Biogen to Present New Data at the Clinical Trials on Alzheimer's Disease (CTAD) 2023 Meeting

October 19, 2023

- Late-breaking Phase 1b data assesses the clinical outcomes of reducing tau in patients with early-stage Alzheimer's disease
- Additional late-breaking presentations from the CLARITY AD study explore predictive biomarkers and novel subcutaneous administration of LEQEMBI® (lecanemab-irmb)

CAMBRIDGE, Mass., Oct. 19, 2023 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) will present new data from its Alzheimer's disease portfolio at the upcoming Clinical Trials on Alzheimer's Disease (CTAD) meeting taking place October 24-27 in Boston, Mass. The presentations will advance the understanding of Alzheimer's disease with data on different treatment approaches, predictive analysis of disease progression, and clinical meaningfulness of amyloid removal for patients and their caregivers.

"We believe these new data represent an important step in our effort to both optimize patient outcomes with current treatments while simultaneously advancing the next wave of breakthroughs in Alzheimer's disease," said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. "We've reached a potential tipping point in this complex field and remain determined to continue moving forward with the community to help the millions of people impacted by Alzheimer's disease."

Biogen presentations will include data from the multiple ascending dose and long-term extension phases of the Phase 1b study evaluating exploratory clinical outcomes associated with tau reduction in patients with early Alzheimer's disease. New data on LEQEMBI, developed in collaboration with Eisai Co., Ltd., will be presented with discussion of preliminary data on a subcutaneous formulation, as well as biomarker assessments from Clarity AD, including the role of tau as a predictive biomarker, and the implications of targeting protofibrils. Select presentations from CTAD will be available on Biogen.com at the time of the conference presentation.

Key Presentations Include:

- Late-breaking oral presentation: Exploratory clinical outcomes from BIIB080 (MAPT ASO) Phase 1b multiple ascending dose and long-term extension study in mild Alzheimer's disease: *Wednesday, October 25, 10:50 a.m.*
- Late-breaking symposium 4: Lecanemab for Early Alzheimer's Disease: Long-Term Outcomes, Predictive Biomarkers and Novel Subcutaneous Administration: *Wednesday, October 25, 5:25 p.m.*
    - The presentation will include the latest data from the CLARITY AD optional tau PET longitudinal sub-study. A post-hoc analysis of the low and intermediate + high-tau subgroups, including the low-tau subgroup specifically studied in the Phase 3 core study, and data from the open-label extension study will be included in the presentation. An update on the investigational subcutaneous formulation with the effect on amyloid as measured by amyloid PET and interim safety, will also be provided.
- Late-breaking oral presentations: Pooled ENGAGE/EMERGE Integrated Placebo-controlled Period and Long-Term Extension (LTE) Topline Results: Slower Clinical Progression at Week 134 in Aducanumab-treated Patients that Became Amyloid PET Negative at Week 78: *Wednesday, October 25, 8:30 a.m.* Aducanumab Phase 3b EMBARK Study Interim Analysis: Topline Safety Results: *Friday, October 27, 2:00 p.m.*
- Oral presentation: Precision medicine analysis of heterogeneity in individual-level treatment response to beta-amyloid removal in early Alzheimer's disease: *Thursday, October 26, 4:35 p.m.*

About LEQEMBI®(lecanemab)
LEQEMBI (lecanemab) is the result of a strategic research alliance between Eisai and BioArctic. LEQEMBI is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). LEQEMBI is an amyloid beta-directed antibody for the treatment for Alzheimer's disease (AD) in the U.S. The U.S. Food and Drug Administration (FDA) granted LEQEMBI traditional approval on July 6, 2023.

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI 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.

Eisai and Biogen have been collaborating on the joint development and commercialization of AD treatments since 2014. Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both companies co-commercializing and co-promoting the product and Eisai having final decision-making authority.

Please see full U.S. Prescribing Information for LEQEMBI, including Boxed WARNING and Medication Guide.

About ADUHELM®(aducanumab-avwa)
ADUHELM (aducanumab-avwa), a human monoclonal antibody, designed to address a defining pathology of Alzheimer's disease by reducing amyloid beta plaques in the brain. ADUHELM is indicated for the treatment of Alzheimer's disease. This indication was granted under accelerated approval based on reduction in amyloid beta plaques in patients treated with ADUHELM. Continued approval for this indication is contingent upon verification of clinical benefit in confirmatory trial(s).

Biogen licensed ADUHELM from Neurimmune in 2007 under a collaborative development and license agreement.

Please see full U.S. Prescribing Information for ADUHELM, including Boxed WARNING and Medication Guide.

About Biogen
Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, and two co-developed treatments to address a defining pathology of Alzheimer's disease. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - X, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, about the potential treatments of Alzheimer's disease; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs, including LEQEMBI; 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 studies may not be indicative of full results or results from later stage or larger scale clinical studies 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 studies; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected 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 Biogen's drug candidates; failure to protect and enforce Biogen's 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 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 speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

References:

1. BrightFocus. Foundation. Tau Protein and Alzheimer's Disease: What's the Connection? https://www.brightfocus.org/alzheimers/article/tau-protein-and-alzheimers-disease-whats-connection.%20Accessed%20March%202023. Accessed September 2023.
2. Alzheimer's Association. Tau Topic Sheet. https://www.alz.org/media/Documents/alzheimers-dementia-tau-ts.pdf. Accessed September 2023.

MEDIA CONTACT:
Biogen
Jack Cox
+ 1 781 464 3260
public.affairs@biogen.com

INVESTOR CONTACT:
Biogen
Chuck Triano
+1 781 464 2442
IR@biogen.com