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Summary

REINITIATION OF OZANIMOD AFTER DOSE INTERRUPTION: ASSESSMENT OF EFFECT ON HEART RATE

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A phase 1 study in 64 healthy adults found that ozanimod can be safely reinitiated at the maintenance dose of 0.92 mg without repeating dose titration within 14 days of drug discontinuation, with no meaningful changes in heart rate observed after 3-, 7-, or 14-day washout intervals.

KEY POINTS

- Ozanimod is a selective S1P receptor 1 and 5 modulator approved for moderately to severely active ulcerative colitis and relapsing multiple sclerosis, and dose titration is implemented to mitigate bradycardia risk associated with S1P receptor modulators.
- In this randomized, double-blind, placebo-controlled study, 64 healthy adults received ozanimod dose titration (0.23 mg Days 1-4, 0.46 mg Days 5-7, 0.92 mg thereafter) or placebo for 28 days, followed by washout periods of 3, 7, or 14 days, then reinitiation with a single 0.92 mg dose.
- Heart rate nadir changes from baseline on reinitiation Day 1 were similar between ozanimod and placebo groups across all washout intervals, with LS mean differences of 1.78 bpm (3-day), -1.02 bpm (7-day), and -1.54 bpm (14-day), all with 90% confidence intervals crossing zero.
- During initial dose escalation, predose heart rate values on Days 5 and 8 were approximately 5 bpm lower than Day 1, and median time to heart rate nadir was 4 hours for ozanimod versus 3-4 hours for placebo.
- Repeated dosing and reinitiation of ozanimod 0.92 mg after all washout intervals was generally safe and well tolerated in healthy participants, and the study was funded by Bristol Myers Squibb.

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