Biogen Announces Late Breakers and Additional New Data Presentations at the 2021 Clinical Trials on Alzheimer's Disease (CTAD) Meeting

November 3, 2021

- *Late breaker will show ADUHELM™ effect on plasma pTau181 reduction, and its correlation with amyloid beta and slowing cognitive and functional decline.*
- *Additional phase 3b late breaker data will shed light on clinical decline and amyloid beta plaque levels after patients stopped treatment.*
- *With data from the largest clinical trial dataset in early Alzheimer's disease, Biogen contributes 11 presentations to CTAD, supporting robust scientific insights and dialogue.*

CAMBRIDGE, Mass., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced the company will present a variety of new data from its Alzheimer's disease product portfolio and clinical development pipeline at the upcoming annual Clinical Trials on Alzheimer's Disease conference (CTAD), held November 9-12 virtually and in Boston, Massachusetts. Biogen's contributions to the conference are driven in part by analyses from the largest clinical trial dataset in early Alzheimer's disease research. This includes over 3,000 patients in Phase 3 trials and approximately 1,700 patients in the ADUHELM (aducanumab-avwa) redosing trial, EMBARK.

A late breaking presentation will highlight important new data from over 7,000 plasma samples from the ADUHELM Phase 3 trials that, for the first time, examines the effect of ADUHELM on plasma phosphorylated tau181 (p-Tau181) and its correlation to amyloid beta plaques and disease progression, as measured by clinical decline endpoints, in patients with early Alzheimer's disease. The accumulation of amyloid beta plaques and tangles of tau proteins in brain cells are the two defining pathologies of Alzheimer's disease.

"We collected an unprecedented sample size—approximately 7,000 plasma samples from more than 1,800 patients—to provide robust answers to questions about the correlation between plasma pTau reduction, amyloid beta plaque levels and clinical decline in Alzheimer's disease. We are eager to engage the scientific community with the findings from this comprehensive dataset," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "The clinical insights we can derive from our data at CTAD are meaningful. These can help inform clinician, patient and caregiver choice and future treatment decisions, as well as advance the field's understanding of this devastating disease."

The data will be discussed at the virtual oral presentation and roundtable: "Dose and time dependent changes in plasma ptau181 in patients treated with aducanumab in the ENGAGE and EMERGE trials," on Thursday, November 11, at 5:10 p.m. EST.

Biogen will also present data from over 1,800 patients that were screened for the EMBARK re-dosing trial with ADUHELM, to shed light on the impact of stopping treatment in clinical trials. Patients who were enrolled in the ADUHELM trials when they were discontinued in 2019 later re-enrolled in the EMBARK trial, after a lengthy off-treatment period of an average of 1.7 years. Some of these patients had been on treatment for more than 4 years in the PRIME Phase 1b long-term extension, as well as for up to 18 months in the Phase 3 trials, EMERGE and ENGAGE. Disease progression and amyloid beta plaque levels during this extended discontinuation of Alzheimer's disease treatment will be examined in the Virtual Oral Presentation, "Baseline EMBARK data from EMERGE, ENGAGE, and PRIME participants in the EMBARK re-dosing study," on Tuesday, November 9, at 8:00 a.m. EST.

In addition, a poster titled, "Urgency to treat before it's too late: Daily transitions to moderate AD dementia in the US and Europe," will examine how many people are estimated to progress daily from mild cognitive impairment due to Alzheimer's disease to mild Alzheimer's disease, and from mild Alzheimer's disease to moderate Alzheimer's disease, pointing to the urgency for earlier detection, diagnosis and treatment.

Abstract details:

- ADUHELM
  - Late Breaking Virtual Oral Presentation: Baseline EMBARK data from EMERGE, ENGAGE, and PRIME participants in the EMBARK re-dosing study (Cohen S; #LBR2) – *Available virtually starting on Tuesday, November 9, 8:00 a.m. EST*
  - Late Breaking Virtual Oral Presentation: Defining a standardized MRI acquisition protocol to be proposed to ICARE AD-US sites for baseline and ARIA monitoring (Benzinger T; #LBR4) – *Available virtually starting on Tuesday, November 9, 8:00 a.m. EST*
  - Late Breaking Virtual Oral Presentation: Dose and time dependent changes in plasma ptau181 in patients treated with aducanumab in the ENGAGE and EMERGE trials (Hanson O, #Late Breaking Readout Roundtable 8) – *Thursday, November 11, 5:10 p.m. EST*
- BIIB092
  - Late-Breaking Virtual Oral Presentation: Top-line results from TANGO, a Phase 2 study of gosuranemab in participants with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease (Shulman; #LBR5, Shulman) – *Available virtually starting on Tuesday, November 9, 8:00 a.m. EST*
- BIIB076
  - Virtual Oral Presentation: Results of A Phase 1, Randomized, Blinded, Placebo-Controlled, Single-Ascending-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of BIIB076 in Healthy Volunteers and Subjects With Alzheimer's Disease (Ratti E; #ROC16) – *Available virtually starting on Tuesday, November 9, 8:00 a.m. EST*

- General Alzheimer's Disease
  - Poster Presentation: Urgency to treat before it's too late: Daily transitions to moderate AD dementia in the US and Europe (Maserejian N; #LP23) – *Wednesday, November 10, through Friday, November 12.*
  - Poster Presentation: Distribution and baseline characteristics of participants with rapid progressing Alzheimer's Disease as measured by CDR-SB over 78 weeks in the National Alzheimer's Coordinating Center (NACC) (Gillis C; #P63) - *Wednesday, November 10, through Friday, November 12.*
  - Poster Presentation: Updated U.S. prevalence estimates accounting for racial and ethnic diversity for trials and therapies targeting mild cognitive impairment due to Alzheimer's disease (AD) and mild AD dementia (Maserejian N; #LP22) - *Wednesday, November 10, through Friday, November 12.*
  - Poster Presentation: Sigmoid methodology allows early prediction of cognitive decline towards Alzheimer's disease across several cognitive domains (Doecke J; #RP25) - *Wednesday, November 10, through Friday, November 12.*
  - Poster Presentation: Global prevalence of Alzheimer's disease across disease stages (Gustavsson A; #RP36) - *Wednesday, November 10, through Friday, November 12.*

- Frontotemporal Dementia
  - Poster Presentation: Estimates of Frontotemporal Dementia by geographic regions (Gillis C; #P61) - *Wednesday, November 10, through Friday, November 12.*

Biogen will host webcasts of its oral presentations on EMBARK and plasma ptau181 on the investors section of Biogen's website at investors.biogen.com concurrent with the presentation times indicated above. Following the webcasts, archived versions will be available on the website.

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
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 the 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; results from the EMBARK study; 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.

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