New Data at AAN Showcase Biogen's Commitment to Advancing Innovation in MS

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- *Patients treated with VUMERITY® (diroximel fumarate) and TECFIDERA® (dimethyl fumarate) showed a significant reduction of gadolinium-enhancing lesions compared to baseline*
- *Additional data show improved gastrointestinal tolerability with VUMERITY compared to TECFIDERA*
- *Further research evaluates extended interval dosing with TYSABRI® (natalizumab) compared to the currently approved dosing regimen*

CAMBRIDGE, Mass., May 19, 2020 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced new data from its robust multiple sclerosis (MS) treatment portfolio. Additional clinical data support VUMERITY® (diroximel fumarate) as an important oral treatment option in relapsing MS and reinforce the efficacy of TECFIDERA® (dimethyl fumarate). In addition, an analysis of TYSABRI® (natalizumab) contributes to data demonstrating the reduced risk of progressive multifocal leukoencephalopathy (PML) through extended interval dosing (EID; approximately every six weeks) as compared to the currently approved dosing of every four weeks. These new data were selected for presentation at the 72nd American Academy of Neurology (AAN) annual meeting and will be available online via the 2020 AAN Science Highlights virtual platform.

"We continue to lead in MS with new data that demonstrate the strength of our portfolio and Biogen's commitment to enhancing the care of individuals with relapsing MS," said Bernd Kieseier, M.D., MHBA, Executive Director, Head of Global MS, Worldwide Medical, Biogen. "The data shared at AAN represent our ongoing efforts to improve the MS treatment experience and deliver therapies that provide clinically meaningful benefits to individuals living with this chronic disease."

Data Demonstrate Early Efficacy of TECFIDERA and VUMERITY
In an analysis of data from the double-blind, randomized, Phase 3 EVOLVE-MS-2 study, patients treated with VUMERITY or TECFIDERA (n=295) demonstrated a significant reduction in gadolinium-enhancing (Gd+) lesion counts as early as seven weeks after treatment initiation. After continuing treatment with VUMERITY in the ongoing, open-label, Phase 3 EVOLVE-MS-1 study (n=82), researchers observed that 96.3 percent of patients were free from Gd+ lesions after one year. Both TECFIDERA and VUMERITY have shown early and sustained efficacy in patients with relapsing-remitting MS (RRMS).

Improved Patient-reported GI Tolerability with VUMERITY
A separate, exploratory analysis of EVOLVE-MS-2 (n=502) data assessed the impact of gastrointestinal (GI) symptoms as reported by RRMS patients and expands understanding of VUMERITY's GI tolerability. GI events including nausea, vomiting, upper and lower abdominal pain and diarrhea were less likely to be disruptive to daily activities for VUMERITY-treated patients. Additionally, patients taking VUMERITY were less likely than patients on TECFIDERA to score 2 or higher—the primary endpoint—for two or more consecutive days on the Individual Gastrointestinal Symptom and Impact Scale (IGISIS) (17.4 percent vs. 29.3 percent), and fewer reported concomitant medications for GI tolerability (19 percent vs. 31 percent).

Real-world Evidence Advances Natalizumab-associated Research
A real-world analysis (n=139) of RRMS patients who switched from the approved every-four-week (Q4W) dosing to natalizumab EID (approximately every six weeks) did not show differences in serum neurofilament light (sNfL) levels from those patients who remained on Q4W dosing. sNfL is emerging as a potential biomarker of MS disease activity. These findings support previous reports that EID may not be associated with increased disease activity and suggest the longer treatment interval may not compromise efficacy.

Additionally, updated analyses of real-world data from the TOUCH® Prescribing Program Database continue to demonstrate natalizumab EID is associated with a lower risk for PML than the approved Q4W dosing in anti-JC virus antibody positive patients. The most recent analysis is consistent with previous findings.

Biogen continues to evaluate the efficacy of EID in NOVA (NCT03689972), a two-year, prospective, randomized, interventional, controlled, open-label, rater-blinded, international Phase 3b study assessing the efficacy, safety and tolerability of six-week natalizumab dosing intervals in people with RRMS.

Continued Efforts to Evaluate the Treatment Experience for People Living With MS
In addition to the presented data, Biogen recently submitted regulatory filings in the U.S. and the European Union for intramuscular (IM) injection of PLEGRIDY® (peginterferon beta-1a). PLEGRIDY is currently approved to be administered by subcutaneous injection and is available in more than 60 countries. Previously presented data have evaluated bioequivalence and adverse reactions after IM dosing compared to subcutaneous injection.[1] In addition, earlier this year, the U.S. Food and Drug Administration updated the prescribing information for PLEGRIDY and AVONEX® (interferon beta-1a) to include additional information on the use of these therapies during pregnancy and breastfeeding in women with relapsing MS.

Data Presentations Featured at AAN:

- Diroximel Fumarate and Dimethyl Fumarate Demonstrate Early Clinical and Radiological Efficacy in Relapsing-Remitting Multiple Sclerosis
- Improved Gastrointestinal Tolerability Profile With Diroximel Fumarate Compared to Dimethyl Fumarate in Relapsing MS Patients
- Serum Neurofilament Light Levels in Patients With Relapsing-Remitting Multiple Sclerosis Switching From Natalizumab Every-4-Week Dosing to Extended Interval Dosing
- Updated Incidence of Natalizumab-Associated Progressive Multifocal Leukoencephalopathy and Its Relationship With Natalizumab Exposure Over Time
- Natalizumab Extended Interval Dosing Is Associated With a Reduced Risk of Progressive Multifocal Leukoencephalopathy

Than Every-4-Week Dosing: Updated Analysis of the TOUCH® Prescribing Program Database
- Interim Analysis of Peginterferon Beta-1a in the Breast Milk of Lactating Patients With Multiple Sclerosis

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 445,000 patients have been treated with it, representing more than 875,000 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 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 208,000 people worldwide have been treated with TYSABRI, with over 805,000 patient-years of experience, based on clinical trials and prescription data.[3]

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) 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 PLEGRIDY® (peginterferon beta-1a)
PLEGRIDY is a subcutaneous 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. Nearly 55,000 people worldwide have been treated with PLEGRIDY, with over 101,000 patient-years of experience, based on prescription data.[4] 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; cardiac problems, including congestive heart failure; autoimmune disorders; decreases in white blood cell or platelet counts; 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.

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 AVONEX® (interferon beta-1a)
AVONEX is prescribed for relapsing forms of MS and is currently approved in over 90 countries. Over 570,000 people worldwide have been treated with AVONEX, with over 2.6 million patient-years of experience, based on prescription data.[5] AVONEX is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Symptoms of depression, suicidal ideation or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving AVONEX. Severe hepatic injury, including cases of hepatic failure has been reported rarely in patients. Rare cases of anaphylaxis have been reported.

While beta interferons do not have any known direct cardiac toxicity, cases of congestive heart failure, cardiomyopathy and cardiomyopathy with congestive heart failure have been reported in patients without known predisposition. Decreased peripheral blood counts have been reported from postmarketing experience. Seizures have been reported in patients using AVONEX, including patients with no prior history of seizure. Autoimmune disorders of multiple target organs have been reported. Routine periodic blood chemistry, hematology, liver function and thyroid function tests are recommended.

Please click here for Important Safety Information and full Prescribing Information, including Medication Guide for AVONEX 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, immunology, neurocognitive disorders, acute neurology and pain.

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 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 VUMERITY, TECFIDERA, TYSABRI and PLEGRIDY; the results of certain real-world data; results from the EVOLVE-MS-2 study; the identification and treatment of MS; our research and development program for the treatment of MS; the potential of Biogen's commercial business, including VUMERITY, TECFIDERA, TYSABRI and PLEGRIDY; and risks and uncertainties associated with drug development and commercialization. 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; unexpected concerns may arise from additional data, analysis or results obtained during clinical trials; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; 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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References:

[1] Zhao Y, et al. A phase 1, open-label, crossover study to evaluate the bioequivalence of intramuscular and subcutaneous peginterferon beta-1a in healthy volunteers. Poster presented at: Americas Committee for Treatment and Research in Multiple Sclerosis - 2020 Forum; 2020 Feb 27-29; West Palm Beach, Florida, USA.

[2] Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of January 31, 2020.

[3] Combined post-marketing data based on prescriptions and clinical trials exposure to TYSABRI as of February 29, 2020.

[4] Combined post-marketing data based on prescriptions for PLEGRIDY as of December 31, 2019.

[5] Combined post-marketing data based on prescriptions for AVONEX as of December 31, 2019.