Ozanimod vs Interferon β-1a: Clinical and Magnetic Resonance Imaging (MRI) Results of RADIANCE Part B – A 2-Year Phase 3 Trial in Relapsing Multiple Sclerosis (RMS)

Short Title: Ozanimod vs IFN β-1a in RMS: Radiance Part B

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Background: Ozanimod is an oral, once-daily immunomodulator that selectively targets sphingosine 1-phosphate 1 and 5 receptors. Results from RADIANCE Part B (NCT02047734), one of two Phase 3 studies evaluating ozanimod efficacy and safety vs interferon β-1a (IFN) in RMS patients are reported.

Methods: This 24-month, multicenter, randomized, double-blind, parallel-group, active-controlled study evaluated daily oral ozanimod 1 or 0.5 mg (initiated with 7-day dose escalation) vs weekly intramuscular 30 μg IFN. Primary endpoint was annualized relapse rate (ARR) at month 24. Key secondary endpoints included MRI assessments measuring T2 lesion changes and gadolinium enhancing (GdE) T1 lesions. Disability will be evaluated on a pooled dataset with a second Phase 3 trial.

Results: 1313 patients were randomized and treated; baseline characteristics were similar across treatment groups. 90% of ozanimod 1 mg and 85% of 0.5 mg patients vs 85% of IFN patients completed the trial. Both doses (1 and 0.5 mg) reduced ARR (0.172, 0.218) vs IFN (0.276) ($p<0.0001$, $p=0.0168$, respectively). Adjusted mean number of new/enlarging T2 lesions over 24 months was reduced 42% for ozanimod 1 mg (1.848) and 35% for 0.5 mg (2.082) vs IFN (3.183) ($p<0.0001$ both comparisons). Adjusted mean number of GdE lesions at 24 months was reduced 53% for ozanimod 1 mg (0.176; $p=0.0006$) and 47% for 0.5 mg (0.197; $p=0.0030$) vs IFN (0.373). Incidence of adverse events (AEs), serious AEs, and AEs leading to discontinuation was balanced across treatment groups. Similar cardiac and infection profiles were observed across groups.

Conclusion: In this Phase 3 study, both doses of ozanimod demonstrated superiority to IFN on relapse and MRI endpoints over 2 years in an active RMS population. These findings, coupled with the safety

and tolerability results, demonstrate that ozanimod has the potential to provide a novel oral therapy option with a favorable benefit-risk profile for RMS patients.