AAN 64th ANNUAL MEETING ABSTRACT

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Abstract Title: A double-blind, placebo-controlled, Phase 2, 26-week DreaMS trial of a selective S1P receptor agonist ONO-4641 in patients with Relapsing-Remitting Multiple Sclerosis.

Objective: To investigate the safety and efficacy of ONO-4641 in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) in a Phase 2b, dose-ranging study (DreaMS; NCT01081782).

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Background: ONO-4641 is a potent, oral, and selective sphingosine-1-phosphate (S1P) receptor agonist (stimulating primarily S1P1 and S1P3 receptors).

Methods: A total of 407 RRMS patients (aged 18-55 years with Expanded Disability Status Scale (EDSS) scores up to 5.5, who had ≥2 relapses during the 2 previous years or ≥1 within the previous year or ≥1 gadolinium (Gd)-enhancing lesion within 3 months) were randomized (1:1:1:1) to placebo, 0.05 mg, 0.10 mg, or 0.15 mg ONO-4641 once daily for 26 weeks.

Results: The primary endpoint of cumulative number of T1 Gd-enhancing lesions from Week 10 to 26 on MRI was statistically lower.

Conclusion: ONO-4641 demonstrated statistically significant efficacy on key endpoints, compared to placebo, and was well tolerated in patients with RRMS.

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