Press release

Interim Report for the period July – September 2021

Eisai initiates Biologics License Application of lecanemab in the US earlier than expected

Events during the third quarter 2021

- Eisai has initiated a rolling submission for the US FDA Biologics License Application of lecanemab, under the
- accelerated approval pathway. The objective is for lecanemab to be approved for the treatment of patients with early Alzheimer's disease.
- Data from the Phase 2b open-label extension study of lecanemab presented at the Alzheimer's Association International Conference provided further support for the clinical effects of the drug candidate. The baseline characteristics for the Clarity AD and AHEAD 3-45 Phase 3 studies were also presented, as well as the possibility of using specific blood biomarkers to monitor the effects of the drug in individual patients.

Financial summary July – September 2021

- Net revenues for the period amounted to MSEK 4.0 (10.5)
- Operating profit amounted to MSEK -37.4 (-20.7)
- Profit for the period amounted to MSEK -37.6 (-20.7) and earnings per share before and after dilution were SEK -0.43 (-0.23)
- Cash flow from operating activities amounted to MSEK -34.8 (-9.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 892 (1,036)

Financial summary January – September 2021

- Net revenues for the period amounted to MSEK 18.4 (54.0)
- Operating profit amounted to MSEK -100.4 (-54.9)
- Profit for the period amounted to MSEK -100.8 (-55.3) and earnings per share before and after dilution were SEK -1.15 (-0.63)
- Cash flow from operating activities amounted to MSEK -101.2 (-65.6)
- Cash and cash equivalents at the end of the period amounted to MSEK 892 (1,036)

Comments from the CEO

"The FDA review of lecanemab for a potential approval is a milestone in the history of BioArctic – and it is only the beginning."

On September 28, we received very positive news from our partner Eisai. After dialogue with the US Food and Drug Administration, Eisai has now initiated an application for market approval of lecanemab – significantly earlier than expected. This follows the FDA granting lecanemab a breakthrough therapy designation this past summer. On this

basis, Eisai and the FDA have now reached an agreement on a time-efficient regulatory process of lecanemab. The solution was a combination of the two regulatory tracks: the Accelerated Approval Program and Rolling Review.

The accelerated approval means that the FDA will decide on a potential approval based on the clinical, biomarker, and safety data that is already available, primarily based on the comprehensive Phase 2b study in 856 patients that was concluded in the summer of 2018. Data from the ongoing open-label Phase 2b extension study and blinded safety data from the ongoing Clarity AD Phase 3 study will also be included in the application documentation. In other words, the FDA does not need the clinical efficacy results from Clarity AD for accelerated approval, but the results can serve as the confirmatory study to verify the clinical benefit of lecanemab. The rolling review in turn means that Eisai will submit completed sections of the application on a step-by-step basis, which can be reviewed on a rolling basis by the FDA. Once all documentation has been submitted, the final review of the application for accelerated market approval in the US will commence. The results of the Clarity AD Phase 3 study are expected in September 2022, after which Eisai can initiate the application for full approval. If Clarity AD confirms the results from the Phase 2b study, our drug candidate will have the possibility of becoming the first disease-modifying treatment of early Alzheimer's disease that receives full approval in the US. It is exciting that this Swedish discovery, after decades of research, in the not-too-distant future, could reach patients and be one of the first disease-modifying treatment of Alzheimer's disease.

Under the agreement with Eisai, BioArctic has certain rights to market and sell lecanemab in the Nordic region. Naturally this requires European market approval, which is a process that will come a bit after the one in the US. BioArctic has already begun the build-up of a Nordic market organization in order to prepare for a potential launch. The introduction of new drugs requires careful preparation in order to provide the right patients access to treatment, and we are pleased that Anna-Kaija Grönblad, who previously was General Manager of Sanofi in Sweden, has now taken the position of Chief Commercial Officer to lead these efforts. Our confidence in lecanemab is the driving force in this initiative, but we also see that our other drug projects could benefit in future from the establishment of a market organization in the Nordic region. It is very satisfying that we now, based on our positive development, are taking the next step and switching into a higher gear from our position as a research and development company to also becoming a company that is ready to help patients and healthcare through the introduction of new drug treatments.

During the quarter, we also saw promising data for ABBV-0805, our antibody against Parkinson's disease that has been outlicensed to AbbVie. In September, both BioArctic and AbbVie presented results, which support continued development of ABBV-0805, at the MDS conference. BioArctic's abstract, which among other things shows that ABBV-0805 is a very selective antibody that impacts the progression of the disease in preclinical models in a positive way, was selected as a Top Abstract presentation at the conference. AbbVie presented the results from a Phase 1 study of ABBV-0805 that showed a favorable pharmacokinetics and a good safety profile for the antibody. With the continued positive results presented for ABBV-0805, we look forward to the development of this potential disease-modifying treatment of Parkinson's disease.

In other words, BioArctic's research continues to be of great interest. The FDA review of lecanemab for a potential approval is an important milestone in the history of BioArctic – and it is only the beginning.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation
BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, October 21, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the interim report and answer questions.

Webcast: https://tv.streamfabriken.com/bioarctic-q3-2021

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The webcast will afterwards also be available on demand at BioArctic's corporate website **https://www.bioarctic.se/en/section/investors/presentations/**

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This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the Swedish Securities Market Act. The information was submitted for publication, though the agency of the named contact persons, at 08:00 a.m. CET on October 21, 2021.

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 partners in the Alzheimer (Eisai) and Parkinson (AbbVie) projects. 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.