Ozanimod Demonstrates Efficacy and Safety in a Phase 3 Trial of Relapsing Multiple Sclerosis (SUNBEAM)


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BACKGROUND
• Ozanimod, an oral, once-daily immunomodulator that selectively targets sphingosine 1-phosphate receptors, is in development for the treatment of multiple sclerosis (MS).
• The SUNBEAM trial was a double-dummy, 12-month, double-blind, parallel-group, active-controlled study that evaluated ozanimod for the treatment of relapsing-remitting MS.

METHODS
• SUNBEAM was a multicenter, randomized, double-blind, double-dummy, parallel-group, phase 3 study (ClinicalTrials.gov Identifier: NCT02304586) (Figure 1).

RESULTS
• In total, 1048 patients with relapsing-remitting MS were randomized to ozanimod 0.5 mg (n=388), 1 mg (n=343), or IFN-β1a (n=317) for 12 months.
• Ozanimod 0.5 mg and 1 mg demonstrated statistically significant and numerically greater reductions in annualized relapse rate (ARR) compared with IFN-β1a (0.171 vs 0.212 vs 0.278, respectively).
• Ozanimod 0.5 mg demonstrated statistically significant and numerically greater reduction in confirmed disability progression compared with IFN-β1a (-1.560% vs -1.000%, respectively).
• Ozanimod was well tolerated, with a similar safety profile across all treatment groups.

CONCLUSIONS
• Ozanimod demonstrated statistically significant and numerically greater reductions in ARR and confirmed disability progression compared with IFN-β1a.
• Ozanimod was well tolerated, with a similar safety profile across all treatment groups.

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Abstract: Ozanimod Demonstrates Efficacy and Safety in a Phase 3 Trial of Relapsing Multiple Sclerosis (SUNBEAM)

Ozanimod, a selective sphingosine 1-phosphate (S1P) receptor modulator, was investigated in a phase 3 study in patients with relapsing-remitting multiple sclerosis (RRMS). In the SUNBEAM Study (NCT02304586), patients were randomized to ozanimod 0.5 mg (n=388), 1 mg (n=343), or interferon β-1a (IFN-β1a) (n=317) for 12 months. Ozanimod demonstrated statistically significant and numerically greater reductions in annualized relapse rate (ARR) compared with IFN-β1a (0.171 vs 0.212 vs 0.278, respectively) and confirmed disability progression compared with IFN-β1a (-1.560% vs -1.000%, respectively). Ozanimod was well tolerated, with a similar safety profile across all treatment groups.