Biogen Idec Reports Positive Top-Line Results from Phase 2 Anti-LINGO-1 Trial in People with Acute Optic Neuritis

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- Data Offer Evidence of Proof of Biology in Acute Optic Neuritis -

- Phase 2 Multiple Sclerosis Trial Ongoing, Data Expected in 2016 Will Further Define Clinical Potential -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today announced top-line results from the Phase 2 acute optic neuritis (AON) RENEW trial in which treatment with anti-LINGO-1 showed evidence of biological repair of the visual system. Anti-LINGO-1 demonstrated an improvement in the study's primary endpoint, recovery of optic nerve latency (time for a signal to travel from the retina to the visual cortex), as measured by full field visual evoked potential (FF-VEP), relative to placebo. The study showed no effect on secondary endpoints, including change in thickness of the retinal layers (optic nerve neurons and axons) and visual function, as measured by spectral domain optical coherence tomography (SD-OCT) and low contrast letter acuity, respectively.

AON damages the optic nerve, causing loss of the myelin sheath and axonal injury, and may result in loss of visual function. AON is considered a good clinical model to measure the hypothesized mechanisms of action of anti-LINGO-1, remyelination and neuroprotection. RENEW was designed to study anti-LINGO-1's ability to enable repair of an optic nerve lesion via axonal remyelination following the onset of a first episode of AON. RENEW is part of the anti-LINGO-1 Phase 2 clinical development program, which includes the SYNERGY trial in multiple sclerosis.

"We believe the RENEW results are encouraging, as this is the first clinical trial to provide evidence of biological repair in the central nervous system (CNS) by facilitating remyelination following an acute inflammatory injury," said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen Idec. "We look forward to the SYNERGY results in 2016 to further advance our understanding of this molecule in MS, including a full dose response. The totality of the data from the two Phase 2 studies may provide us with a clearer understanding of anti-LINGO-1's clinical potential."

RENEW studied the effects on remyelination by measuring the latency of nerve conduction between the retina and the visual cortex in the brain using FF-VEP. The primary endpoint measured FF-VEP latency for the affected eye at week 24 compared to the unaffected fellow eye at baseline. Results demonstrated a 34 percent improvement (p=0.0504) in the recovery of optic nerve latency compared to placebo in the per-protocol population. The analysis of the intent-to-treat (ITT) population, which includes patients in both arms who did not complete the study, showed a positive trend but did not reach statistical significance.

Anti-LINGO-1 was generally well tolerated. The overall incidence and severity of adverse events (AEs) was comparable across treatment arms. Treatment-related anti-LINGO-1 serious adverse events (SAEs) consisted of two patients with hypersensitivity reactions occurring around the time of infusion and one patient with an asymptomatic elevation in liver transaminases which resolved after drug discontinuation. No deaths occurred during the trial. No immunogenicity was observed.

RENEW data analysis is ongoing and full results will be presented at a medical meeting later this year.

About the anti-LINGO-1 Phase 2 Development Program

Two Phase 2 trials (RENEW and SYNERGY) were designed to assess anti-LINGO-1's biological activity and clinical potential in demyelinating diseases.

RENEW was a randomized, double-blind, placebo controlled, Phase 2 study to evaluate the effect of anti-LINGO-1 in patients treated following a first episode of AON. The study, which was the first to combine functional, structural and clinical efficacy endpoints in AON, enrolled 82 patients across 33 sites in Europe, Canada and Australia. Patients received a total of 6 intravenous infusions of 100 mg/kg anti-LINGO-1 or placebo every four weeks.

A separate Phase 2 dose-range finding, double-blind, placebo-controlled randomized 22 month study (SYNERGY) investigating anti-LINGO-1 in people with relapsing forms of MS (both RRMS and SPMS) is ongoing. SYNERGY is fully enrolled, and results are anticipated in 2016.

Additional information about RENEW and SYNERGY are available at www.clinicaltrials.gov (NCT01721161) and (NCT01864148), respectively.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the Company, please visit www.biogenidec.com.

Biogen Idec Safe Harbor

This press release contains forward-looking statements, including statements about the clinical potential of anti-LINGO-1 and the expected timing of results from the SYNERGY trial. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of results from later stage or larger scale clinical trials or trials in other potential indications. Factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional data or analysis obtained during our clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the

Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements.

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