New Data at AAN 2021 from Across Biogen's MS Portfolio Demonstrate Positive Impact of Treatment on People Living with Relapsing Multiple Sclerosis

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- *New findings from MS PATHS show that treatment with TYSABRI® (natalizumab) can lead to meaningful improvements in mental and social health compared to Ocrevus® (ocrelizumab)*
- *Real-world data from VUMERITY® (diroximel fumarate) reinforce the treatment's positive gastrointestinal tolerability profile*
- *Biogen advances leading research to help inform future patient management including new information on the clinical profile of extended interval dosing with natalizumab*

CAMBRIDGE, Mass., April 16, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced new data from its industry-leading portfolio of multiple sclerosis (MS) therapies to be presented at the American Academy of Neurology (AAN) 2021 Virtual Annual Meeting, April 17-22. The presentations include data on quality of life benefits and analyses of extended interval dosing (EID) with TYSABRI® (natalizumab) as well as new real-world experience data from VUMERITY® (diroximel fumarate). The research adds to the vast clinical knowledge Biogen continues to advance as part of its commitment to the care of people living with MS.

"With chronic conditions like MS, where every patient has a different experience with the disease, it is critically important to understand how treatment impacts their daily living and quality of life," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "These data show that the benefits TYSABRI provides in terms of a patient's quality of life are substantial and that the positive gastrointestinal tolerability profile of VUMERITY can help people with relapsing MS continue with treatment, which is essential to delay its progression."

Analyses Demonstrate Improved Quality of Life Outcomes with TYSABRI and Further Evaluate Extended Interval Dosing
To better understand clinically meaningful quality of life benefits following treatment with TYSABRI, MS PATHS (Partners Advancing Technology and Health Solutions) researchers analyzed patient reported data on 12 different domains on the Neuro-QoL (Quality of Life in Neurological Disorders) questionnaire such as sleep disturbance, anxiety, fatigue, depression and participation in daily activities. Results included:

- In people treated with TYSABRI or Ocrevus® (ocrelizumab) with baseline impairment, statistically significant improvements were seen in 10 of 12 and 8 of 12 Neuro-QoL domains, respectively. In 11 of 12 domains on the Neuro-QoL questionnaire, the adjusted annualized rate of improvement was greater with TYSABRI as compared to Ocrevus.
- The difference between the two therapies was statistically significant in favor of TYSABRI in three of the domains: satisfaction with social roles and activities (p=0.02), participation in social roles and activities (p=0.0001) and emotional and behavioral dyscontrol (p=0.01).

Neuro-QoL is an independently validated set of patient-reported outcome measurements that assess the physical, mental and social effects of people living with neurological conditions such as MS. Biogen established the MS PATHS network to foster collaboration between leading MS centers in Europe and the U.S. to help transform patient care by generating standardized data from a diverse, real-world patient population.

Additionally, results from two new analyses investigating EID with natalizumab may help further inform the drug's benefit-risk profile. Biogen continues to evaluate the efficacy, safety and tolerability of natalizumab EID through the prospective NOVA trial (NCT03689972) with initial results expected in 2021.

- From an analysis of data in MS PATHS, natalizumab patients receiving either EID or Standard Interval Dosing (SID) had comparable real-world effectiveness on quantitative magnetic resonance imaging (MRI) outcomes (p>0.05 for all MRI outcomes).
- An updated analysis of data from the TOUCH Prescribing Program demonstrated in the primary analysis that EID is associated with a significant (P<0.0001) 88% reduction in the risk of progressive multifocal leukoencephalopathy (PML) in comparison to the approved every four-week dose. The data, which included more patients followed for a longer period and with slightly greater exposures, reinforces results from earlier analyses of EID.

Data Confirm Positive Gastrointestinal Tolerability Profile With VUMERITY in Real-World Setting
New findings on the use of VUMERITY in a real-world setting reinforce the benefits of improved gastrointestinal (GI) tolerability and confirm that the experience in clinical trials is consistent with clinical practice. In a retrospective analysis of data from December 2019 to August 2020 of 160 patients with relapsing MS, the treatment discontinuation rate due to GI side effects was low (3.8%) with 88.6% estimated to still be on therapy at the end of analysis and a high rate of adherence (91.4%). In a subgroup of patients who switched from TECFIDERA® (dimethyl fumarate) to VUMERITY, the majority of patients switched as a result of gastrointestinal tolerability with most remaining on therapy (92.3%).

Biogen Continues Leading Research in MS
The presentations at AAN are part of Biogen's ongoing commitment to the MS community, improving the understanding of the disease and advancing treatment through innovation. The company recently launched a subcutaneous injection of TYSABRI in Europe and an intramuscular administration of PLEGRIDY® (peginterferon beta-1a) in the United States and Europe. Biogen currently has more than 25 MS clinical trials underway including research on considerations around COVID-19 vaccination for people with MS.

Data Presentations Featured at AAN:

- Impact of Natalizumab on Quality of Life in a Real-World Cohort of Patients with Multiple Sclerosis: Results from MS

Partners Advancing Technology and Health Solutions (MS PATHS) – P15.023
- No Difference in Radiologic Outcomes for Natalizumab Patients on Extended Interval Dosing Compared with Standard Interval Dosing in MS PATHS – P15.210
- Natalizumab Extended Interval Dosing (EID) is Associated with a Reduced Risk of Progressive Multifocal Leukoencephalopathy (PML) Compared with Every-4-week (Q4W) Dosing: Updated Analysis of the TOUCH® Prescribing Program Database – P15.201
- Multiple Sclerosis Patients Treated with Diroximel Fumarate in the Real-world Setting have High Rates of Persistence and Adherence – P15.227

About TYSABRI® (natalizumab)
TYSABRI is a well-established relapsing multiple sclerosis (RMS) treatment indicated for relapsing forms of MS in adults that has been proven in clinical trials to slow physical disability progression, reduce the formation of new brain lesions and cut relapses. TYSABRI is approved in 80 countries, and over 220,000 people worldwide have been treated with TYSABRI, with over 880,000 patient-years of experience, based on clinical trials and prescription data.[1]

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), a rare opportunistic viral infection of the brain which has been associated with death or severe disability. Risk factors that increase the risk of PML are the presence of anti-JC virus antibodies, prior immunosuppressant use and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.

TYSABRI also increases the risk of developing encephalitis and meningitis caused by herpes simplex and varicella zoster viruses, and serious, life-threatening and sometimes fatal cases have been reported in the post-marketing setting in MS patients receiving TYSABRI. Clinically significant liver injury, including acute liver failure requiring transplant, has also been reported in the post-marketing setting. Other serious adverse events that have occurred in TYSABRI-treated patients include hypersensitivity reactions (e.g., anaphylaxis), a decrease in lymphocyte counts and infections, including opportunistic and other atypical infections.

Please click here for Important Safety Information, including Boxed Warning, and full Prescribing Information, including Medication Guide for TYSABRI in the U.S., or visit your respective country's product website.

About VUMERITY® (diroximel fumarate)
VUMERITY is an oral fumarate with a distinct chemical structure from TECFIDERA® (dimethyl fumarate), approved in the U.S. for the treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Once in the body, VUMERITY rapidly converts to monomethyl fumarate, the same active metabolite of dimethyl fumarate.

VUMERITY is contraindicated in patients with known hypersensitivity to diroximel fumarate, dimethyl fumarate or to any of the excipients of VUMERITY; and in patients taking dimethyl fumarate. Serious side effects for VUMERITY are based on data from dimethyl fumarate (which has the same active metabolite as VUMERITY) and include anaphylaxis and angioedema, progressive multifocal leukoencephalopathy, which is a rare opportunistic viral infection of the brain that has been associated with death or severe disability, a decrease in mean lymphocyte counts during the first year of treatment, herpes zoster and other serious infections, liver injury and flushing. The most common adverse events, obtained using data from dimethyl fumarate (which has the same active metabolite as VUMERITY), were flushing, abdominal pain, diarrhea and nausea.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for VUMERITY in the U.S.

About TECFIDERA® (dimethyl fumarate)
TECFIDERA, a treatment for relapsing forms of multiple sclerosis (MS) in adults, is the most prescribed oral medication for relapsing MS in the world and has been shown to reduce the rate of MS relapses, slow the progression of disability and impact the number of MS brain lesions, while demonstrating a well-characterized safety profile in people with relapsing forms of MS. TECFIDERA is approved in 69 countries, and more than 500,000 patients have been treated with it, representing more than 950,000 patient-years of exposure across clinical trial use and patients prescribed TECFIDERA. Of these, 6,335 patients (14,241 patient-years) were from clinical trials.[2]

TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Serious side effects include anaphylaxis and angioedema, and cases of progressive multifocal leukoencephalopathy, a rare opportunistic viral infection of the brain which has been associated with death or severe disability, have been seen with TECFIDERA patients in the setting of prolonged lymphopenia although the role of lymphopenia in these cases is uncertain. Other serious side effects include a decrease in mean lymphocyte counts during the first year of treatment, herpes zoster and other serious infections, liver injury and flushing. In clinical trials, the most common adverse events associated with TECFIDERA were flushing, abdominal pain, diarrhea and nausea.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for TECFIDERA in the U.S., or visit your respective country's product website.

About PLEGRIDY® (peginterferon beta-1a)
PLEGRIDY is a pegylated interferon dosed once every two weeks for relapsing forms of multiple sclerosis (MS) in adults, the most common form of MS. PLEGRIDY is currently approved in over 60 countries including the U.S., Canada, Australia and Switzerland and across the European Union. Over 61,000 people worldwide have been treated with PLEGRIDY, with over 120,000 patient-years of experience, based on prescription data.[3] Biogen continues to work toward making PLEGRIDY available in additional countries across the globe.

The efficacy and safety of PLEGRIDY are supported by one of the largest pivotal studies with interferons conducted in people living with relapsing-remitting MS. In clinical studies, PLEGRIDY has been proven to significantly reduce the rate of MS relapses, slow the progression of disability and reduce the number of MS brain lesions while demonstrating a well-characterized safety profile for patients with relapsing forms of MS. Side effects reported include liver problems, including liver failure and increases in liver enzymes; depression or suicidal thoughts; serious allergic reactions; injection site reactions, cardiac problems, including congestive heart failure; blood problems, such as decreases in white blood cell or platelet counts; autoimmune disorders; and seizures. In clinical trials, the most common adverse events associated with PLEGRIDY were injection site reactions and flu-like symptoms. A list of adverse events can be found in the full PLEGRIDY product labeling for each country where it is approved. PLEGRIDY can be considered for use in relapsing MS patients throughout the full course of pregnancy and during breast-feeding, if clinically needed.

Please click here for Important Safety Information and full Prescribing Information, including Medication Guide for PLEGRIDY in the U.S., or visit your respective country's product website.

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.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media Twitter, LinkedIn, Facebook, YouTube.

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 potential benefits, safety and efficacy of TYSABRI and VUMERITY; the results of certain real-world data; clinical trials and data readouts and presentations; the identification and treatment of MS; our research and development program for the treatment of MS; and the potential of our commercial business, including TYSABRI and VUMERITY. 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. 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.

References:

1. Combined post-marketing data based on prescriptions and clinical trials exposure to TYSABRI as of January 31, 2021.
2. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of December 31, 2020.
3. Combined post-marketing data based on prescriptions for PLEGRIDY as of September 30, 2020.

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