and 3.6%.
- Most common adverse events in UC were lymphopenia (12.3%), anemia (8.4%), lymphocyte count decreased (7.9%), and nasopharyngitis (7.9%); in RMS, nasopharyngitis (20.6%), headache (16.9%), and upper respiratory infection (11.9%).
- Exposure-adjusted incidence rates per 100 patient-years for serious infection were 1.6 in UC and 0.8 in RMS, for opportunistic infection were 1.2 and 1.4, and for malignancy were 0.6 and 0.3.
- Alanine aminotransferase elevation to five times the upper limit of normal occurred in 2.3% of UC patients and 0.8% of RMS patients.
- This pooled analysis from phase 2, phase 3, and open-label extension trials provides long-term safety data relevant to clinicians treating moderately to severely active ulcerative colitis with ozanimod.

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