



## Press release

### Interim Report for the period July – September 2023

#### LEQEMBI launched in the US

##### Events during the third quarter 2023

- In July, the FDA approved LEQEMBI® for the treatment of Alzheimer's disease in the US and the Centers for Medicare and Medicaid Services, CMS, announced that LEQEMBI will be reimbursed according to the FDA approved label
- In September, LEQEMBI was approved for the treatment of Alzheimer's disease in Japan, which entitled BioArctic to a milestone payment of EUR 17 M, equivalent to SEK 201.0 M
- The board has decided to initiate a Phase 2a study of exidavnebab (BAN0805) in Parkinson's disease. The study is expected to start in the second half of 2024

##### Events after the end of the period

- Data presented at the CTAD congress further support LEQEMBI, among other things showing that subcutaneous treatment with LEQEMBI leads to a greater reduction of amyloid plaques than the intravenous treatment
- BioArctic and Eisai have agreed on commercialization and co-promotion for the Nordic countries
- Eisai aims to have 10,000 patients on treatment at the end of March 2024, and to achieve 10 billion yen (M ~700 SEK) level revenue from LEQEMBI in their fiscal year 2023 ending March 2024

##### Financial summary July – September 2023

- Net revenues for the period amounted to SEK 208.8 M (218.2)
- Operating profit amounted to SEK 131.0 M (132.4)
- Profit for the period amounted to SEK 124.9 M (136.8)
- Earnings per share before dilution was SEK 1.42 (1.55) and after dilution SEK 1.41 (1.54)
- Cash flow from operating activities amounted to a negative SEK -52.9 M (111.8)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 998 M (863)

##### Financial summary January – September 2023

- Net revenues for the period amounted to SEK 605.0 M (226.2)
- Operating profit amounted to SEK 330.7 M (43.2)
- Profit for the period amounted to SEK 316.5 M (46.7)
- Earnings per share was SEK 3.59 (0.53) before dilution and SEK 3.58 (0.53) after dilution
- Cash flow from operating activities amounted to SEK 182.3 M (26.6)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 998 M (863)

#### Comments from the CEO

*"During the quarter, BioArctic's Board of Directors decided that the company would conduct a Phase 2a trial with our drug candidate exidavnebab for Parkinson's disease."*

Since July 6, lecanemab has been fully approved in the US, reimbursed by Medicare and sold under the brand name Leqembi. Following the approval, our partner Eisai intensified its efforts to ensure that our patients will have access to treatment as soon as possible. This is an effort that requires great patience. Since Leqembi is the first fully approved disease-modifying treatment for Alzheimer's disease, there are many parts of the medical treatment process that need to be reviewed and adjusted. Eisai is very pleased with developments so far, as are we. 60% of the top 100 Integrated Delivery Networks (IDN) in the U.S. have now approved LEQEMBI, and more

than 2,500 neurologists or other Alzheimer disease (AD) specialists are ready to diagnose, treat and monitor patients. Eisai estimates that 800 patients were on treatment towards the end of October and have reiterated their aim that the number of patients will reach 10,000 by the end of March 2024. In addition, Eisai aims to achieve 10 billion yen (M ~700 SEK) level revenue from LEQEMBI in their fiscal year 2023, ending March 2024, of which BioArctic has right to high single digit royalty. Royalty for the third quarter was SEK 2.5 M.

In September, lecanemab was approved in Japan. The efforts on price and subsidization are in progress, and we look forward to launch in Japan as well shortly. In conjunction with Japanese approval, BioArctic received a milestone payment of MEUR 17. The approval shows, once again, that Eisai has been working diligently to ensure that this treatment reaches patients around the world. Applications for approval have been submitted in EU, China, Canada, Great Britain, Australia, Switzerland, South Korea, Israel, Singapore, Taiwan, Brazil and Hong Kong.

Moreover, we have come to an agreement with Eisai on how we are to collaborate to commercialize and market lecanemab in the Nordic region. We have already been working together on preparations, and these efforts will intensify upon approval in the EU, which Eisai expects to happen in the first quarter of 2024.

In parallel with the market introductions, Eisai continues to present new data for lecanemab. During the Clinical Trials on Alzheimer's Disease conference (CTAD), which was held in Boston in late October, Eisai presented further results that, gratifyingly enough, showed that treatment with the subcutaneous (SC) formulation of lecanemab – which is under development – appears to be a potentially excellent alternative to intravenous (IV) treatment. The data showed that SC resulted in a greater amyloid plaque removal compared with IV, a better side-effect profile as regards infusion reaction rates and ARIA similar to IV. Eisai intends to submit an application for market approval in the US for the subcutaneous formulation by the end of March next year. Furthermore, data was presented indicating that patients could have even better efficacy if treatment is begun early in the progression of the disease before any greater tau pathology has built up in the brain, as well as data showing that

treatment after the 18 months of the Phase 3 study continued to have an effect. Professor Lars Lannfelt also held an oral presentation on how the binding profile for lecanemab could explain why it shows a significantly lower frequency of the ARIA-E side effect compared with other antibodies.

During the quarter, BioArctic's Board of Directors decided that the company will conduct a Phase 2a study with our drug candidate exidavnemab (BAN0805) for Parkinson's disease. For some time, intensive efforts have been underway to transfer all data generated by our former partner, AbbVie, analyze it, write a final report for the Phase 1 study and prepare production of new drug products ahead of continued clinical studies. We expect to initiate the Phase 2 study in the second half of 2024. Expanded patient protection for exidavnemab was granted in Japan in August, which means that we now have a very long patent both there and in the US until 2046, including patent extension.

Exidavnemab, like our other antibodies against proteins in the progression of Alzheimer's disease, ALS and Parkinson's disease, is grounded in our unique competence in developing highly specific and selective antibodies against pathological misfolded proteins that generate diseases in the central nervous system. All projects – as well as our BrainTransporter technology – are continuing to perform well. Our conviction that the BrainTransporter technology will work was further strengthened after positive clinical data for a similar technology was presented at CTAD. It is a sign of BioArctic's strength that, owing to our successes with lecanemab, we can continue to develop our project portfolio with a high degree of scientific quality and at a high tempo.

We are experiencing a paradigm shift in the treatment of Alzheimers disease. I am extremely proud of the fact that the world's first fully approved disease-modifying drug originates from BioArctic's research. It is highly gratifying that we can now help patients, their families and society as a whole.

*Gunilla Osswald*  
*CEO, BioArctic AB*

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**Invitation to presentation**

BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, November 8, 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-q3-report-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=5009576>

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**

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*The interim report is such information as BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on November 8, 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](http://www.bioarctic.com).