



Press release

Modeling published in *Neurology and Therapy* suggests that lecanemab could delay progression to Alzheimer's dementia by several years

Stockholm, April 27, 2022 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that an article about long-term health outcomes of the investigational anti-amyloid-beta (A β) protofibril antibody lecanemab (BAN2401) in people living with early Alzheimer's disease (AD), using disease modeling, was published in the peer-reviewed journal *Neurology and Therapy*. In this simulation, lecanemab treatment is estimated to slow the rate of disease progression, maintaining treated patients for a longer duration in earlier stages of the disease.

The article focuses on the long-term clinical outcomes for people living with early AD (mild cognitive impairment (MCI) and mild AD) who have amyloid pathology, comparing lecanemab together with standard of care (SoC) versus SoC alone (acetylcholinesterase inhibitor or memantine). The simulation is based on patients being treated until they reach the moderate AD stage. The disease simulation model (AD ACE model¹) is based on the results of the Phase 2b clinical trial evaluating the efficacy and safety of lecanemab, and from ADNI (Alzheimer's Disease Neuroimaging Initiative) study results.

Lecanemab treatment was estimated to slow the rate of disease progression, resulting in an extended duration of MCI due to AD and mild AD dementia and shortened the duration in moderate and severe AD dementia. In the model the mean time advancing to mild, moderate, and severe AD dementia was longer for patients in the lecanemab-treated group than for patients in the SoC group by 2.51 years, 3.13 and 2.34, respectively. The model also predicted a lower life-time probability of admission to institutional care with lecanemab treatment.

"The results from the simulation done by Eisai demonstrate the potential clinical value of lecanemab for patients with early AD and how it could slow the rate of disease progression, delay progression to AD dementia with several years and reduce the need for institutionalized care. Analyses such as these are important to understand the potential long-term effects for patient, families and society offered by lecanemab treatment beyond what can be seen in clinical trials. The outcome of the Clarity AD Phase 3 study will be essential to further refining this model, and we are looking forward to the topline results later this year," said Gunilla Osswald, BioArctic's CEO.

Lecanemab was granted Breakthrough Therapy and Fast Track designations by the U.S. Food and Drug Administration (FDA) in June and December 2021, respectively. Eisai anticipates completing lecanemab's rolling submission of a Biologics License Application for the treatment of early AD to the FDA under the accelerated approval pathway in the second quarter 2022. Additionally, the readout of the Phase 3 confirmatory Clarity AD clinical trial is expected by end of September 2022. Eisai



initiated a submission to the Pharmaceuticals and Medical Devices Agency (PMDA) of application data of lecanemab under the prior assessment consultation system in Japan in March 2022.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.

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The information was released for public disclosure, through the agency of the contact persons above, on April 27, 2022, at 08:00 a.m. CET.

About lecanemab (BAN2401)

Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to, neutralize and eliminate soluble toxic A β aggregates (protofibrils) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab 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 lecanemab for the treatment of AD 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 lecanemab. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase 2b clinical study (Study 201). In addition, the Phase 3 clinical study, AHEAD 3-45, for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of brain amyloid, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, part of the National Institutes of Health, and Eisai. In 2021, DIAN-TU selected lecanemab for a clinical trial for dominantly inherited Alzheimer's disease as a background anti-amyloid treatment when exploring combination therapies with anti tau treatments in dominantly inherited Alzheimer's disease subjects. In June 2021, FDA granted lecanemab Breakthrough Therapy designation and in September 2021, Eisai initiated a rolling submission for the US FDA Biologics license application of lecanemab for early Alzheimer's disease under the accelerated approval pathway. In December 2021, FDA granted lecanemab Fast track designation and the second part of the rolling application was submitted. Eisai expects the rolling submission to be completed during the second quarter 2022.

About the collaboration between BioArctic and Eisai

Since 2005, BioArctic has long-term collaboration with Eisai regarding the development and commercialization of drugs for the treatment of Alzheimer's disease. The most important agreements are the Development and Commercialization Agreement for the lecanemab antibody, which was signed in December 2007, and the Development and Commercialization agreement for the antibody BAN2401 back-up for Alzheimer's disease,



which was signed in May 2015. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for Alzheimer's disease. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory filings, approvals, and sales milestones as well as royalties on global sales.

About BioArctic AB

BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on innovative research from Uppsala University, Sweden. Collaborations with universities are of great importance to the company together with its strategically important global partner Eisai in Alzheimer disease. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. BioArctic's Class B share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.

ⁱ Kansal AR, Tafazzoli A, Ishak KJ, Krotneva S. Alzheimer's disease Archimedes condition-event simulator: Development and validation. *Alzheimers Dement* (NY). 2018;4:76-88. Published 2018 Feb 16. doi:10.1016/j.trci.2018.01.001

Tafazzoli and Kansal. Disease simulation in drug development, External validation confirms benefit in decision making. *The Evidence Forum*. 2018.

https://www.evidera.com/wp-content/uploads/2018/10/07-Disease-Simulation-in-Drug-Development_Fall2018.pdf