Press release

BioArctic to initiate next cohorts in exidavnemab Phase 2a study after positive safety review

Stockholm, June 13, 2025 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the interim safety review of the clinical Phase 2a study EXIST showed exidavnemab to be safe and well-tolerated, whereby the second dose cohorts will now be initiated. The EXIST study evaluates exidavnemab, a drug candidate being developed as a treatment for Parkinson's disease and Multiple System Atrophy (MSA).

The first cohort in the ongoing clinical Phase 2a study EXIST evaluated a lower dose of exidavnemab compared to placebo in patients with Parkinson's disease. An interim safety review showed that exidavnemab was safe and well tolerated. The positive outcome will result in the initiation of two further cohorts, to evaluate a higher dose of exidavnemab in comparison with placebo in patients with Parkinson's disease as well as MSA.

"Exidavnemab is BioArctic's second disease modifying treatment for severe brain diseases, building on a similar scientific approach as Leqembi®. Both originate from our antibody platform, selectively targeting aggregated, toxic misfolded proteins. I am pleased that the interim safety review of our phase 2a study EXIST of exidavnemab showed a good safety and tolerability profile as expected, supporting progression into higher doses in both Parkinson's disease and MSA," says Gunilla Osswald, CEO at BioArctic.

The Phase 2a study EXIST (EXIdavnemab Synucleinopathy Trial), is a randomized, double-blinded, placebo-controlled study to evaluate the safety and tolerability of exidavnemab and its pharmacokinetic profile. In addition, a broad range of biomarkers will be evaluated in plasma, cerebrospinal fluid (CSF), and using digital measurements.

Exidavnemab is being developed as a novel disease-modifying treatment for synucleinopathies such as Parkinson's disease and MSA. Exidavnemab is a monoclonal antibody (mAb) that selectively targets pathological alpha-synuclein aggregates, while sparing the physiological forms. Aggregated alpha-synuclein damages nerve cells, and by selectively binding and removing these aggregates, exidavnemab is intended to preserve nerve cell function and slow the disease.

There is a large unmet medical need for slowing disease progression in diseases such as Parkinson's disease and MSA. Exidavnemab has recently been granted orphan drug designation (ODD) in the US and a positive opinion regarding orphan medicinal product designation (OD) in the EU for the treatment of MSA.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that such investigational agents will successfully complete clinical development or gain health authority approval.

This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact person below, on June 13, 2025, at 08:00 CET.

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About Exidavnemab
Exidavnemab is a monoclonal antibody drug candidate that is designed to selectively target and eliminate pathological alpha-synuclein aggregates, while sparing the physiological forms. Aggregates of alpha-synuclein participate in neurodegenerative disorders including Parkinson's disease and Multiple System Atrophy (MSA). The goal is to develop a disease modifying treatment that stops or slow down the progression of alpha-synucleinopathies e.g. Parkinson's disease and MSA. BioArctic's phase 2a study EXIST with exidavnemab is ongoing since 2024. EXIST is an important step towards a proof-of-concept study focusing on the efficacy of the drug candidate.

Exidavnemab has been granted orphan drug designation (ODD) in the US and a positive opinion regarding orphan medicinal product designation (OD) in the EU for the treatment of Multiple System Atrophy (MSA).

About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on innovative treatments that can delay or stop the progression of neurodegenerative diseases. The company is the originator of 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 Eisai. BioArctic has a broad research portfolio within Alzheimer's disease, Parkinson's disease, ALS and enzyme deficiency diseases. Several of the projects utilize the company's proprietary BrainTransporter™ technology, which improves the transport of drugs into the brain. BioArctic's B share (BIOA B) is listed on Nasdaq Stockholm Large Cap. For more information, please visit www.bioarctic.com.