Press release

Interim Report for the period April – June 2023

LEQEMBI® approved in the US – the world's first fully approved disease-modifying treatment for Alzheimer's disease

Events during the second quarter 2023

- The U.S. Food and Drug Administration's (FDA) Advisory Committee voted unanimously that the data from BioArctic's partner Eisai's Phase 3 Clarity AD clinical trial confirms the clinical benefit of LEQEMBI® (US brand name for lecanemab)
- Eisai submitted applications for marketing authorization for lecanemab in South Korea and Great Britain
- Health Canada initiated the review of New Drug Submission for lecanemab as treatment for early Alzheimer's disease

Events after the end of the period

- On July 6, the FDA granted traditional approval for LEQEMBI in the US for the treatment of Alzheimer's disease
- In conjunction with the approval the Centers for Medicare and Medicaid Services, CMS, announced that Medicare will provide broad coverage of LEQEMBI according to the FDA approved label provided that real-world evidence is collected in an existing and easy-to-use patient registry

Financial summary April – June 2023

- Net revenues for the period amounted to SEK 2.7 M (4.2)
- Operating loss amounted to SEK 100.9 M (45.8)
- Loss for the period amounted to SEK 102.3 M (45.8)
- Loss per share before and after dilution was SEK 1.16 (0.52)
- Cash flow from operating activities amounted to a negative SEK -63.8 M (neg. 45.6)
    - Cash and cash equivalents at the end of the period amounted to SEK 1,042 M (752)

Financial summary January – June 2023

- Net revenues for the period amounted to SEK 396.1 M (8.0)
- Operating profit amounted to SEK 199.7 M (loss: 90.0)
- Profit for the period amounted to SEK 191.5 M (loss: 90.1)
- Earnings per share was SEK 2.17 (loss: 1.02) before dilution and SEK 2.16 (loss: 1.02) after dilution
- Cash flow from operating activities amounted to SEK 235.2 M (neg. 85.3)
- Cash and cash equivalents at the end of the period amounted to SEK M 1,042 (752)

Comments from the CEO

"The full approval of LEQEMBI in the US, combined with the broad Medicare reimbursement, is a paradigm-shifting step in the fight against Alzheimer's disease. "

On July 6, a much anticipated decision was announced by the US Food and Drug Administration (FDA) that LEQEMBI, the US brand name for lecanemab, had been granted traditional approval for the treatment of Alzheimer's disease. LEQEMBI thereby became the first and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline in adults with Alzheimer's disease. This is a historic decision and we are delighted for all the patients who can now gain access to this treatment.

The decision was preceded by a meeting of the FDA's Advisory Committee that scrutinized and discussed lecanemab in detail. In addition to a review of all efficacy and safety data from the large global confirmatory Phase 3 clinical Clarity AD trial, the patient perspective was also highlighted. It was clear that both patients, relatives and

prescribing physicians appreciate that treatment can begin early and reduce progression already in the early phases of the disease. Lecanemab has demonstrated a slowing of clinical decline by 26–37 percent using various clinical scales compared to placebo. When assessing the health-related quality of life from a patient and family perspective, patients who were treated with lecanemab showed 38–56 precent less impairment after 18 months of treatment. This underlines the ability of lecanemab to help patients function independently longer, including being able to dress, feed themselves and participate in community activities.

During the Advisory Committee meeting, it was also emphasized that the Phase 3 study was conducted in a diversified patient population in terms of age, other medications, other concurrent diseases, race and ethnicity, which makes the results of the study relevant also in a clinical context. Also, the safety profile was discussed in detail, in particular ARIA, a class-related side effect. Following the review of all data, the FDA Advisory Committee unanimously confirmed that clinical benefit had been demonstrated for LEQEMBI.

In conjunction with the FDA approval, the Centers for Medicare and Medicaid Services, CMS, announced that Medicare will provide broad coverage of LEQEMBI according to the FDA approved label provided that real-world evidence is collected in an existing and easy-to-use patient registry This will facilitate reimbursement and access to LEQEMBI in the United States.

The full approval of LEQEMBI in the US, combined with the broad Medicare reimbursement, is a paradigm-shifting step in the fight against Alzheimer's disease. Doctors in the US will now have a tool to combat this terrible chronic disease already at an early stage, with the potential to provide clinically meaningful benefit for patients and their families. More than two decades of research and development has led up to this moment, and I am impressed by the diligent efforts of our partner Eisai to ensure that this important innovation can now reach the patients BioArctic was founded to serve.

Lecanemab and other drugs for slowing the decline of Alzheimer's disease entail a major transformation for the healthcare system and society as a whole. Eisai is now in close dialogue with healthcare providers and payors in the US to ensure a responsible introduction that balances the desire to offer the treatment to as many patients as possible as quickly as possible with the need for careful monitoring. Together with Eisai we are making similar preparations in the Nordic market to be ready if lecanemab is approved in Europe.

Next, Eisai is awaiting a decision from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in the fall, and decisions from the European and Chinese authorities are expected in the first quarter of 2024. During the quarter, Eisai also submitted marketing authorization applications in South Korea, the UK and Canada. In parallel, subcutaneous dosing is being evaluated in the Clarity AD open label extension study and Eisai has announced plans to submit a regulatory application in the US for the new formulation during the first quarter of 2024.

It is fantastic that BioArctic, a company founded on Swedish research, is behind a medical breakthrough of this magnitude. But BioArctic is more than lecanemab and our company stands strong with a broad and innovative project portfolio based on similar scientific principles as lecanemab. The launch of LEQEMBI in the US offers us and the entire Alzheimer field a strong tailwind that we are firmly committed to fully exploit when building a world-leading biopharma company in neurodegenerative diseases.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation
BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, July 12, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Anders Martin-Löf will present BioArctic, comment on the interim report and answer questions.

If you wish to participate via webcast, please use the link below. Via the webcast you are able to ask written questions.
Webcast: https://ir.financialhearings.com/bioarctic-q2-2023/register

If you wish to participate via teleconference, please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference.
https://conference.financialhearings.com/teleconference/?id=200811

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

For more information, please contact
Anders Martin-Löf, CFO, anders.martin.lof@bioarctic.se, phone + 46 70-683 79 77
Oskar Bosson, VP Communications & Investor Relations, oskar.bosson@bioarctic.se, phone +46 70 410 71 80

The interim report is such information as BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on July 12, 2023.

About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments for neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and ALS. 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 Large Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.