Långtidsdata från fas 3-studie visar att ADUHELM® fortsätter att minska underliggande patologier av Alzheimers sjukdom hos patienter som behandlats i mer än två år

- Aducanumab-avwa (ADUHELM®) fortsatte att minska två viktiga sjukdomspatologier för Alzheimers sjukdom, amyloid beta-plack och p-tau181, hos patienter som behandlats i upp till två och ett halvt år
- Data från båda fas 3-studierna visar också att den kliniska nedgången minskade hos patienter som hade plasma-p-tau181-reduktion vid 78 veckor
- Dessa data ger ytterligare vetenskapligt stöd för amyloid som en surrogatbiomarkör och vikten av att fortsätta behandlingen
- Aducanumab-avwa granskas för närvarande av EMA och är ännu inte godkänt i Sverige

CAMBRIDGE, Mass. – March 16, 2022 – Biogen Inc. (Nasdaq: BIIB) announced new data showing that after nearly two and a half years of treatment (128 weeks) with aducanumab-avwa injection 100 mg/mL for intravenous use, patients in the long-term extension phase of the Phase 3 trials continued to experience significant reductions in two key Alzheimer's disease pathologies, amyloid beta plaques and plasma p-tau181. The data also show that in both Phase 3 trials, at 78 weeks, patients with reduced levels of plasma p-tau181 had less clinical decline than those whose plasma p-tau181 levels were not reduced.

Data from the long-term extension study showed that aducanumab-avwa significantly reduced amyloid beta plaque levels out to Week 132. The data also showed that aducanumab-avwa continued to decrease plasma p-tau181 levels at 128 weeks. Patients with more effective amyloid beta clearance (SUVR lower than 1.1 by 78 weeks) also had greater decreases in p-tau181 at week 128. These findings point to the potential of continued benefit of treatment in the longer term with continued reduction of amyloid beta plaques.

"These are findings, which further our understanding of amyloid and downstream biomarkers, such as p-tau 181, in Alzheimer's disease and can help inform how long patients may benefit from treatment to reduce amyloid beta plaque," said Samantha Budd Haeberlein, Ph.D., SVP, Head of Neurodegeneration Development at Biogen. "These data demonstrate that long-term treatment with aducanumab-avwa continues to reduce the underlying pathologies of Alzheimer's disease beyond two years."

Data showed that patients with a reduction in plasma p-tau181, an exploratory endpoint, had less clinical progression across all four clinical endpoints (CDR-SB, MMSE, ADAS-Cog13, and ADCS-ADL-MCI) measuring cognition and function in both Phase 3 trials at Week 78.

In the placebo-controlled period of the Phase 3 trials, the incidence of ARIA-E in the 10 mg/kg group was 35.2%. The incidence was higher among APOE ε4 carriers (43.0%) than non-carriers (20.3%). While the majority of ARIA is asymptomatic, serious symptoms in the setting of ARIA can occur (0.3% of participants in the 10 mg/kg group of the Phase 3 trials. Most events (98.2%) of ARIA-E resolved on study, with the majority resolving within 12-16 weeks. Biogen is committed to continuing to work with the aim that ARIA is further characterized and that the risk of ARIA is well understood.

An archived version of the presentation is available on the investors section of Biogen's website at investors.biogen.com.

The long-term Phase 3 extension study was presented today at the International Conference on Alzheimer's and Parkinson's Diseases (AD/PD 2022), currently underway in Barcelona, Spain, and virtually from March 15-20.

These latest data are part of Biogen's ongoing commitment to generate additional clinical data to further characterize and understand aducanumab-avwa's profile and engage with the scientific community. Additional research data was presented at AD/PD, along with multiple presentations describing various aspects of aducanumab-avwa's clinical program.

About aducanumab-avwa 100 mg/mL injection for intravenous use

Aducanumab-avwa is indicated in the U.S. for the treatment of Alzheimer's disease. Treatment with aducanumab-avwa 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 aducanumab-avwa. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). Aducanumab-avwa is not approved in Sweden.

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 aducanumab-avwa has been granted based on data from clinical trials showing the effect of aducanumab-avwa on reducing amyloid beta plaques, a surrogate biomarker that is reasonably likely to predict clinical benefit, in this case a reduction in clinical decline.

Aducanumab-avwa 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 aducanumab-avwa to check for ARIA. Aducanumab-avwa can also cause serious allergic reactions. The most common side effects of aducanumab-avwa 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.

From 2017 to March 13, 2022, Biogen and Eisai jointly collaborated on the development and commercialization of aducanumab-avwa. Effective March 14, 2022, Biogen has sole decision-making authority over the development, commercialization and manufacturing of aducanumab-avwa. In 2022 the parties will continue in a global profit/loss sharing arrangement subject to a cap on Eisai's expenses for 2022. Eisai will be entitled to a tiered royalty on net sales of aducanumab-avwa as of January 1, 2023.

Please click here for full Prescribing Information, including Medication Guide, for aducanumab-avwa.

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 a 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 aducanumab-avwa; the potential benefits, safety and efficacy of aducanumab-avwa; the treatment of Alzheimer's disease; 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.

###

MEDIA CONTACT(S):

Biogen
Ashleigh Koss
+ 1 908 205 2572
public.affairs@biogen.com

INVESTOR CONTACT(S):

Biogen
Mike Hencke
+1 781 464 2442
IR@biogen.com

PRESSKONTAKT Biogen Sverige:
Gabriella Brunlid
+46 706 36 50 76
infosweden@biogen.com