New Data at ECTRIMS 2022 Highlight Biogen's Commitment to Advancing Individualized Disease Management for People Living with MS

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- *Final safety and efficacy results from the Phase 3 EVOLVE-MS-1 trial demonstrate decreases in disease activity and favorable tolerability for VUMERITY® (diroximel fumarate) consistent with previous assessments*
- *Patient-reported outcomes favored TYSABRI® (natalizumab) compared to Ocrevus® (ocrelizumab); new insights on subcutaneous administration one year after approval in Germany*
- *Data on interferon exposure during pregnancy showed that treatment with PLEGRIDY® (peginterferon beta-1a) or AVONEX® (interferon beta-1a) did not negatively impact child development*

CAMBRIDGE, Mass., Oct. 26, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced new data from its industry-leading portfolio of multiple sclerosis (MS) therapies being presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting October 26-28, 2022. The presentations include the final safety and efficacy results of the VUMERITY® (diroximel fumarate) EVOLVE-MS-1 study, as well as a matching analysis comparing treatment with VUMERITY to Ponvory® (ponesimod) and Aubagio® (teriflunomide); patient-reported outcomes and an analysis of the proprietary StratifyJCV™ assay for TYSABRI® (natalizumab); a study evaluating treatment with TECFIDERA® (dimethyl fumarate) to prevent first clinical manifestation of MS for people with radiologically isolated syndrome; and studies assessing the impact of PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a) on pregnancy, breastfeeding and child development.

"Presentations at this year's ECTRIMS meeting highlight Biogen's commitment to pursuing research that has a meaningful impact on patients," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "These new data provide patients and healthcare professionals with further insight on the safety and efficacy of Biogen's robust MS portfolio to help inform treatment decisions throughout the lifelong MS journey, from the earliest phase of the disease to important milestones such as pregnancy."

Final Safety and Efficacy Results of VUMERITY EVOLVE-MS-1 Study Reported
Presentations including data from EVOLVE-MS-1 and OPTIMUM clinical studies further support the safety and efficacy of VUMERITY:

- Final safety and efficacy results from EVOLVE-MS-1 demonstrate decreases in disease activity and favorable tolerability for VUMERITY in 1,057 patients over 96 weeks, in line with previous assessments. The reduction in annualized relapse rate (ARR) was 81.6%, the estimated proportion of patients who were relapse-free was 82.4%, and the estimated proportion with no evidence of disease activity (NEDA-3) was 41.1%. While 24.3% of patients discontinued treatment, discontinuation due to gastrointestinal adverse events (0.7%) and flushing (0.5%) were low.
- A matching-adjusted indirect comparison was done between VUMERITY (EVOLVE-MS-1) and Ponvory and Aubagio (OPTIMUM) clinical studies for ARR, 12-week confirmed disability progression (CDP), 24-week CDP, absence of gadolinium-enhancing (Gd+) T1 lesions and absence of new/enlarging T2 lesions. After weighting for cross-trial differences, VUMERITY was associated with a higher proportion of patients free of Gd+ T1 lesions and new/enlarging T2 lesions at the end of follow-up compared to Ponvory, with similar efficacy for ARR and 12- and 24-week CDP. VUMERITY had greater efficacy than Aubagio for all clinical and radiological outcome measures, except for 24-week CDP, in which there was similar efficacy.

Studies Highlight Patient-Reported Outcomes for TYSABRI; Analysis Shows Impact of StratifyJCV Assay
Two presentations highlight improvements in patient-reported outcomes following treatment with TYSABRI along with preference and satisfaction for the TYSABRI subcutaneous (SC) route of administration:

- The results of recent survey analysis, which included TYSABRI [n=52] and Ocrevus (ocrelizumab)-treated [n=92] relapsing-remitting multiple sclerosis (RRMS) patients aged 21 and older who had taken at least one prior disease modifying treatment (DMT), found more patients treated with TYSABRI versus Ocrevus reported improvements in disease activity (84.6% vs 59.8%), emotional symptoms (73.1% vs 35.9%), physical symptoms (69.2% vs 43.5%), cognitive symptoms (61.5% vs 32.6%) and social roles/activities (71.2% vs 35.9%). In addition, more patients treated with TYSABRI reported their DMT met or exceeded treatment expectations in comparison to those treated with Ocrevus (96.2% vs 72.8%).
- In the first interim analysis of 206 patients in the observational, prospective, multi-center SISTER study in Germany, the TYSABRI SC route of administration was preferred by individuals (89.6%; 163 patients) compared with intravenous administration; nearly all patients receiving SC treatment expressed satisfaction with their choice (98.7%; 156 patients) and the most frequent reasons for SC preference were shorter and more convenient administration. The TYSABRI SC administration is available in 26 countries and over 16,000 patients have been treated with SC therapy.[1]

"Given the recent introduction of natalizumab subcutaneous administration in Europe, these findings validate clinical study data with real-world insights," said Prof. Ralf Gold, Ruhr-University Bochum, Bochum, Germany. "In our study, we found that nearly 90% of patients prefer subcutaneous administration given its shorter duration and convenience of dosing."

Separately, an analysis assessed utilization of Biogen's StratifyJCV™ -- a proprietary antibody assay used to detect the presence of anti-JC virus (JCV) antibodies in serum and to quantify antibody index values, which are correlated to progressive multifocal leukoencephalopathy (PML) risk in

patients treated with TYSABRI. More than 2 million StratifyJCV tests have been conducted worldwide. Aggregated data of the results of 845,498 StratifyJCV tests conducted from January 2015 to December 2021 showed a decrease in percentage of JCV-positive index results >1.5 in retests, from 15% in 2015 to 8% in 2021, demonstrating that healthcare professionals are using the assay to appropriately identify, monitor and manage patients on TYSABRI.

Effect of TECFIDERA on Radiologically Isolated Syndrome Reported for the First Time
Results of the Assessment of TECFIDERA in Radiologically Isolated Syndrome (ARISE) study, a placebo-controlled, multi-center, double-blinded clinical trial, will be presented in the late-breaking section. ARISE investigated the impact of therapeutic intervention in preventing the first clinical manifestation of MS for people with radiologically isolated syndrome (RIS). ARISE enrolled 87 patients who were randomized to TECFIDERA or placebo and treated for up to 96 weeks. Researchers found treatment with TECFIDERA resulted in an 82% risk reduction relative to placebo in the prevention of a first clinical event related to CNS demyelination.

Impact of PLEGRIDY and AVONEX on Pregnancy, Breastfeeding and Child Development
Two presentations assessed the impact of interferon exposure on pregnancy, breastfeeding and child development. Data from the PRIMA post-authorization safety study was consistent with results from previous studies showing that exposure to PLEGRIDY or AVONEX during pregnancy or lactation did not negatively impact child development or intrauterine growth. Further, a preliminary analysis of the German Multiple Sclerosis and Pregnancy Registry assessed child development in infants born to mothers with AVONEX or PLEGRIDY exposure during pregnancy, and treatment did not negatively impact children's development.

Title and Times of Data Presentations Featured at ECTRIMS:

- Natalizumab-Treated RRMS Patients with Prior DMT Use Report Better Outcomes, Treatment Satisfaction and Unique Benefits Than Similar Patients Treated with Ocrelizumab – EP0851 – October 26, 8 a.m. CET / 2 a.m. ET
- Disease Activity and Pregnancy Outcomes After Long-Term Exposure to Natalizumab During Pregnancy – 0039 – October 26, 2:56 p.m. CET / 8:56 a.m. ET
- SISTER – Subcutaneous: Non-Interventional, Observational, Prospective, German Multicentre, Open Label Study Over 12-Months for TYSABRI Patient Preference – Experience from Real-World – Preliminary Results of the 1st Interim Analysis – P365 – October 26, 8 a.m. CET / 2 a.m. ET
- Long-Term Effectiveness of Natalizumab for RRMS: Dutch and Global Interim Results from TYSABRI Observational Program – P373 – October 26, 8 a.m. CET / 2 a.m. ET
- Exploratory Magnetic Resonance Imaging Endpoints from NOVA: A Randomized Controlled Study of the Efficacy of 6-Week Dosing of Natalizumab vs Continued 4-Week Treatment for Multiple Sclerosis – P350 – October 26, 8 a.m. CET / 2 a.m. ET
- Interferon- or Peginterferon-Beta 1a Exposure During Pregnancy in Women with Multiple Sclerosis: Outcomes on Child Development – P075 – October 26, 8 a.m. CET / 2 a.m. ET and October 27, 1:05 p.m. CET / 7:05 a.m. ET
- StratifyJCV™ Serum Anti-JCV Antibody Assay for Natalizumab Patients: Unilabs Global Cohort Data Descriptive Analysis and Unilabs Customer Satisfaction Survey Results – P750 – October 26, 8 a.m. CET / 2 a.m. ET
- Matching-Adjusted Indirect Comparisons of Diroximel Fumarate, Ponesimod, and Teriflunomide for Relapsing Multiple Sclerosis – P708 – October 26, 8 a.m. CET / 2 a.m. ET
- Diroximel Fumarate in Patients with Relapsing-Remitting Multiple Sclerosis: Final Safety and Efficacy Results from the Phase 3 EVOLVE-MS-1 Study – P712 – October 26, 8 a.m. CET / 2 a.m. ET
- Interferon-Beta Exposure During Pregnancy and Breastfeeding: Impact on Birth Outcome and Child Development – Results from the Post-Authorisation Safety Study PRIMA – P478 – October 26, 8 a.m. CET / 2 a.m. ET
- Multi-Center, Randomized, Double-Blinded Assessment of Dimethyl Fumarate in Extending the Time to a First Clinical Demyelinating Event in Radiologically Isolated Syndrome (ARISE) – 0179 – October 28, 3:49 p.m. CET / 9:49 a.m. ET

About VUMERITY® (diroximel fumarate)
VUMERITY is an oral fumarate approved in the U.S. for the treatment of relapsing forms of multiple sclerosis in adults, including 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 (TECFIDERA). VUMERITY is available in 15 countries, and more than 28,200 patients have been treated with it, representing more than 24,200 patient-years of exposure across clinical trial use and patients prescribed VUMERITY.[2]

VUMERITY is contraindicated in patients with a known hypersensitivity to diroximel fumarate, dimethyl fumarate or any of the excipients of VUMERITY and in patients taking dimethyl fumarate. VUMERITY can cause anaphylaxis and angioedema after the first dose or at any time during treatment. PML has occurred in patients with MS treated with dimethyl fumarate (which has the same active metabolite as VUMERITY). PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. A fatal case of PML occurred in a patient who received dimethyl fumarate for four years while enrolled in a clinical trial. Serious cases of herpes zoster have occurred with dimethyl fumarate, including disseminated herpes zoster, herpes zoster ophthalmicus, herpes zoster meningoencephalitis, and herpes zoster meningomyelitis. These events may occur at any time during treatment. Other serious opportunistic infections have occurred with dimethyl fumarate, including cases of serious viral (herpes simplex virus, West Nile virus, cytomegalovirus), fungal (Candida and Aspergillus), and bacterial (Nocardia, Listeria monocytogenes, Mycobacterium tuberculosis) infections. VUMERITY may decrease lymphocyte counts. In the MS placebo-controlled trials, mean lymphocyte counts decreased by approximately 30% during the first year of treatment with dimethyl fumarate and then remained stable. Four weeks after stopping dimethyl fumarate, mean lymphocyte counts increased but did not return to baseline. Clinically significant cases of liver injury have been reported in patients treated with dimethyl fumarate in the post-marketing setting. The onset has ranged from a few days to several months after initiation of treatment. Signs and symptoms of liver injury, including elevation of serum aminotransferases to greater than five-fold the upper limit of normal and elevation of total bilirubin to greater than two-fold the upper limit of normal have been observed. VUMERITY may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). Forty percent of patients taking dimethyl fumarate reported flushing, which was mostly mild to moderate in severity. Three percent of patients discontinued dimethyl fumarate for flushing and <1% had serious flushing events that led to hospitalization. The most common adverse events associated with dimethyl fumarate (incidence ≥10% and ≥2% more than placebo) were flushing, abdominal pain, diarrhea and nausea. A list of adverse events can be found in the full VUMERITY product labeling for each country where it is approved.

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

About TECFIDERA® (dimethyl fumarate)
TECFIDERA is approved for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. TECFIDERA 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 580,500 patients have been treated with it, representing more than 1.2 million patient-years of exposure across clinical trial use and patients prescribed TECFIDERA.[3]

TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. TECFIDERA can cause anaphylaxis and angioedema after the first dose or at any time during treatment. PML has occurred in patients with MS treated with TECFIDERA. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. A fatal case of PML occurred in a patient who received TECFIDERA for four years while enrolled in a clinical trial. Serious cases of herpes zoster have occurred with TECFIDERA, including disseminated herpes zoster, herpes zoster ophthalmicus, herpes zoster meningoencephalitis, and herpes zoster meningomyelitis. These events may occur at any time during treatment. Other serious opportunistic infections have occurred with TECFIDERA, including cases of serious viral (herpes simplex virus, West Nile virus, cytomegalovirus), fungal (Candida and Aspergillus), and bacterial (Nocardia, Listeria monocytogenes, Mycobacterium tuberculosis) infections. TECFIDERA may decrease lymphocyte counts. In the MS placebo-controlled trials, mean lymphocyte counts decreased by approximately 30% during the first year of treatment with TECFIDERA and then remained stable. Four weeks after stopping TECFIDERA, mean lymphocyte counts increased but did not return to baseline. Clinically significant cases of liver injury have been reported in patients treated with TECFIDERA in the post-marketing setting. The onset has ranged from a few days to several months after initiation of treatment. Signs and symptoms of liver injury, including elevation of serum aminotransferases to greater than five-fold the upper limit of normal and elevation of total bilirubin to greater than two-fold the upper limit of normal have been observed. TECFIDERA may cause flushing (e.g. warmth, redness, itching, and/or burning sensation). Forty percent of patients taking TECFIDERA reported flushing, which was mostly mild to moderate in severity. Three percent of patients discontinued TECFIDERA for flushing and <1% had serious flushing events that led to hospitalization. The most common adverse events associated with TECFIDERA (incidence ≥10% and ≥2% more than placebo) were flushing, abdominal pain, diarrhea and nausea. A list of adverse events can be found in the full TECFIDERA product labeling for each country where it is approved.

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 approved in the U.S. as monotherapy for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk. TYSABRI is approved in more than 80 countries, and over 248,000 people worldwide have been treated with TYSABRI, with more than 1 million patient-years of experience, based on clinical trials and prescription data.[1]

TYSABRI increases the risk of 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. These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI. Healthcare professionals should monitor patients on TYSABRI for any new sign or symptom that may be suggestive of PML. TYSABRI dosing should be withheld immediately at the first sign or symptom suggestive of PML. TYSABRI is contraindicated in patients who have or have had PML and in patients who have had a hypersensitivity reaction to TYSABRI.

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. Signs of liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as six days after the first dose; signs of liver injury have also been reported for the first time after multiple doses. Hypersensitivity reactions have occurred in patients receiving TYSABRI, including serious systemic reactions (e.g., anaphylaxis) which occurred at an incidence of <1%. The immune system effects of TYSABRI may increase the risk for infections. In Study MS1, certain types of infections—including pneumonias and urinary tract infections (including serious cases), gastroenteritis, vaginal infections, tooth infections, tonsillitis, and herpes infections—occurred more often in TYSABRI-treated patients than in placebo-treated patients. In clinical trials, TYSABRI was observed to induce increases in circulating lymphocytes, monocytes, eosinophils, basophils, and nucleated red blood cells. Observed changes persisted during TYSABRI exposure, but were reversible, returning to baseline levels usually within 16 weeks after the last dose. Cases of thrombocytopenia, including immune thrombocytopenic purpura, have been reported with the use of TYSABRI in the post-marketing setting. Cases of neonatal thrombocytopenia, at times associated with anemia, have been reported in newborns with in utero exposure to TYSABRI. The most common adverse reactions associated with TYSABRI (incidence ≥10% and ≥2% more than placebo) were headache, fatigue, infusion reactions, urinary tract infections, arthralgia, depression, pain in extremity, rash, gastroenteritis, and vaginitis. A list of adverse events can be found in the full TYSABRI product labeling for each country where it is approved.

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 (peginterferon beta-1a) is indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. PLEGRIDY is currently approved in over 60 countries including the U.S., Canada, Australia and Switzerland and across the European Union. Over 81,000 people worldwide have been treated with PLEGRIDY, with over 170,000 patient-years of experience, based on prescription data.[4] Biogen continues to work toward making PLEGRIDY available in additional countries across the globe.

PLEGRIDY is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, or any other component of the formulation. Rare cases of severe hepatic injury, including cases of hepatic failure have been reported in patients taking PLEGRIDY. Symptoms of depression, suicidal ideation or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving PLEGRIDY. Serious allergic reactions are rare complications of interferon beta; anaphylaxis has been reported with use of PLEGRIDY. Injection site reactions, including injection site necrosis, can occur with the use of interferon beta, including PLEGRIDY; injection site abscesses and cellulitis have been reported in the post-marketing setting with use of PLEGRIDY. Some cases required treatment with hospitalization for surgical drainage and intravenous antibiotics. 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 post-marketing experience; monitor patients for infections, bleeding and anemia; monitor complete blood cell counts, differential white cell counts, and platelet counts. Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, some fatal, have been reported several weeks to

years after starting interferon beta products. Autoimmune disorders of multiple target organs including idiopathic thrombocytopenia, hyper- and hypothyroidism, and autoimmune hepatitis have been reported. Seizures have been reported in patients using PLEGRIDY. The most common adverse reactions in clinical trials of subcutaneous PLEGRIDY (incidence ≥10% and at least 2% more frequent on PLEGRIDY than on placebo) were injection site erythema, influenza-like illness, pyrexia, headache, myalgia, chills, injection site pain, asthenia, injection site pruritus, and arthralgia. 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 indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. AVONEX is approved in over 90 countries and over 625,000 people worldwide have been treated with AVONEX, with over 2.8 million patient-years of experience, based on prescription data.[5]

Avonex is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, or any other component of the formulation. Symptoms of depression, suicidal ideation or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving AVONEX. Rare cases of severe hepatic injury, including cases of hepatic failure have been reported in patients taking AVONEX. Anaphylaxis has been reported as a rare complication of AVONEX use; other allergic reactions have included dyspnea, orolingual edema, skin rash and urticaria. Injection site reactions, including injection site necrosis, can occur with the use of interferon beta, including AVONEX. Injection site abscesses and cellulitis and injection site necrosis have been reported in the post-marketing setting with use of AVONEX. Some cases required treatment with hospitalization for surgical drainage and intravenous antibiotics. 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 post-marketing experience. Cases of thrombotic microangiopathy (TMA), including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, some fatal, have been reported several weeks to years after starting interferon beta products. Seizures have been temporally associated with the use of beta interferons in clinical trials and post-marketing safety surveillance. Post-marketing reports of autoimmune disorders of multiple target organs in AVONEX-treated patients including idiopathic thrombocytopenia, hyper- and hypothyroidism, and rare cases of autoimmune hepatitis. Routine periodic blood chemistry, hematology, liver function and thyroid function tests are recommended. The most commonly reported adverse reactions (at least 5% more frequent on AVONEX than on placebo) were flu-like symptoms. A list of adverse events can be found in the full AVONEX product labeling for each country where it is approved.

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
As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological 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, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry's most diversified pipelines in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

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 July 31, 2022. TYSABRI subcutaneous administration exposure as of September 30, 2022.
2. Combined post-marketing data based on prescriptions and clinical trials exposure to VUMERITY as of June 30, 2022.
3. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of June 30, 2022.
4. Post-marketing data based on PLEGRIDY prescriptions as of June 30, 2022.
5. Post-marketing data based on AVONEX prescriptions as of June 30, 2022.

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