Press release

Interim Report for the period April – June 2021

FDA grants Breakthrough Therapy designation for lecanemab

Events during the second quarter 2021

- The US Food and Drug Administration (FDA) granted Breakthrough Therapy designation for lecanemab in Alzheimer's disease, which is a program intended to facilitate and accelerate the development and review of drugs for serious or life-threatening conditions.

Financial summary April – June 2021

- Net revenues for the period amounted to MSEK 7.3 (7.0)
- Operating profit amounted to MSEK -33.8 (-37.9)
- Profit for the period amounted to MSEK -34.2 (-38.2) and earnings per share before and after dilution were SEK -0.39 (-0.43)
- Cash flow from operating activities amounted to MSEK -28.9 (-19.8)
- Cash and cash equivalents at the end of the period amounted to MSEK 929.6 (1,049.9)

Financial summary January – June 2021

- Net revenues for the period amounted to MSEK 14.5 (43.4)
- Operating profit amounted to MSEK -63.0 (-34.1)
- Profit for the period amounted to MSEK -63.3 (-34.7) and earnings per share before and after dilution were SEK -0.72 (-0.39)
- Cash flow from operating activities amounted to MSEK -66.4 (-56.1)
- Cash and cash equivalents at the end of the period amounted to MSEK 929.6 (1,049.9)

Comments from the CEO

"Society and healthcare have everything to gain from preparing for a paradigm shift."

This is a time of hope for the 30 million patients around the world – and their families – who are living with Alzheimer's disease. In the latest quarter, BioArctic and its industry colleagues from around the world have announced positive news, and developments in both diagnostics as well as treatment are proceeding rapidly. In the near future, early diagnosis using blood tests will be much easier thanks to new biomarkers. Later, when early diagnosis is paired with new disease-modifying treatments, the much-anticipated paradigm shift in the care of Alzheimer's patients can finally take place. In the US, the first antibody against amyloid beta, aducanumab, has obtained an accelerated approval with requirements from the FDA in early June. The decision was not based on clinical effect but on biomarkers that are reasonably likely to predict a clinical effect.

The pivotal Phase 3 study in early Alzheimer disease (Clarity AD) is now in progress with lecanemab, the antibody developed by BioArctic against amyloid beta, designed to demonstrate an effect on both biomarkers and symptoms of

the disease. The need for new treatments is enormous, and analyses of the findings from both our own and others' studies we see indications of lecanemab demonstrating a more rapid clinical effect on several relevant parameters and a better tolerability profile than other antibodies in late development. In March, our partner Eisai finished recruitment for Clarity AD and the readout of the primary endpoint is expected by the end of September 2022. However, the results of the Phase 2b study, which encompassed 856 patients with early Alzheimer's disease, provide evidence of effects on several clinical endpoints and biomarkers:

- *Phase 2 data demonstrated a rapid, dose-dependent, and robust decrease of amyloid plaques in the brain. After 18 months, more than 90 percent of the patients had decreased plaque levels corresponding to those seen in healthy individuals*
- *A positive impact on several other biomarkers in the brain was also noted, which indicates that the progress of the disease had been affected and that the improvements observed were due to lecanemab*
- *In addition to the positive biomarker findings, the study also demonstrated a rapid, dose-dependent clinical effect as measured by ADCOMS, ADAS-cog and CDR-Sum of Boxes*

Based on these results, the FDA granted lecanemab a Breakthrough Therapy designation in late June, which means that the agency can contribute to and accelerate the development and review of the drug candidate. This decision demonstrates the strength and potential in the data we and our partner have generated to date.

A further advantage for lecanemab is its tolerability profile. All other antibodies in late development must be administered to patients in gradually increasing doses owing to the risk of side effects, whereas the effective dose of lecanemab can be administered immediately. The side effect ARIA-E, a form of cerebral edema, under particular observation. Treatments with other antibodies in late development have in various studies shown ARIA-E in approximately 30 percent of patients treated, and approximately 5–10 percent of patients display symptoms despite carefully increased doses. Whereas in treatment with lecanemab we observed ARIA-E in less than 10 percent of patients and only approximately 1 percent developed symptoms.

If the Phase 2 results are confirmed in the ongoing Phase 3 study, we are convinced that lecanemab will be a major breakthrough in care for patients with Alzheimer's disease. This is only the beginning, however. More treatment options are needed. We will continue to dedicate ourselves to and focus on our research with our other antibody projects against Alzheimer's disease. Moreover, we have connected two of them – AD-BT2802 and AD-BT2803 – to our new Brain Transporter technology, which aims to facilitates transport across the blood-brain barrier. The difficulty in transporting antibodies across the blood-brain barrier has long held development back. The fact that we have now begun to find safe methods for circumventing this problem opens the way to a future with many effective therapies.

As stated, it is a time of hope. There are now selective antibodies as disease-modifying treatments and increasingly effective diagnoses using blood-biomarkers in late-stage development. Society and healthcare have everything to gain from preparing for a paradigm shift in the care of patients with Alzheimer's disease, and we are proud of the fact that our research is enabling this development.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation
BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, July 9, 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-q2-2021

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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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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.