Biogen Announces AFFINITY Phase 2 Trial Initiation for Opicinumab (Anti-LINGO-1) in Multiple Sclerosis

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- *AFFINITY to evaluate opicinumab as an investigational add-on therapy in people with relapsing multiple sclerosis (MS) with trial design guided by the findings from SYNERGY*
- *Comprehensive review of the SYNERGY trial data identified a specific patient population that merits more study of opicinumab*
- *Opicinumab – a first-in-class human monoclonal antibody directed against LINGO-1 – is being evaluated to determine its potential for improving pre-existing disability in relapsing MS patients through remyelination*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) announced today the recent initiation of the Phase 2 clinical trial AFFINITY, designed to evaluate opicinumab as an investigational add-on therapy in people with relapsing multiple sclerosis (MS). The trial follows the comprehensive review of SYNERGY, a Phase 2 trial, which identified a specific population that may be more likely to respond to treatment.

These data are being presented at MSParis2017, the seventh Joint Meeting of the European Committee for Treatment and Research in MS and Americas Committee for Treatment and Research in MS (ECTRIMS-ACTRIMS; 25 – 28 October).

The post-hoc analysis of SYNERGY data indicated an increased clinical effect of opicinumab versus placebo (when used at the same time as interferon beta-1a intramuscular injection) in patients who had the disease for shorter periods of time and in whom MRI showed certain brain features that suggest repair of MS lesions may be possible through remyelination.[1]

“As part of our long-standing commitment to the MS community, Biogen remains dedicated to advancing the treatment of MS and continues to pursue next-generation research to understand the therapeutic potential of repairing damage caused by the disease,” said Michael Ehlers, executive vice president, Research & Development at Biogen. “The SYNERGY data provide intriguing evidence that opicinumab, which has demonstrated remyelination properties in a previous Phase 2 study, may have a treatment effect in certain patients.”

The recently-initiated AFFINITY study is a multicenter, randomized, double-blind, placebo-controlled, Phase 2 study that aims to enroll 240 people with relapsing MS. It will evaluate opicinumab as an add-on therapy in patients who are adequately controlled on their anti-inflammatory disease-modifying therapy (DMT), versus the DMT alone. The primary endpoint of the study, Overall Response Score (ORS), is an integrated measure of both the improvement and worsening of disability over time.

“When analyzing the SYNERGY results, we discovered which patients with relapsing MS may be more responsive to opicinumab, and this became a significant component of the trial design for AFFINITY,” said Professor Gavin Giovannoni, chair of Neurology, Blizard Institute, Barts and The London School of Medicine and Dentistry. “We now have an exciting opportunity to apply a more precise biological approach when evaluating the potential of opicinumab as a therapy that may improve patients’ disability and lead to a better overall outcome.”

Data on opicinumab will be presented as follows:

- Predictors of an Opicinumab Treatment Effect and Identification of an Efficacy Subpopulation: A Post Hoc Analysis of the SYNERGY Study – *Poster P718 – Thursday, 26 October, 15:30-17:00 CET*
- Overall Response Score: A Novel Disability Endpoint That Allows for the Integrated Assessment of Improvement and Worsening Over Time in Patients with MS – *Poster P777 –Thursday, 26 October, 15:30-17:00 CET*

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. Founded in 1978 as one of the world’s first global biotechnology companies by Charles Weissman and Nobel Prize winners Walter Gilbert and Phillip Sharp , today Biogen has the leading portfolio of medicines to treat multiple sclerosis; has introduced the first and only approved treatment for spinal muscular atrophy; and is focused on advancing neuroscience research programs in Alzheimer’s disease and dementia, neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry, and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics. We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This press release contains forward-looking statements, including statements relating to the development of and potential benefits, safety and efficacy of the investigational drug, opicinumab, results of certain clinical studies and real-world data. These statements may be identified by words such as “aim,” “believe,” “except,” “may,” “plan,” “potential,” “will” and similar expressions, and are based on our current beliefs and expectations. You should not place undue reliance on these statements or the scientific data presented. 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 full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. Factors which could cause actual results to differ materially from our current expectations include: uncertainty of success in the development of opicinumab, which may be impacted by, among other things, the occurrence of adverse safety events, the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected, unexpected concerns that may arise from additional data or analysis, including data, analysis or results 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 such as, among other things, failure to obtain regulatory approvals in certain jurisdictions,

failure to protect intellectual property and other proprietary rights, product liability claims, third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

[1] As measured by magnetization transfer ratio (MTR) and diffusion tensor imaging-radial diffusivity (DTI-RD).

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