Biogen to Present New Research at the International Conference on Alzheimer's and Parkinson's Diseases (AD/PD 2022)

March 11, 2022

CAMBRIDGE, Mass., March 11, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced the company will present new Alzheimer's disease research, as well as data for ADUHELM® (aducanumab-avwa) injection 100 mg/mL for intravenous use, at the upcoming International Conference on Alzheimer's and Parkinson's Diseases (AD/PD 2022), taking place March 15-20 in Barcelona, Spain and virtually. These data include analyses of treatment effect on biomarkers of Alzheimer's disease in the long-term extension studies, with over two years of Phase 3 data.

An invited plenary lecture, "Key Milestones in Alzheimer's Disease" on March 16, will include an examination of the ability of ADUHELM to reduce amyloid beta plaque and plasma p-tau181, and the relationship between these biomarkers and clinical endpoints during the long-term extension phase of the ADUHELM clinical program.

An oral presentation on March 18, "Effect of Reduction in Brain β-Amyloid Levels on Cognitive Decline in Randomized Clinical Trials: An Updated Instrumental Variable Meta-Analysis," will discuss the details of a meta-analysis on the causality between reduction of amyloid beta levels and reduction of cognitive decline in randomized clinical trials.

Presentation details:

- Plenary Lecture
  - Key Milestones in Alzheimer's Disease [Budd Haeberlein S; 0290 – Plenary Lecture 3; PL003 / #12, Room: 115-117] – *Wednesday, March 16, 12:30 p.m. – 1:00 p.m. CET; 7:30 a.m. – 8:00 a.m. EDT*
- Onsite Oral Presentations
  - Evaluating the Evidence of Aducanumab Treatment Benefit Using Standardized Test Statistics and Global Statistical Tests [Dickson S, *et al.*; 1200 – ABETA Targeting Therapies in AD (ID 66); SO198 / #2220, Room: 112] - *Friday, March 18, 2:45 p.m. – 3:00 p.m. CET; 9:45 a.m. – 10:00 a.m. EDT*
  - Heterogeneity in Symptom Progression and Treatment Response: An Analysis of Participants with Early Alzheimer's Disease from the EMERGE Aducanumab Trial [Cohen S, *et al.*; 1200 – ABETA Targeting Therapies in AD (ID 66); SO199 / #2219, Room: 112] – *Friday, March 18, 3:00 p.m. – 3:15 p.m. CET; 10:00 a.m. – 10:15 a.m. EDT*
  - Subgroup Analyses of the Plasma P-tau^{181} Population From EMERGE/ENGAGE, Phase 3 Clinical Trials Evaluating Aducanumab in Early Alzheimer's Disease [Hansson O, *et al.*; 1200 – ABETA Targeting Therapies in AD (ID 66); SO200 / #1894, Room: 112] – *Friday, March 18, 3:15 p.m. – 3:30 p.m. CET; 10:15 a.m. – 10:30 a.m. EDT*
  - Effect of Reduction in Brain β-Amyloid Levels on Cognitive Decline in Randomized Clinical Trials: An Updated Instrumental Variable Meta-Analysis [Shen C, *et al.*; 1060 – Translational Treatment Strategies and New Targets in AD, Room: 112] – *Friday, March 18, 10:40 a.m. – 10:55 a.m. CET; 5:40 a.m. – 5:55 a.m. EDT*
- Virtual Poster
  - Aducanumab Phase 3 Studies: Exposure-Response Analysis Evaluating the Relationship Between Amyloid Removal and Slowing of Clinical Decline on CDR-SB Scores [Kandadi Muralidharan K, *et al.*; P225 / #1868, Virtual Poster Presentation] – *Tuesday, March 15, starting at 8:00 a.m. CET; 3:00 a.m. EDT*

Archived versions of the presentations will be available at the same time on the investors section of Biogen's website at investors.biogen.com.

About ADUHELM® (aducanumab-avwa) injection 100 mg/mL for intravenous use
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).

ADUHELM 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

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 is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline 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.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen 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, about 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 Biogen's collaboration arrangements with Eisai; clinical development programs, clinical trials and data readouts and presentations; and risks and uncertainties associated with drug development and commercialization. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "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 unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks associated with current and potential future healthcare reforms; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's 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 Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and 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.

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

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