Biogen R&D Day to Provide Overview of Diversified Pipeline and Capabilities with Potential for Multiple Novel Therapies in Neuroscience

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- *33 early and late-stage clinical programs across modalities and innovative discovery platforms*
- *Uniquely positioned to lead in Alzheimer's disease with ADUHELM ® (aducanumab-avwa) and industry-leading pipeline including Phase 3 lecanemab*
- *Potential to transform standard of care in several areas of high unmet need in depression, ALS, stroke and lupus*
- *Biomarkers and digital health to enable early diagnosis and personalized medicine*
- *Continued leadership in neuroscience sustained by distinct capabilities and talent*

CAMBRIDGE, Mass., Sept. 21, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) will hold a virtual Investor R&D Day today, providing a comprehensive overview of the company's diversified pipeline in neuroscience. Biogen plans to advance innovative therapies for patients through the work of its world-class researchers and the strength of its global network of collaborators. As part of R&D Day, Biogen's scientific leaders will discuss ongoing research and highlight key advancements among Biogen's 33 clinical programs, including 12 programs in Phase 3 or filed.

"Biogen is helping to change the Alzheimer's disease treatment paradigm by providing the first therapy in 20 years, and we continue to lead the way in neuroscience with our diversified pipeline," said Michel Vounatsos, Chief Executive Officer at Biogen. "Across our portfolio, we have achieved significant scientific progress, and I believe our specialization in terms of people, capabilities, and programs positions us to deliver multiple novel therapies with the potential to address the most complex neurological diseases."

Key R&D Highlights
"The talented team at Biogen is at the forefront of innovation in neuroscience. We look forward to sharing the assets and approaches we have developed aimed at addressing some of the most difficult challenges in healthcare," said Alfred Sandrock, Jr., M.D., Ph.D., Head of Research and Development at Biogen. "Scientific advancements have increased our understanding of human genetics and allow us to advance the appropriate treatment modality for the right target for each disease. We believe this will mitigate risk in neuroscience, increase the probability of success for each program, and create opportunities for early and targeted treatments towards prevention."

Alzheimer's Disease
Biogen will present an overview of its Alzheimer's disease pipeline with the recent FDA-approved ADUHELM serving as the foundation of a multi-target, multi-modality Alzheimer's disease franchise. In addition to ADUHELM, the company will present progress on lecanemab (BAN2401), a new amyloid beta-directed antibody therapy in Phase 3 being developed by Eisai in collaboration with Biogen, and BIIB080 (IONIS-MAPTRx), a tau-directed antisense oligonucleotide (ASO).

Lecanemab received Breakthrough Therapy designation from the FDA in June 2021. In clinical studies, lecanemab has shown potential to slow clinical decline in Alzheimer's disease and is now being studied in patients with early Alzheimer's disease as well as the preclinical setting, when individuals are clinically normal and have intermediate or elevated levels of amyloid in their brains.

A Phase 1b study of BIIB080 met the primary objective of safety and tolerability, and demonstrated a durable time and dose dependent reduction of tau protein in cerebrospinal fluid. Growing evidence suggests tau may be a key driver of neurodegeneration in Alzheimer's disease.

Neuropsychiatry
In neuropsychiatry, Biogen and Sage Therapeutics are co-developing zuranolone, and will present an overview of the two-week, once-daily drug being studied in major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone has demonstrated positive Phase 3 results.

In clinical trials, zuranolone, which represents a potential new class of drug, demonstrated rapid-acting efficacy and was generally well-tolerated. Beyond MDD and PPD, zuranolone may have potential for development in other psychiatric disorders, including treatment-resistant depression, bipolar disorder, and generalized anxiety disorder.

Major depressive disorder is a common comorbidity of multiple neurological disorders in Biogen's core therapeutic areas.

Biogen will also present an overview of BIIB104, currently under investigation in a Phase 2 study for cognitive impairment associated with schizophrenia.

Amyotrophic Lateral Sclerosis (ALS)
Biogen has multiple ALS assets in development, which target both genetic subtypes of ALS and the broader population. Tofersen, developed in collaboration with Ionis Pharmaceuticals, is currently in Phase 3 studies. The program targets SOD1, a gene believed to be a genetic driver of disease in two percent of all ALS cases.

In the recently announced ATLAS study, Biogen will be exploring the use of tofersen prior to symptoms in SOD1 carriers with the intent to delay or slow the decline in function associated with ALS.

Based on learnings from the company's prior and ongoing trials, Biogen is also advancing BIIB078, an ASO targeting C9orf72, another potential genetic driver of ALS, and BIIB105, an ASO targeting ATXN2, a potential treatment for ALS in the broader population supported by human genetics.

Stroke

Biogen is progressing its research in the treatment of stroke. The potential to expand the stroke treatment window has been shown in positive proof of concept studies for BIIB131, a next generation thrombolytic agent, and BIIB093, a treatment for brain swelling in large hemispheric infarctions.

BIIB131, a treatment for acute ischemic stroke, was recently acquired based on positive Phase 2 data. BIIB093 is in a Phase 3 study for large hemispheric infarction, and a Phase 2 trial for lesion expansion in brain contusion.

Lupus
Decades of study by Biogen at the intersection of neurological and immunological pathways provide the company with expertise in immunology. Biogen is advancing two lupus therapies in Phase 3 trials. Dapirolizumab pegol is being developed in collaboration with UCB for systemic lupus erythematosus (SLE). The second, BIIB059, was fully developed in-house at Biogen and is now in Phase 3 for SLE, with plans for further study in cutaneous lupus erythematosus.

Distinct Capabilities and World-Class Talent
Biogen has attracted and collaborated with leading scientists from industry and academia to focus on treatments with the highest unmet need. This focus also includes 27 business development transactions and collaborations since 2017, including with Sangamo Therapeutics, Inc., Denali Therapeutics Inc., Sage Therapeutics Inc, and InnoCare Pharma Limited. Biogen will continue to bolster the pipeline through both internal development and external collaborations.

Biogen has refined the early discovery process with new approaches to patient selection, target engagement, and monitoring of disease progression, increasing the probability of success for each program. Biogen centers its R&D methodologies on human biology, employing the predictive effects of genetics to validate potential targets. Utilizing biomarkers to measure modulation of disease early on in the drug development process can contribute to lowering the risk associated with developing novel therapies for neurological diseases.

Biogen Digital Health
Today's technological advances open a new era of opportunities for digital health in neuroscience. In April 2021, the company formed Biogen Digital Health, a global unit that aspires to transform patients' lives and Biogen by making personalized and digital medicine in neuroscience a reality. In an on-demand presentation, Biogen Digital Health will share key areas of focus and highlights, including progress on digital biomarkers and efforts to develop deep-learning software.

Investor R&D Day Presenters
Biogen scientific leaders will be joined by executives from Eisai, Sage Therapeutics, and Denali Therapeutics.

To join today's event, please go to the investors section of the Biogen website at investors.biogen.com or access the event link directly here.

An archived version of the webcast and slides, as well as additional video presentations and slides, will be available here.

About ADUHELM® (aducanumab-avwa) injection 100 mg/mL solution
ADUHELM is indicated for the treatment of Alzheimer's disease. Treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Aducanumab-avwa is a monoclonal antibody directed against amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. The accelerated approval of ADUHELM has been granted based on data from clinical trials showing the effect of ADUHELM on reducing amyloid beta plaques, a surrogate biomarker that is reasonably likely to predict clinical benefit, in this case a reduction in clinical decline.

ADUHELM can cause serious side effects including: Amyloid Related Imaging Abnormalities or "ARIA". ARIA is a common side effect that does not usually cause any symptoms but can be serious. Although most people do not have symptoms, some people may have symptoms such as: headache, confusion, dizziness, vision changes and nausea. The patient's healthcare provider will do magnetic resonance imaging (MRI) scans before and during treatment with ADUHELM to check for ARIA. ADUHELM can also cause serious allergic reactions. The most common side effects of ADUHELM include: swelling in areas of the brain, with or without small spots of bleeding in the brain or on the surface of the brain (ARIA); headache; and fall. Patients should call their healthcare provider for medical advice about side effects.

As of October 2017, Biogen and Eisai Co., Ltd. are collaborating on the global co-development and co-promotion of aducanumab.

Please click here for full Prescribing Information, including Medication Guide, for ADUHELM.

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. 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: Biogen's strategy and plans; potential of, and expectations for, Biogen's commercial business and pipeline programs, including ADUHELM, lecanemab, and zuranolone; the potential clinical effects of ADUHELM, lecanemab, and zuranolone; the potential benefits, safety and efficacy of ADUHELM , lecanemab, and zuranolone; planning and timing for the commercial launch of, and access to, ADUHELM; anticipated manufacturing, distribution and supply of ADUHELM; the treatment of Alzheimer's disease, MDD, BPD, ALS, stroke and lupus; the anticipated benefits and potential of our collaboration arrangements with Eisai and Sage; clinical development programs, clinical trials and data readouts and presentations; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "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: uncertainty of success in the development and commercialization of ADUHELM, lecanemab, and zuranolone; risks relating to the launch of ADUHELM, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for ADUHELM and other unexpected difficulties or hurdles; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates, including ADUHELM, lecanemab, and zuranolone; unexpected concerns that may arise from additional data or analysis obtained during clinical trials; actual timing and content of submissions to and decisions made by the regulatory authorities regarding ADUHELM; the occurrence of adverse safety events, restrictions on use or product liability claims; risks of unexpected costs or delays; the risk of other unexpected hurdles; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; third party collaboration risks; risks associated with current and potential future healthcare reforms; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

MEDIA CONTACT:
Ashleigh Koss
+ 1 908 205 2572
public.affairs@biogen.com

INVESTOR CONTACT:
Mike Hencke
+1 781 464 2442
IR@biogen.com