Biogen Confirms Commitment to Tackle Multiple Sclerosis Through Comprehensive Approach

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- *New data from more than 80 oral and poster presentations, including research on potential predictive and digital biomarkers*
- *Updates on real-world data generation initiatives, including MS PATHS, which leverages technology in routine care to produce real-time data, and the Big MS Data Network, intended to provide pooled registry data from more than 140,000 people living with multiple sclerosis (MS)*
- *Data supporting the Phase 2 investigational molecule opicinumab (anti-LINGO-1) as a potential therapy to repair damage to the central nervous system caused by MS*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) confirms its comprehensive approach to tackle multiple sclerosis (MS) at 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).

“With more than 25 years of scientific leadership in MS, Biogen’s commitment is unwavering,” said Michael Ehlers, executive vice president, Research & Development at Biogen. “Our expertise puts Biogen in a unique position with a comprehensive approach including active research and clinical development on how to repair the damage to the central nervous system from relapsing forms of MS, a portfolio of new drug candidates that we are advancing to the clinic, our collaboration to identify a digital biomarker, our focus to advance understanding of the disease through global data collection with MS PATHS, active pursuit of the genetic origins of progressive forms of MS, and our innovation in value-based contract pilots in the U.S.”

Key updates at ECTRIMS-ACTRIMS from Biogen include:

- The latest from the collaboration with Verily and Brigham and Women’s Hospital whose goal is to explore the use of digital biosensors to assess patients outside of the clinic. Additional data on the possible utility of predictive biomarkers to inform MS diagnosis and ongoing disease monitoring, with the goal of assisting clinicians with their decisions on how to treat based on the heterogeneic differences of those living with MS, will also be presented.
- Interim reports from MS PATHS (Partners Advancing Technology and Health Solutions), a collaboration with 10 leading MS centers in Europe and the U.S. to leverage technology deployed in routine care to generate standardized, high-quality data from a diverse, real-world patient population. MS PATHS collects clinical, MRI and biologic data from all patients in real-time, at the point of care, to better understand the disease and ultimately improve the lives of those living with MS.
- An assessment of the Big Multiple Sclerosis Data (BMSD) Network, comprised of five MS registries and facilitated by Biogen. The network will merge data from large MS registries that have collected longitudinal data on nearly 140,000 people with MS. The scale of this pooled MS data may enable greater understanding of MS and its impact.
- A comprehensive review of the Phase 2 SYNERGY trial that identified a specific patient population for the investigational molecule opicinumab (anti-LINGO-1) as a potential therapy to repair damage to the central nervous system caused by MS.
- An innovative economic model using real-world data from the MSBase Registry with a goal to demonstrate cost-effectiveness of treatment in highly-active MS patients. The analysis supports value-based reimbursement initiatives linked to patient outcomes. In July, Biogen announced four pilots for value-based contracts with health plans across the U.S. The contracts utilize real-world data to align price with patient outcomes.

“With 10 centers now active and strong patient enrollment, our MS PATHS collaboration provides a glimpse into the future of MS care and research,” said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen. “By leveraging technology we are able to collect a robust set of real-world data that is unprecedented in scale and will contribute to a more precise approach to managing patients by supporting providers in real-time to meet the diverse needs of people living with MS.”

Highlights of Biogen’s more than 80 platform and poster presentations:

Opicinumab

- 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*

MS Franchise

- Temporal Variability Profile of Serum Neurofilament Light Levels in Multiple Sclerosis Patients – *Platform 102 – Thursday, 26 October, 11:37–11:49 CET*
- Biosensor Measures in Clinic and Free-living Settings Correlate with Multiple Sclerosis Disease Severity – *Platform 191 – Friday, 27 October, 09:15-09:27 CET*
- Big Multiple Sclerosis Data Network: Data Sharing Among Five Large MS Registries – *Poster P738 – Thursday, 26 October, 15:30-17:00 CET*
- The Multiple Sclerosis Partners Advancing Technology and Health Solutions (MS PATHS) Patient Cohort – *Poster P336 – Thursday, 26 October, 15:30-17:00 CET*
- Comparison of Case-mix in Multiple Sclerosis Patients Participating in Randomized Control Trials, Prospective Observational Studies, and Multiple Sclerosis Partners Advancing Technology and Health Solutions (MS PATHS) – *Poster P351 – Thursday, 26 October, 15:30-17:00 CET*
- A Cost-effectiveness Analysis Using Real-world Data from the MSBase Registry: Comparing Natalizumab to Fingolimod in Patients with Inadequate Response to Disease Modifying Therapies in Relapsing-remitting Multiple Sclerosis in Scotland – *Poster P700 – 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 potential impact of our programs, development and potential benefits, safety and efficacy of investigational drugs, including 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 the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected, unexpected concerns 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 which may be impacted by, among other things, the occurrence of adverse safety events, 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.

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