Biogen Reports Top-Line Results from Phase 2 Study of Opicinumab (Anti-LINGO-1) in Multiple Sclerosis

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-- Opicinumab Missed the Primary Endpoint --

-- Biogen Continues to Analyze Data to Inform Next Step in Clinical Development Program --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen (NASDAQ: BIIB) reported top-line results from the Phase 2 SYNERGY study evaluating opicinumab (anti-LINGO-1), an investigational, fully human monoclonal antibody being developed as a potential neuroreparative therapy in people with relapsing forms of multiple sclerosis (RMS). In the study, opicinumab missed the primary endpoint, a multicomponent measure evaluating improvement of physical function, cognitive function, and disability. However, evidence of a clinical effect with a complex, unexpected dose-response was observed.

“It is only through taking thoughtful, calculated risks that we can bring major advances to patients,” said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen. “Achieving repair of the human central nervous system through remyelination would be a substantial achievement, and while we missed the primary endpoint, the SYNERGY study results suggest evidence of a clinical effect of opicinumab. Due to the complex nature of the data set, we continue to analyze the results to inform the design of our next study.”

Opicinumab also did not meet the secondary efficacy endpoint in SYNERGY, which evaluated the slowing of disability progression. Safety and pharmacokinetics (PK) were also assessed as secondary endpoints. Opicinumab was generally well-tolerated and the safety profile was consistent with what has been observed in prior studies. Opicinumab showed a linear, well-behaved PK profile over the studied dose range. SYNERGY results will be presented at future medical meetings.

About the Opicinumab (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 opicinumab (anti-LINGO-1) in central nervous system (CNS) demyelinating diseases.

RENEW was a randomized, double-blind, placebo-controlled Phase 2 study designed to evaluate the effect of opicinumab treatment following a first episode of acute optic neuritis. Opicinumab 100 mg/kg was administered intravenously once every four weeks for 20 weeks (total of six doses). Results from RENEW showed improved latency recovery, as measured by the primary endpoint full-field visual evoked potential (FF-VEP), among opicinumab participants, compared with placebo. 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.

SYNERGY was a randomized, double-blind, placebo-controlled, dose-ranging Phase 2 study that evaluated the impact of opicinumab among 418 participants with relapsing forms of multiple sclerosis (both relapsing-remitting and secondary progressive) over 72 weeks. The primary endpoint of the SYNERGY study was a multicomponent measure evaluating the number of study participants who experienced three month confirmed improvement of ambulation (Timed 25-Foot Walk; T25FW), upper extremity function (9-Hole Peg Test; 9HPT), cognition (3-Second Paced Auditory Serial Addition Test; PASAT) and standard measures of physical disability (Expanded Disability Status Scale; EDSS). Secondary endpoints measured slowing of progression on the same components, as well as the safety and pharmacokinetics of opicinumab. Statistical testing assessed the dose-response trend based on the primary or secondary endpoint. Opicinumab was administered intravenously every four weeks at doses of 3 mg/kg, 10 mg/kg, 30 mg/kg or 100 mg/kg. All study participants received concurrent treatment with 30 mcg interferon beta-1a intramuscular injection once weekly.

About Biogen
Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world’s oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit www.biogen.com. Follow us on Twitter.

Safe Harbor
This press release contains forward-looking statements, including statements relating to further analysis of the results of the Phase 2 SYNERGY trial of opicinumab (anti-LINGO-1) for the treatment of MS and any future study designs. 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. Factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional analysis of the results obtained during the Phase 2 SYNERGY trial. 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, +1 781-464-3260
public.affairs@biogen.com
or

INVESTOR CONTACT:
Benjamin Strain, +1 781-464-2442
IR@biogen.com