Biogen to Present Data at Virtual 2020 Alzheimer's Association International Conference Highlighting Comprehensive Approach to Alzheimer's Disease

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CAMBRIDGE, Mass., July 24, 2020 (GLOBE NEWSWIRE) -- Biogen (Nasdaq: BIIB) today announced there will be multiple data presentations from its Alzheimer's disease (AD) clinical development portfolio, a virtual satellite symposium and AD PACE poster presentations at the Alzheimer's Association International Conference (AAIC), which will be held online July 27-31. The company's contributions to AAIC showcase its work to build a broad AD franchise across multiple targets and modalities, as well as to advance knowledge about early diagnosis, unmet patient needs and health system capacity to diagnose and treat people living with AD.

Biogen's AD portfolio of investigational assets includes aducanumab, an investigational treatment that, if approved, could meaningfully change the course of the disease. At the conference, Biogen will share an encore platform presentation of the previously reported topline results from the aducanumab Phase 3 EMERGE and ENGAGE studies. No new data from the studies are included in the encore presentation, which will be pre-recorded and followed by a live, virtual question and answer (Q&A) session. This presentation and Q&A session will be held on Wednesday, July 29, 7:00 am – 8:00 am Central Daylight Time (CDT) as part of Developing Topic Session: Developments in Clinical Trials and Cognitive Assessment (SO3-02). To access the presentation and Q&A session, please complete a free registration for AAIC in advance at aaic2020.vfairs.com/en/register. The presentation and Q&A session will be held in the Live Auditorium on the AAIC platform and can be accessed from either aaic2020.vfairs.com or the Investor's section of Biogen's website at investors.biogen.com. Following the webcast, an archived version will be available on the Investor's section of Biogen's website.

In addition, Biogen's drug candidates and research will be featured in a platform presentation about the Phase 2 TANGO study to evaluate gosuranemab (BIIB092) in patients with early AD; a poster about the feasibility of clinical research studies reported by patients with behavioral variant frontotemporal dementia and their caregivers; and a poster on tau protein interactions. Conference activities also include a virtual satellite symposium about early diagnosis and readying the health system for the potential entry of a disease-modifying treatment for AD.

Posters and presentations will be available for 30 days on the AAIC conference website.

Biogen Presentations and Symposium:

- Encore platform presentation and Q&A: EMERGE and ENGAGE topline results: phase 3 studies of aducanumab in early AD. Part of the Developing Topic Session: Developments in Clinical Trials and Cognitive Assessment (SO3-02) - *Wednesday, July 29, 7:00 am – 8:00 am Central Daylight Time (CDT), Live Auditorium*

- Platform presentation: Baseline characteristics from TANGO: phase 2 study to evaluate gosuranemab (BIIB092) in patients with early AD - *Wednesday, July 29, on-demand session available 12:00 am CDT*, *Human: Improving Clinical Trial Methodology, Scheduled Chatroom Q&A Session 11:30 am – 11:55 am CDT*

- Poster presentation: Feasibility of clinical research studies reported by patients with behavioral variant frontotemporal dementia (bvFTD) and their caregivers (FORWARD study). Session: Drug Development: Clinical Trial Design and Implementation – *Wednesday, July 29*

- Poster presentation: Proteomics studies to investigate alterations in the tau interactome under conditions of elevated cellular O-GlcNAcylation. Session: Basic Science and Pathogenesis: Inflammation: From Basic Science To Biomarkers - *Monday, July 27*

- Virtual satellite symposium: The Diagnosis of Early Alzheimer's Disease: Readying the System. Panel will feature Dr. José Luis Molinuevo, Barcelonaβeta Brain Research Center, Dr. Christopher Rowe, Austin Health, Dr. Marwan Sabbagh, Cleveland Clinic Lou Ruvo Center for Brain Health, and Dr. Kathleen Welsh-Bohmer, Duke Clinical Research Institute. The symposium will be available on the AAIC website starting on July 27 and will remain available for 30 days after the conference.

As part of the conference, the Alzheimer's Disease Patient and Caregiver Engagement (AD PACE) initiative, a collaboration from advocacy group Us Against Alzheimer's that includes Biogen and other participants from the pharmaceutical industry, academia, government agencies and patient advocates, will present three posters from the What Matters Most study. The aim of the collaboration is to build a persistent platform to deliver new insights to research, regulatory and payer authorities on preferred treatment and health outcomes sought by those living with AD and their caregivers.

AD PACE Presentations:

- Poster presentation: Quantifying what matters most to patients and care partners in Alzheimer's disease

- Poster presentation: The importance of care partner input in Alzheimer's disease drug development

- Poster presentation: Evaluation of what matters most in existing clinical outcomes assessments in Alzheimer's disease

In addition, Biogen will also be part of a presentation from The Critical Path for Alzheimer's Disease (CPAD) Consortium.

- Poster presentation: Pre-competitive data sharing and generation of innovative high-impact quantitative tools to support Alzheimer's disease drug development. Session: Drug Development, Human/Trial design - *Wednesday, July 29*

Biogen's collaboration partner Eisai Co., Ltd. (Eisai) will also present data from the companies' shared AD portfolio.

Eisai Presentations:

- Poster presentation: A preliminary account of ARIA-E in the open label extension phase of BAN2401-G000-201 in subjects with early AD (BAN2401) – Wednesday, *July 29*
- Poster presentation: A preliminary assessment of longitudinal amyloid status in the ongoing open label extension phase in subjects with early AD (BAN2401) – Wednesday, *July 29*
- Platform presentation: AHEAD3-45 study design (BAN2401) – Wednesday, *July 29, 11:00 am - 11:25 am CDT*
- Poster presentation: Amyloid burden assessed by three amyloid PET tracers in the elenbecestat MissionAD phase 3 program (the MissionAD program has been discontinued) – *July 29*

About Aducanumab
Aducanumab (BIIB037) is an investigational human monoclonal antibody studied for the treatment of Alzheimer's disease. Based on clinical data, aducanumab has the potential to impact underlying disease pathophysiology, slow cognitive and functional decline and provide benefits on patients' ability to perform activities of daily living, including conducting personal finances, performing household chores, such as cleaning, shopping and doing laundry, and independently traveling out of the home. If approved, aducanumab would be the first treatment to meaningfully change the course of the disease for individuals living with Alzheimer's.

Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Since October 2017 Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally.

EMERGE and ENGAGE were Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies designed to evaluate the efficacy and safety of aducanumab. The primary objective of the studies was to evaluate the efficacy of monthly doses of aducanumab as compared with placebo in reducing cognitive and functional impairment as measured by changes in the Clinical Dementia Rating-Sum of Boxes (CDR-SB) score. Secondary objectives were to assess the effect of monthly doses of aducanumab as compared to placebo on clinical decline as measured by the Mini-Mental State Examination (MMSE), Alzheimer's Disease Assessment Scale-Cognitive Subscale 13 Items (ADAS-Cog 13) and Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Mild Cognitive Impairment Version (ADCS-ADL-MCI).

About BAN2401
BAN2401 is a humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic. BAN2401 selectively binds to neutralize and eliminate soluble, toxic Aβ aggregates that are thought to contribute to the neurodegenerative process in AD. As such, BAN2401 may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Eisai obtained the global rights to study, develop, manufacture and market BAN2401 for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. Currently, a global clinical Phase 3 study (Clarity AD) of BAN2401 in early AD is underway. BAN2401 is being jointly developed by Eisai and Biogen Inc. The National Institute on Aging, a division of the National Institutes of Health, is providing funding for the A45 Study (grant number R01AG061848) and A3 Study (grant number R01AG054029).

About Gosuranemab
Gosuranemab (BIIB092) is a humanized monoclonal antibody that targets N-terminal tau. Gosuranemab is currently being evaluated in the Phase 2 TANGO study in participants with mild cognitive impairment due to Alzheimer's disease or with mild Alzheimer's disease. Biogen licensed gosuranemab from Bristol-Myers Squibb Company.

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, immunology, neurocognitive disorders, acute neurology and 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, about the potential clinical effects of aducanumab, BAN2401 and gosuranemab; the potential benefits, safety and efficacy of aducanumab, BAN2401 and gosuranemab; the results of the Phase 3 studies and Phase 1b study of aducanumab and the Phase 2 study of gosuranemab; the identification and treatment of Alzheimer's disease; potential regulatory approvals and the timing thereof; the anticipated benefits and potential of our collaboration arrangements with Eisai; the potential of our commercial business and pipeline programs, including aducanumab, BAN2401 and gosuranemab; 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; actual timing and content of submissions to and decisions made by the regulatory authorities regarding aducanumab; 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 aducanumab, BAN2401 and gosuranemab; uncertainty of success in the development and potential commercialization of aducanumab; risks relating to the potential launch of aducanumab, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for aducanumab and other unexpected difficulties or hurdles; failure to protect and enforce our 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 our 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 our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do 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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