



Data to be Presented From Biogen's Alzheimer's Disease Clinical Development Portfolio at the 2018 Alzheimer's Association International Conference (AAIC)

July 18, 2018

- Ongoing Alzheimer's disease research programs target possible causes of the disease through multiple modalities
- Data to be presented from Alzheimer's disease clinical development portfolio including aducanumab, elenbecestat, and BAN2401
- Data underscore Biogen's long-term commitment to furthering Alzheimer's disease research and treatment, with a focus on patients with early stage disease

CAMBRIDGE, Mass., July 18, 2018 (GLOBE NEWSWIRE) -- [Biogen](#) (Nasdaq:BIIB) announced it will present data from its Alzheimer's disease clinical development portfolio at the upcoming Alzheimer's Association International Conference (AAIC) in Chicago (July 22-26). Data being presented are part of Biogen's research programs targeting several of the identified causes of Alzheimer's disease, focusing on early-stage disease.

"The data to be presented at AAIC exemplify our belief that treatments are needed at the earliest stages of Alzheimer's disease to impact the underlying pathophysiology and delay disease progression," said Samantha Budd Haeberlein, vice president, clinical development at Biogen. "We are pleased to present new findings at this year's meeting and continue to demonstrate our commitment to the millions of people living with Alzheimer's disease."

Biogen presentations will include a new analysis from the Phase 1b (PRIME) study of aducanumab, an investigational anti-amyloid beta antibody therapy for mild cognitive impairment (MCI) due to Alzheimer's disease and mild dementia due to Alzheimer's disease. Aducanumab is currently being evaluated in two global Phase 3 studies, ENGAGE and EMERGE, which are designed to evaluate its safety and efficacy in slowing cognitive and functional impairment in people with MCI due to Alzheimer's disease and mild Alzheimer's disease dementia, and is being co-developed with Eisai as of October 2017.

In addition, Biogen's collaborator Eisai will present topline Phase 2 clinical study results of BAN2401, an anti-amyloid beta protofibril antibody, and data on elenbecestat, a BACE (beta amyloid cleaving enzyme) inhibitor. Elenbecestat is currently being evaluated in two global Phase 3 clinical studies (MISSION AD 1/2) in early Alzheimer's disease.

These presentations will highlight:

Alzheimer's disease investigational therapies:

- 24-Month Analysis of APOE ϵ 4 Carriers in PRIME, a Randomized Phase 1B Study of the Anti-Amyloid Beta Monoclonal Antibody Aducanumab – *Poster #22959 – Sunday, July 22, 9:30 a.m.–4:15 p.m. CT*
- Elenbecestat, a Novel BACE Inhibitor, Demonstrates Similar Pharmacokinetics and Safety in Japanese Subjects During Multiple Dosings as in Other Studies – *Poster #P1-01 – Sunday, July 22, 9:30 a.m.–4:15 p.m. CT*
- 24-Month Analysis of Change From Baseline in Clinical Dementia Rating Scale Cognitive and Functional Domains in PRIME, a Randomized Phase 1B Study of the Anti-Amyloid Beta Monoclonal Antibody Aducanumab – *Oral #22962 – Sunday, July 22, 3:15-3:30 p.m. CT*
- Treatment of Early AD subjects with BAN2401, an Anti-A β Protofibril Monoclonal Antibody, Significantly Clears Amyloid Plaque and Reduces Clinical Decline – *Presentation # DT-01-07 – Wednesday, July 25, 3:30 p.m.–4:00 p.m. CT*
- Elenbecestat, E2609, a BACE Inhibitor: Results from a Phase-2 Study in Subjects with Mild Cognitive Impairment and Mild-to-Moderate Dementia Due to Alzheimer's Disease – *Poster #P4-389 – Wednesday, July 25, 9:30 a.m.–4:15 p.m. CT*
- Lumipulse® G Total Tau to β -Amyloid 1-42 Ratio Cut-Point Determination for Amyloid Eligibility Screening – *Poster #P4-075 – Wednesday, July 25, 9:30 a.m.–4:15 p.m. CT*
- Anti-Tau Antibody BIIB092 Binds Secreted Tau in Preclinical Models and Alzheimer's Disease Cerebrospinal Fluid – *Poster #P4-021 – Wednesday, July 25, 9:30 a.m.–4:15 p.m. CT*

General Alzheimer's disease research:

- Cognitive and Other Neuropsychological Assessments Documented in Electronic Health Records Prior to or at Alzheimer's Disease Diagnosis – *Poster #22897 – Sunday, July 22, 9:30 a.m.–4:15 p.m. CT*
- Supporting Disease Modification via Analyses of the Link between Clinical Endpoints and Biomarkers in Alzheimer's Disease Clinical Trials – *Poster #24795 – Sunday, July 22, 9:30 a.m.–4:15 p.m. CT*
- Translational Research – the View from Pharma – *Platform #S2-02-02 – Monday, July 23, 8:20-8:40 a.m. CT*
- Cognitive Reserve Modulates the Association of Cerebral Amyloid Pathology with Cognitive Performance in Persons with Alzheimer's Disease Dementia – *Poster #22491 – Tuesday, July 24, 9:30 a.m.–4:15 p.m. CT*
- AD PACE: Alzheimer's Disease Patient And Caregiver Engagement Initiative-- Determining What Matters Most to Alzheimer's Patients and Care Partners to Inform the Design and Development of New Therapies, Determinations of Payment and Coverage, and the Delivery of Care and Services – *Poster #P4-164 – Wednesday, July 25, 9:30 a.m.–4:15 p.m. CT*

Biogen's platform presentation on the 24-month Clinical Dementia Rating Scale analysis of PRIME and the APOE ϵ 4 analysis of PRIME poster will be

available concurrently with the applicable sessions on the Investors section of the Biogen company website, www.biogen.com.

Eisai's BAN2401 slide presentation will be available concurrently with the AAIC presentation on the Investor section of the Eisai company website at www.eisai.com.

About Aducanumab

Aducanumab (BIIB037) is an investigational compound being studied for the treatment of early Alzheimer's disease. Aducanumab is a human recombinant 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). Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. As of October 22, 2017, Biogen and Eisai Co. Ltd. are collaborating 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 A β 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 A β peptides, elenbecestat reduces A β 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 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 Eisai's presentation on the results from the Phase 2 study of BAN2401, 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, 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 the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected; unexpected concerns 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; we may encounter other unexpected hurdles; uncertainty of success in the development and potential commercialization of aducanumab, BAN2401 and/or elenbecestat, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; failure to protect intellectual property and other proprietary rights; 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 Biogen has 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.

MEDIA CONTACT:

David Caouette
+1 617 679 4945
public.affairs@biogen.com

INVESTOR CONTACT:

Matt Calistri
+1 781 464 2442
IR@biogen.com