EFFECT OF OZANIMOD AT THERAPEUTIC AND SUPRATHERAPEUTIC DOSES ON ABSOLUTE LYMPHOCYTE COUNT AND HEART RATE IN HEALTHY ADULTS

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A phase 1 placebo-controlled study in healthy adults examined absolute lymphocyte count and heart rate changes during 65 days of ozanimod treatment at therapeutic (0.92 mg) and supratherapeutic (1.84 mg) doses.

KEY POINTS

- Absolute lymphocyte count decreased as expected with ozanimod, beginning to plateau after approximately 14 days, with mean decreases of 0.82×10^9/L (0.92 mg) and 1.09×10^9/L (1.84 mg) at Day 21; the decrease was similar across ozanimod groups and was not dose dependent.
- Two participants discontinued due to treatment-related lymphopenia (one moderate in the 0.92 mg group, one mild in the 1.84 mg group); neither had a reported infection or associated adverse event, and both events resolved by end of study.
- Heart rate was slightly lower with ozanimod 1.84 mg on Days 8–15 and normalized thereafter; no clinically meaningful trends in mean heart rate or change from daily baseline occurred across groups.
- No clinically significant changes from baseline or new cardiac safety signals were observed in this study of healthy participants.

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