Biogen and Eisai amend collaboration agreements on Alzheimer’s disease treatments

- Aducanumab collaboration to convert from Eisai sharing of global profits and losses to a global royalty arrangement, effective January 1, 2023.
- Lecanemab collaboration to continue unchanged globally
- Lecanemab supply agreement to extend to 10 years from 5 years for commercial manufacturing by Biogen
- Both companies will continue to collaborate together with the goal of bringing more options to patients and maximizing the value of both products

CAMBRIDGE, Mass., and TOKYO, March 14, 2022: Biogen Inc. (Nasdaq: BIB) and Eisai Co., Ltd. (Tokyo, Japan) announced today that the companies have amended their existing collaboration agreement on aducanumab, which is commercialized in the United States as ADUHELM® (aducanumab-avwa). Effective as of January 1, 2023, Eisai will receive a tiered royalty based on net sales of ADUHELM rather than sharing global profits and losses. The royalty rate starts at 2% and reaches 8% when annual sales exceed $1 billion. Effective immediately Biogen’s existing final decision-making rights on ADUHELM have converted to sole decision making and commercialization rights worldwide. Overall, economic arrangements for both companies in 2022 are expected to remain materially unchanged with Eisai’s share of expenses capped at an agreed amount for the costs related to development, commercialization and manufacturing of ADUHELM for the period from January 1, 2022, to December 31, 2022. Once the tiered royalty model commences on January 1, 2023, Eisai will not participate in ADUHELM’s economics beyond these royalties.

The companies will continue to jointly develop and commercialize the investigational therapy lecanemab. Eisai continues to serve as the lead of lecanemab development and regulatory submissions globally with both companies co-commercializing and co-promoting the product, and Eisai having final decision-making authority. Both companies share economics equally with Eisai booking all sales for lecanemab and Biogen reflecting its 50% share of profits and losses. The supply agreement related to lecanemab has been extended from five to 10 years. Biogen will manufacture the lecanemab drug substance in its Solothurn, Switzerland facility with the goal of providing reliable commercial supply worldwide.

“This amended collaboration agreement will increase operational efficiency and agility in addressing market developments, including the final determination of CMS on coverage of ADUHELM,” said Michel Vounatsos, Chief Executive Officer at Biogen. “In addition we are pleased to be expanding our agreement with Eisai through a new long-term manufacturing contract.”

“The collaboration between both companies has resulted in the approval of ADUHELM in the U.S. as the first treatment to address a defining pathology of Alzheimer’s disease, which is a significant step into a new chapter of Alzheimer’s therapy.” said Haruo Naito, Chief Executive Officer at Eisai Co., Ltd. “We believe this new arrangement will be more effective and enable more focused execution with the goal of maximizing the value of both ADUHELM and lecanemab. Eisai will increase its focus on lecanemab and remains committed to bringing a new treatment option expeditiously to patients in need worldwide.”
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.

About Eisai
Eisai Co., Ltd. is a leading global pharmaceutical company headquartered in Japan. Eisai’s corporate philosophy is based on the human health care (hhc) concept, which is to give first thought to patients and their families, and to increase the benefits that health care provides to them. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

Leveraging the experience gained from the development and marketing of a treatment for Alzheimer’s disease, Eisai aims to establish the “Eisai Dementia Platform.” Through this platform, Eisai plans to deliver novel benefits to those living with dementia and their families through constructing a “Dementia Ecosystem,” by collaborating with partners such as medical organizations, diagnostic development companies, research organizations, and bio-ventures in addition to private insurance agencies, finance industries, fitness clubs, automobile makers, retailers, and care facilities. For more information about Eisai Co., Ltd., please visit https://www.eisai.com.

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 ADUHELM and lecanemab; the potential benefits, safety and efficacy of ADUHELM and lecanemab; the treatment of Alzheimer’s disease; the anticipated benefits and potential of Biogen’s collaboration arrangements with Eisai; clinical development programs, the anticipated benefits and potential of Biogen’s manufacturing of lecanemab, 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.

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