Biogen Presents New Anti-LINGO-1 Phase 2 Acute Optic Neuritis Data Demonstrating Neurological Repair

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- First evidence of treatment-related remyelination in the human central nervous system -

- Ongoing SYNERGY trial will further inform potential for anti-LINGO-1 in MS -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today, Biogen (NASDAQ: BIIB) announced detailed results from the Phase 2 RENEW study of anti-LINGO-1 in acute optic neuritis (AON) – the first clinical study to demonstrate remyelination (the formation of new myelin on axons) following an inflammatory injury in humans. These data will be presented at the 67th Annual Meeting of the American Academy of Neurology (AAN) in Washington, DC, next week.

The new data demonstrate a statistically significant improvement in recovery of optic nerve conduction latency (time for a signal to travel from the retina to the brain's visual cortex), as measured by the primary endpoint full-field visual evoked potential (FF-VEP), among anti-LINGO-1-treated participants at the last study visit (week 32), as compared to placebo. Results from a sub study of multifocal VEP (mfVEP) are consistent with the FF-VEP findings. These data supplement the top-line, 24-week RENEW results reported by Biogen in January 2015.

"RENEW is the first study to show repair of the human central nervous system (CNS) through remyelination, and the results support our ongoing development of this molecule," said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen. "We believe the anti-LINGO-1 data point toward a potential new approach to treating demyelinating diseases, and we look forward to the ongoing Phase 2 SYNERGY study results to further clarify the potential of this investigational therapy in MS."

RENEW Results in AON

Primary endpoint: FF-VEP

Results from RENEW show improved latency recovery, as measured by the primary endpoint, FF-VEP, among anti-LINGO-1 participants, compared with placebo. Per-protocol participants (those who were treated with at least five of the six doses of anti-LINGO-1) showed a 34 percent improvement of 7.55 milliseconds in optic nerve conduction latency at week 24, compared with placebo (p=0.05). Further latency recovery was observed at the last study visit (week 32), with a statistically significant 41 percent improvement of 9.13 milliseconds, compared with placebo (p=0.01). Together, the data demonstrate evidence of treatment effect with continuous improvement observed 12 weeks following the last study dose (week 20).

In a pre-specified analysis, 53 percent of anti-LINGO-1 participants demonstrated normal or nearly normal (within 10 percent of the normal, unaffected eye) FF-VEP latency, compared with 26 percent of participants in the placebo group.

Additional endpoints

The study showed no effect on the secondary endpoints of change in thickness of the retinal layers (optic nerve neurons and axons) or visual function, as measured by spectral domain optical coherence tomography (SD-OCT) and low contrast letter acuity, respectively. The retinal ganglion cell layer analysis demonstrated that considerable thinning had taken place before treatment was administered. As a result, anti-LINGO-1 may not have had an opportunity to provide evidence of neuroprotection in this study.

"RENEW studied two distinct mechanisms of action – remyelination and neuroprotection," said Dr. Sandrock. "We believe that the opportunity to impact neuroprotection was limited by the rapidity with which retinal ganglion cells and their nerve fibers were damaged by the disease. This insight offers valuable information on the speed of axonal loss following an AON attack, and combined with the positive primary endpoint results, will help inform future studies."

The FF-VEP RENEW findings were consistent with results from a sub study of 39 participants using mfVEP, a novel, more sensitive method of measuring latency recovery and amplitude changes following AON.

Safety & tolerability

Anti-LINGO-1 was generally well tolerated. The overall incidence and severity of adverse events (AEs) was comparable across treatment arms. The most common AEs occurring at higher rates in the anti-LINGO-1 arm than the placebo arm were fatigue, nausea and paresthesia. Treatment related anti-LINGO-1 serious adverse events (SAEs) consisted of two participants with hypersensitivity reactions occurring around the time of infusion and one participant with an asymptomatic elevation in liver transaminases, all of which resolved after drug discontinuation. No deaths occurred during the trial. No immunogenicity was observed.

SYNERGY Study in MS

SYNERGY, a separate Phase 2 clinical trial studying the impact of anti-LINGO-1 on improving and slowing disease progression among participants with relapsing forms of MS (both relapsing-remitting and secondary progressive), is ongoing with results anticipated in 2016. The primary SYNERGY endpoint is the composite change in neuro-physical and/or cognitive function, and the trial is designed to last for 84 weeks. It also includes several imaging biomarkers to investigate the potential for anti-LINGO-1 to repair MS brain lesions.

Key RENEW and SYNERGY data will be presented in the following Emerging Science Oral Session and poster presentation:

- *Evidence of Remyelination with the Anti-LINGO-1 Monoclonal Antibody BIIB033 after Acute Optic Neuritis* (data blitz and poster 008) at the Emerging Science Session on Wednesday, April 22, 2015, at 6:36 p.m. ET. The poster will be available

immediately following the data blitz presentation from 6:15 to 7:45 p.m. ET.

- *BIIB033, Anti-LINGO-1 Antibody, for Treatment of Relapsing Forms of Multiple Sclerosis: Baseline Data of the Phase 2 SYNERGY Trial* (poster P7.204) on Thursday, April 23, 2015, from 5:00 to 6:30 p.m. ET.

Additional clinical study data will also be presented.

About the Anti-LINGO-1 Phase 2 Development Program

The two Phase 2 trials (RENEW and SYNERGY) were designed to assess the biological activity and clinical potential of anti-LINGO-1 in CNS demyelinating diseases.

RENEW was a randomized, double-blind, placebo controlled Phase 2 study designed to evaluate the effect of anti-LINGO-1 treatment following a first episode of AON. The study was the first to combine functional, structural and clinical efficacy endpoints in AON and enrolled 82 participants across 33 sites in Europe, Canada and Australia. Study participants received a total of six intravenous infusions of 100 mg/kg anti-LINGO-1 or placebo every four weeks. SYNERGY is a separate Phase 2 study investigating anti-LINGO-1 in people with relapsing forms of MS (both RRMS and SPMS) and is ongoing with results expected in 2016.

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

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen is one of 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.biogen.com.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the clinical potential of anti-LINGO-1 as well as the expected timing and potential information we may obtain from the SYNERGY trial related to MS. 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.

Contact:

Biogen
MEDIA CONTACT:
Ligia Del Bianco, Ph: +1-781-464-3260
public.affairs@biogen.com
or
INVESTOR CONTACT:
Carlo Tanzi, Ph.D., Ph: + 1-781-464-2442
IR@biogen.com