



## Press release

### Interim Report for the period October – December 2023

#### Leqembi launched in Japan and approved in China

##### Events during the fourth quarter 2023

- Leqembi was launched in Japan on December 20 which meant that the country was the second market in the world after the USA where the drug is available
- Data presented at the CTAD congress further supported Leqembi's disease modifying characteristics and safety profile as well as the subcutaneous formulation
- BioArctic and Eisai have agreed on commercialization and co-promotion for the Nordic countries

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

- The European Medicines Agency (EMA) announced that its Scientific Advisory Group will convene to discuss the Marketing Authorisation Application of lecanemab. The meeting is expected to take place in the first quarter of 2024
- Leqembi was approved for the treatment of Alzheimer's disease in China – launch expected in the third quarter of 2024
- The Board adopted a new dividend policy and proposed that no dividend is to be paid for the fiscal year 2023

##### Financial summary October – December 2023

- Net revenues for the period amounted to SEK 11.0 M (2.1)
- Operating profit amounted to SEK -78.1 M (-59.8)
- Profit for the period amounted to SEK -87.2 M (-57.9)
- Earnings per share before and after dilution was SEK -0.99 (-0.66)
- Cash flow from operating activities amounted to a negative SEK 116.8 M (-58.2)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 1 112 M (805)

##### Financial summary January – December 2023

- Net revenues for the period amounted to SEK 616.0 M (228.3)
- Operating profit amounted to SEK 252.6 M (-17.3)
- Profit for the period amounted to SEK 229.2 M (-11.2)
- Earnings per share was SEK 2.60 (-0.13) before dilution and SEK 2.59 (-0.13) after dilution
- Cash flow from operating activities amounted to SEK 299.0 M (-31.6)
- Cash and cash equivalents and short-term investments at the end of the period amounted to SEK 1 112 M (805)

#### Comments from the CEO

*"We are now looking forward to regulatory market approval decisions in 14 additional countries and regions – in particular the UK, Canada and the EU."*

We can look back on yet another successful year for BioArctic and are proud to see that our groundbreaking research has now led to a treatment that slows the disease progression and improves the lives for an increasing number of patients with early Alzheimer's disease. Since Leqembi received full approval in the US in July 2023, the drug has also been approved in Japan and China. The launch in Japan commenced in late December. Patient interest in Japan is significant, and 100 patients were already on treatment by the end of January. Eisai's expectation is to reach 7,000 patients in Japan by end of March 2025. In China the launch is planned for the third quarter of 2024. We are now looking forward to regulatory market approval decisions in 14 additional countries

and regions – in particular the UK, Canada and the EU, while our partner Eisai is preparing more applications in other parts of the world.

Maximizing the benefit that Leqembi can offer patients and their families requires in-depth knowledge of the drug in the health care setting, as well as establishment of new infrastructure and a transformed patient journey. All of this takes time, and use of the drug will therefore grow gradually but at an increasingly rapid pace. In the fourth quarter, Eisai reported sales of JPY 1.1 billion, which resulted in royalty income of SEK 7.3 M for BioArctic. In the US, a greater number of hospitals have begun dosing patients, and a clear difference in uptake has been noted after diagnosis with PET was granted expanded reimbursement in mid-October. According to Eisai, approximately 2,000 had been treated at the end of January, and around four times as many were waiting to begin treatment. Eisai continues to actively engage in training health care practitioners, and about 4,000 specialist physicians are now ready to prescribe Leqembi. Furthermore, Eisai's partner Biogen recently announced that they will now realign resources to advance Leqembi. This will add more resources to the Eisai led US sales force going forward. We are still in the early stages of the Leqembi launch, and with the potential addition of new ways to diagnose, subcutaneous administration and maintenance dosing, this drug will continue to grow and could, according to Eisai, serve approximately 100,000 patients as early as 2026.

In addition to ensuring that Leqembi is becoming available to greater numbers of patients, Eisai is continuing to compile new clinical data for purposes that include evaluating lecanemab as a maintenance treatment and as a subcutaneous treatment with an autoinjector. New data is continuously presented at international scientific congresses, most recently at the CTAD Alzheimer's congress in Boston in October, at which Eisai showed six-month data with the subcutaneous formulation that resulted in an even greater amyloid plaque reduction, fewer infusion reactions and no increase in the incidence of ARIA compared with intravenous treatment. The AD/PD™ conference in Lisbon in March now awaits, where both we and Eisai will present new data.

The success with Leqembi has given us the strength to further intensify our efforts to develop more groundbreaking treatments for neurodegenerative diseases. In the past quarter, we nominated two drug candidates – an important step in the process of preclinical development, which signals the scientific viability of the projects. Both drug candidates, BAN2802 and BAN2803, utilize BioArctic's Brain Transporter technology and are being developed as disease-modifying treatments for Alzheimer's disease. Activity levels in our other projects are high as well, especially as regards exidavnemab, our drug candidate for Parkinson's disease. The project is expected to go into clinical Phase 2 later this year. At the same time, Eisai is preparing regulatory applications for the use of Leqembi as a maintenance treatment of Alzheimer's disease, and for the subcutaneous drug formulation that would simplify treatment for the patients and their families.

Along with Eisai, we can take pleasure in several prestigious awards including the prizes for Best New Drug and Clinical Advance of the Year from Scrip, the leading international industry periodical. TIME magazine recognized Leqembi as well, naming it one of the year's best innovations in the category of medical care. Our co-founder, professor Lars Lannfelt, was awarded the Forska!Sverige research award and I was named Public CEO of the Year within Life Science in Europe at the European Lifestars Awards in London. The increased international interest in BioArctic was reflected in the fact that two renowned banks, Goldman Sachs and Kempen, initiated coverage of our share.

Our value-driven leadership is a key component of BioArctic's positive performance. We are extremely proud of the outcome in our quarterly employee evaluations of our corporate culture, which continuously give us world-class ratings. I feel these results are particularly gratifying, considering that the organization is in a phase of robust growth.

For us the story of Leqembi is just beginning, and we are looking forward to continuing our efforts to improve the lives of millions of patients and their families around the world our, in close collaboration with our partners.

*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, February 14, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Anders Martin-Löf will present BioArctic, comment on the full year 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-q4-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=5004790>

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](mailto:anders.martin.lof@bioarctic.se), phone + 46 70-683 79 77

Oskar Bosson, VP Communications & Investor Relations, [oskar.bosson@bioarctic.se](mailto: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. The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on February 14, 2024.*

**About BioArctic AB**

BioArctic AB (publ) is a Swedish research-based biopharma company focusing on treatments that can delay or stop the progression of neurodegenerative diseases. The company invented Leqembi® (lecanemab) – the world's first drug proven to slow the progression of the disease and reduce cognitive impairment in early Alzheimer's disease. Leqembi has been developed together with BioArctic's partner Eisai, who are responsible for regulatory interactions and commercialization globally. In addition to Leqembi, BioArctic has a broad research portfolio with antibodies against Parkinson's disease and ALS as well as additional projects against Alzheimer's disease. Several of the projects utilize the company's proprietary BrainTransporter™ technology, which has the potential to actively transport antibodies across the blood-brain barrier to enhance the efficacy of the treatment. BioArctic's B share (BIOA B) is listed on Nasdaq Stockholm Large Cap. For further information, please visit [www.bioarctic.se](http://www.bioarctic.se).