New MS PATHS Data at ECTRIMS 2021 Confirm Biogen's Disease-Modifying Therapies Do Not Reduce Antibody Response to COVID-19 Vaccines in People with Multiple Sclerosis

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- *MS PATHS data indicate that 100 percent of people with MS treated with natalizumab, interferons or fumarates achieved an antibody response following COVID-19 vaccination*
- *Data from this analysis also suggest that approximately 40 percent of people with MS treated with anti-CD20 and S1P disease-modifying therapies (DMT) mount an antibody response to the COVID-19 vaccine*
- *Collaborative MS PATHS network enabled rapid collection of data in the COVID-19 environment*

CAMBRIDGE, Mass., Oct. 13, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced results of a new analysis of immune response to the COVID-19 vaccine among people with multiple sclerosis (MS). The results, which demonstrate that patients treated with Biogen's portfolio of MS therapies mount an effective antibody response to COVID-19 vaccination, are being presented at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) virtual meeting, October 13-15, 2021.

Using data from the MS PATHS network in the U.S., Germany and Spain, researchers evaluated blood samples from 322 participants 28-90 days after their last COVID-19 vaccine dose. Preliminary results suggest that anti-CD20 and sphingosine 1-phosphate (S1P) therapies may reduce the antibody response to COVID-19 vaccination. For all other classes evaluated in the analysis, including the broad range of MS therapies offered by Biogen, the antibody response to vaccination is consistent with the response of patients not being treated with an MS disease-modifying therapy (DMT).

"These results demonstrate that MS DMTs impact antibody responses to COVID-19 vaccination in different ways and understanding these differences is crucial," said Jeffrey Cohen, M.D., Cleveland Clinic, and a paid consultant for Biogen. "These insights are important in helping providers and patients alike manage MS while seeking to protect patients from COVID-19 through vaccination."

Approximately 92 percent of participants in the analysis received an mRNA vaccine. Immune response was measured using immunoglobulin G (IgG) assays. Specific IgG rates (IgG index >1) from initial post-vaccination testing (28-90 days post last vaccination dose) were 40 percent (32/80) for anti-CD20s (ocrelizumab, rituximab and ofatumumab), 41 percent (16/39) for S1P therapies (fingolimod, ozanimod, and siponimod) and 100 percent (175/175) for all other DMTs (fumarates – dimethyl-fumarate and diroximel fumarate, glatiramer acetate, interferons – IM IFN beta-1a, pegylated IFN beta-1a and IFN beta-1b, natalizumab, teriflunomide and alemtuzumab).

"We care deeply about people with MS and wanted them and their health care providers to have timely information to help address key questions about COVID-19," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "Leveraging the unique MS PATHS network, we were able to quickly generate data on the impact of the different MS DMTs on COVID-19 vaccine antibody responses. This is part of a comprehensive plan to understand B and T cell activation in the context of people with MS on DMTs being vaccinated for COVID-19 and will add to efforts by researchers to gather these important data."

Additional Data Presentations Featured at ECTRIMS
Biogen is presenting a total of 38 abstracts from across its MS portfolio as part of its ongoing commitment to improving the understanding of the disease and advancing treatment through innovation. Presentations at ECTRIMS include:

- IgG Immune Response to SARS-CoV-2 Vaccination in People Living With Multiple Sclerosis Within MS PATHS (P652)
- Flushing and Flushing-Related Adverse Events With Diroximel Fumarate in Patients With Relapsing-Remitting Multiple Sclerosis: Results from the Phase 3 EVOLVE-MS-2 Study (P673)
- Early Data Suggest Diroximel Fumarate Has High Rates of Real-World Adherence and Persistence (P850)
- Diroximel Fumarate in Patients With Relapsing-Remitting Multiple Sclerosis: Interim Safety and Efficacy Results from the Phase 3 EVOLVE-MS-1 Study (P739)
- Comparison of Time to Clinically Meaningful Improvement in Neuro-QoL in Patients Treated With Natalizumab Versus Ocrelizumab (P252)
- Comparison of Pharmacokinetic Profiles and Safety Outcomes with Peginterferon Beta-1a Administration in Black/African American and White Participants (P663)
- Efficacy and Safety of Opicinumab in Participants With Relapsing Multiple Sclerosis: A Randomized, Placebo-Controlled, Phase 2 Trial (AFFINITY Part 1) (P147)

About MS PATHS
Biogen sponsored the MS PATHS (Partners Advancing Technology and Health Solutions) network to foster collaboration between leading MS centers in the U.S. and Europe to help transform patient care by generating standardized data from a diverse, real-world patient population. MS PATHS is uniquely able to collect 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.

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 as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray 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 approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

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Biogen Safe Harbor
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the results of certain real-world data; the identification and treatment of MS and the effect of our therapies in relation to COVID-19 vaccination; and our research and development program for the treatment of MS. These forward-looking statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. 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. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis; risks of unexpected costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. 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 our most recent annual or quarterly report and in other reports we have 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 news 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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