

## **Phase 2 AFFINITY Trial Evaluates Opicinumab in a Targeted Population of Patients With Relapsing Multiple Sclerosis: Rationale, Design and Baseline Characteristics**

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**Objective:** To present the design of the AFFINITY study (NCT03222973) as well as participant baseline characteristics.

**Background:** Opicinumab is a human monoclonal antibody against LINGO-1, a negative regulator of oligodendrocyte differentiation and axonal regeneration. The Phase 2 SYNERGY study identified a dose (10 mg/kg) and subpopulation that were associated with enhanced treatment response.

**Design/Methods:** AFFINITY is an ongoing Phase 2, 72-week, randomized, double-blind, placebo-controlled study evaluating the efficacy/safety of opicinumab (intravenous 750 mg every 4 weeks) versus placebo as an add-on to disease-modifying therapies (DMTs) in a population with relapsing MS. Inclusion criteria include: age 18–58 years with relapsing-remitting or secondary progressive MS; disease duration  $\leq 20$  years; Expanded Disability Status Scale (EDSS) 2.0–6.0; clinical relapse between 24 weeks–24 months or brain MRI evidence of disease activity  $\leq 24$  months; stable on IFN-beta, dimethyl fumarate, or natalizumab for  $\geq 24$  weeks; and characteristics on magnetization transfer ratio and diffusion tensor imaging-radial diffusivity, suggestive of lower myelin content and more preserved tissue integrity in brain T2 lesions by average. The primary endpoint is the Overall Response Score, an integrated assessment of disability improvement and worsening based on the EDSS, Timed 25-Foot Walk, and 9-Hole Peg Test (dominant and non-dominant).

**Results:** Enrollment began in November 2017 and was completed in September 2018. As of August 20, 2018, AFFINITY enrolled 188 participants and 174 received  $\geq 1$  dose of placebo or opicinumab. Of the 174 participants who received study drug, mean (SD) age was 38.7 (9.1) years, median (range) EDSS score was 2.5 (2-6), and mean (SD) MS disease duration was 7.8 (5.4) years. Detailed baseline characteristics of all randomized participants (N=263) will be presented.

**Conclusions:** AFFINITY is investigating the efficacy and safety of opicinumab as an add-on therapy to anti-inflammatory DMTs in a subpopulation of patients with MS with potentially enhanced responses to opicinumab.