Biogen to Present Data from Alzheimer's Disease Portfolio at the 2018 Clinical Trials on Alzheimer's Disease (CTAD) Meeting

October 18, 2018

Data to be presented across the Alzheimer's disease clinical development portfolio, including aducanumab, BAN2401 and elenbecestat

CAMBRIDGE, Mass., Oct. 18, 2018 (GLOBE NEWSWIRE) -- Biogen (Nasdaq: BIIB) announced it will present data from its Alzheimer's disease (AD) clinical development portfolio at the upcoming Clinical Trials on Alzheimer's Disease (CTAD) annual meeting in Barcelona, Spain (October 24-27). The data being presented are part of Biogen's ongoing research programs targeting possible causes of the disease through multiple modalities.

"We are excited to engage with the scientific community at CTAD, to share learnings from our Alzheimer's disease clinical research and to learn from the work of our colleagues around the world. We have hopes that our collective research will one day help the millions of people living with Alzheimer's disease," said Samantha Budd Haeberlein, Ph.D., vice president, Alzheimer's disease, dementia and movement disorders, late stage clinical development at Biogen.

Biogen will share a late-breaking oral presentation and a late-breaking poster on the efficacy of aducanumab and the cumulative safety data from the Phase 1b PRIME long-term extension study of patients with prodromal and mild Alzheimer's disease. Aducanumab is Biogen's late-stage Alzheimer's disease investigational treatment, and is being co-developed with Eisai.

In addition to presentations from our clinical research programs, Dr. Budd Haeberlein will deliver a keynote titled "What Have We Learned from Aducanumab*?*" that focuses on the lessons learned from the aducanumab research.

Biogen presentations will highlight:

- Oral Presentation: Aducanumab Titration Dosing Regimen: 36-Month Analyses from PRIME, a Phase 1b Study in Patients with Early Alzheimer's Disease – *Friday, October 26, 3:15-3:30 p.m. CEST*
- Keynote: What Have We Learned from Aducanumab? – *Thursday, October 25, 1:30-2:00 p.m. CEST*
- Poster Presentation: Cumulative Aducanumab Safety Data from PRIME: A Randomized, Double-blind, Placebo-controlled, Phase 1b Study – *Wednesday, October 24, through Saturday, October 27*. The poster will be available on Biogen.com
- Poster Presentation: Aducanumab 48-Month Analyses from PRIME, a Phase 1b Study in Patients with Early Alzheimer's Disease – *Wednesday, October 24, through Saturday, October 27.* The poster will be available on Biogen.com

Biogen will also host live webcasts of its oral presentation and keynote address, as well as a Q&A session related to its Alzheimer's disease investigational therapies. To access the live webcasts, please go to the Investors section of Biogen's website at investors.biogen.com. Following the live webcasts, archived versions will be available on the website.

Biogen Webcast Details:

- Thursday, October 25, 7:30-8:00 a.m. ET / 1:30-2:00 p.m. CEST - *Keynote: What Have We Learned from Aducanumab?*
- Thursday, October 25, 4:15 p.m. ET / 10:15 p.m. CEST - *Investor Q&A call with Alfred Sandrock, Jr., M.D., Ph.D., executive vice president and chief medical officer at Biogen, and Samantha Budd Haeberlein, Ph.D., vice president, Alzheimer's disease, dementia and movement disorders, late stage clinical development at Biogen*
- Friday, October 26, 9:15-9:30 a.m. ET / 3:15-3:30 p.m. CEST - *Oral Presentation: Aducanumab Titration Dosing Regimen: 36-Month Analyses from PRIME, a Phase 1b Study in Patients with Early Alzheimer's Disease*

Biogen's collaborator Eisai will present safety and efficacy data for the BACE inhibitor, elenbecestat, from the Phase 2 study in MCI-to-moderate Alzheimer's diseas *e*, along with clinical and biomarker updates from the Phase 2 study of BAN2401, an anti-amyloid beta antibody.

Eisai presentations will highlight:

- Oral Presentation: Elenbecestat in MCI-to-Moderate Alzheimer's Disease – *Thursday, October 25, 9:30-9:45 a.m. CEST*
- Symposium: Clinical and Biomarker Updates from BAN2401 Study 201 in Early AD – *Thursday, October 25, 2:30-3:30 p.m. CEST*

Eisai Webcast Details:

- Symposium: Clinical and Biomarker Updates from BAN2401 Study 201 in Early AD - *Thursday, October 25, 2:30-3:30 p.m. CEST.* To access the live webcast, please visit https://www.eisai.com/ir/index.html

About Aducanumab
Aducanumab (BIIB037) is an investigational compound being studied for the treatment of early Alzheimer's disease. Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Aducanumab is a human monoclonal antibody (mAb) derived from a de-identified library of B cells collected from healthy elderly subjects with no signs of cognitive impairment or cognitively impaired elderly subjects with unusually slow cognitive decline using Neurimmune's technology platform called Reverse Translational Medicine (RTM). Since October 2017, Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally. In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of aducanumab, a process allowing priority reviews by the FDA for drugs deemed as having potential to treat serious conditions and tackle key unmet medical needs.

About BAN2401
BAN2401 is a humanized monoclonal antibody for Alzheimer's disease 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 Alzheimer's disease. 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 Alzheimer's disease pursuant to an agreement concluded with BioArctic in December 2007. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for BAN2401 and the parties amended that agreement in October 2017.

About Elenbecestat
Elenbecestat is an oral BACE (beta amyloid cleaving enzyme) inhibitor currently being investigated in Phase 3 clinical studies for Alzheimer's disease discovered by Eisai and in collaboration with Biogen. By inhibiting BACE, a key enzyme in the production of Aβ peptides, elenbecestat reduces Aβ production, which is thought to lead to a reduction in amyloid plaque formations caused by the aggregation of toxic oligomers and protofibrils in the brain. Currently, two global Phase 3 clinical studies (MISSION AD1/2) of elenbecestat in early Alzheimer's disease including mild cognitive impairment (MCI) due to AD/Prodromal AD and the early stages of mild AD are underway. In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of elenbecestat, a process to facilitate development and expedite review by the FDA for drugs deemed as having potential to treat serious conditions and addressing unmet medical needs.

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. 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, and today has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy; and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, multiple sclerosis and neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This press 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 Phase 1b study of aducanumab and results of certain subgroup analyses in the Phase 1b study, about results from the Phase 2 study of BAN2401, about results from the Phase 2 study of elenbecestat, the potential clinical effects of aducanumab, BAN2401 and elenbecestat the potential benefits, safety and efficacy of aducanumab, BAN2401 and elenbecestat, the identification and treatment of Alzheimer's disease, the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai and the potential of Biogen's commercial business and pipeline programs, including aducanumab, BAN2401 and elenbecestat. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will" 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 our clinical trials; 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/or elenbecestat; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; uncertainty of success in the development and potential commercialization of aducanumab, BAN2401 and/or elenbecestat; 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; and third party collaboration risks. 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 Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this press 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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