Biogen to Present Data from ADUHELM and Alzheimer's Disease Portfolio at 2021 Alzheimer's Association International Conference

July 23, 2021

CAMBRIDGE, Mass., July 23, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced it will share multiple oral and poster presentations from its Alzheimer's disease clinical development portfolio at the Alzheimer's Association International Conference (AAIC), which will be held in Denver, Colorado and online July 26-30, 2021. The company's contributions to AAIC will include several presentations highlighting data on ADUHELM™ (aducanumab-avwa) injection 100 mg/mL solution, which was recently granted accelerated approval by the U.S. Food and Drug Administration (FDA) as a treatment for Alzheimer's disease, as well as its broader Alzheimer's disease portfolio and research in the field.

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).

Data presentations on ADUHELM will include presentations on multiple topics, including results of an analysis of the PRIME, EMERGE and ENGAGE studies on the correlation between reductions in biomarkers of Alzheimer's disease and clinical decline after treatment with ADUHELM. The company's contributions to the congress include four presentations on ADUHELM data and a total of 11 abstracts.

The company will also lead a late-breaking presentation on the design of the real-world observational Phase 4 study in Alzheimer's disease, a prospective registry of ADUHELM, called International Collaboration for Real-World Evidence in Alzheimer's Disease (ICARE AD-US). ICARE AD-US is focused on collecting real-world, long-term effectiveness and safety data on ADUHELM.

Biogen's commitment to generate new data about ADUHELM includes three components: the ICARE AD study, the ongoing redosing study, EMBARK, for eligible patients previously enrolled in aducanumab trials, and the upcoming confirmatory, controlled Phase 4 trial that is part of the post-marketing requirement in connection with ADUHELM's accelerated approval.

Posters and presentations will be available for 30 days on the AAIC conference website. Biogen will also post the aducanumab and BIIB080 posters and presentations on the investors section of its website at investors.biogen.com at the times indicated below.

Biogen Oral and Poster Presentations:

- Oral presentation: ICARE AD-US: Design of a Prospective, Single-arm, Multicenter, Noninterventional Real-world Study of Aducanumab in United States: July 29, 10:00 am to 11:15 am ET (#57522). This presentation will be available on Biogen's website concurrent with the presentation.

- Poster presentation: Reduction in Biomarkers of Alzheimer's Disease Pathophysiology Following Treatment with Aducanumab Were Associated with Slowing Clinical Decline – virtual poster #57499. This poster will be available on Biogen's website on July 26 at 10:00 am ET.

- Poster presentation: Subgroup Analyses of the Amyloid PET Substudies from EMERGE and ENGAGE, Phase 3 Clinical Trials Evaluating Aducanumab in Patients with Early Alzheimer's Disease– virtual poster #57496. This poster will be available on Biogen's website on July 26 at 10:00 am ET.

- Poster presentation: Considerations for the Real-World Management of ARIA from the Aducanumab Phase 3 Studies EMERGE and ENGAGE – virtual poster #57498. This poster will be available on Biogen's website on July 26 at 10:00 am ET.

- Poster presentation: Item-level Analysis of Clinical Measures in Patients with Early Symptomatic Alzheimer's Disease Following Treatment with High-Dose Aducanumab in the Phase 3 Study EMERGE – virtual poster #57619. This poster will be available on Biogen's website on July 26 at 10:00 am ET.

- Poster presentation: Ten-minute Cognitive Screening Tool for Mild Cognitive Impairment and Prediction of Pathological ß-amyloid - virtual poster #54618.

- Oral presentation: Development of a Site Readiness Framework to Improve Health System Preparedness for Potential New Alzheimer's Disease Therapies –July 29, 3:00 pm – 4:15 pm ET (#57672).

- Oral presentation: Drivers and Barriers to Participation of Black and Hispanic Groups in Alzheimer's Disease Clinical Trials: a Qualitative Study – Developing Topics 1 - July 29, 10:00 am – 11:15 am ET (#57652).

- Poster presentation: Baseline Biomarker (Tau PET) Characteristics from TANGO: A Phase 2 Trial of Gosuranemab (BIIB092) in Early Alzheimer's Disease – virtual poster #54952.

- Poster presentation: Results of the First-in-Human, Randomized, Double-Blind, Placebo-Controlled Phase 1b Study of Lumbar Intrathecal Bolus Administrations of Antisense Oligonucleotide (ISIS 814907; BIIB080) Targeting Tau mRNA in Patients with Mild Alzheimer's Disease– virtual poster #51871. This poster will be available on Biogen's website on July 26 at 10:00 am ET.

- Poster presentation: Clinical performance of the b-amyloid (1-42/1-40) ratio determined from automated Lumipulse G1200 cerebrospinal fluid Ab1-42 and Ab1-40 assays, assessed by concordance with PET imaging status– virtual poster #57725.

About ADUHELM™(aducanumab-avwa) injection 100 mg/mL solution
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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.

Please see full Prescribing Information including Medication Guide.

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: Biogen's strategy and plans; potential of, and expectations for, Biogen's commercial business, including ADUHELM; the potential clinical effects of ADUHELM; the potential benefits, safety and efficacy of ADUHELM; the treatment of Alzheimer's disease; the anticipated benefits and potential of our collaboration arrangements with Eisai; the clinical development program, clinical trial(s) and data readouts and presentations for ADUHELM; 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: 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; 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; 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; 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 Biogen has 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.

Contacts
MEDIA CONTACT:
Biogen Inc.
Allison Parks
+1-781-464-3260
public.affairs@biogen.com

INVESTOR CONTACT:
Biogen Inc.
Mike Hencke
+1-781-464-2442

IR@biogen.com