Press release

Exidavnemab Phase 2a study successfully concluded – preparing for Phase 2b

Stockholm, Sweden, November 23, 2026 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced topline results from the completed Phase 2a EXIST study evaluating exidavnemab in patients with Parkinson's disease (PD) and multiple system atrophy (MSA). In the study, exidavnemab was well tolerated and showed a favorable safety profile across all dose groups and patient populations studied.

Exidavnemab is a monoclonal antibody that selectively targets aggregated pathological forms of α-synuclein, while sparing the physiological forms i.e. the monomers. Aggregation of pathological α-synuclein is increasingly recognized as a defining characteristic of several progressive neurodegenerative diseases, including PD and MSA.

The randomized, double-blind, placebo-controlled Phase 2a EXIST study was designed primarily to evaluate the safety, tolerability and pharmacokinetics (how the body processes the drug) of repeated dosing of exidavnemab. In total, 38 participants were randomly assigned in a 2:1 ratio to receive exidavnemab or placebo. Following an interim safety review of 13 participants in the first cohort, where a lower dose was evaluated, 13 additional participants with PD and 12 with MSA were enrolled in the higher-dose cohorts.

Exidavnemab exhibited a favorable pharmacokinetic profile with a half-life in serum of approximately 32 days. The incidence of anti-drug antibodies was negligible. The ratio between cerebrospinal fluid and serum exposure was 0.4% in both PD and MSA participants, indicating a higher brain exposure than is normally seen with antibody therapies.

The pharmacokinetic profile, in conjunction with exidavnemab's high affinity and selectivity for pathological aggregated forms of alpha-synuclein, support the potential for the doses evaluated in EXIST to attain a sustained target engagement to alpha-synuclein.

No serious adverse events (SAEs) related to treatment were reported and no adverse events related to infusion-site reactions or to allergic reactions associated with administration of the study drug were reported. The most frequently reported adverse events after randomization to exidavnemab, which all were reported twice, were gastroesophageal reflux disease, headache and constipation.

"The interim safety review last year gave us the confidence to progress EXIST into the higher-dose cohorts, and we are very pleased that the completed study now confirms the safety and tolerability of exidavnemab in the studied populations. Particularly encouraging is that no infusion-site-related adverse events or allergic reactions associated with study treatment administration were reported at either of the doses tested," said Gabrielle Åhlberg Hillert, Chief Medical Officer at BioArctic.

"These results provide important support for the continued development of exidavnemab, and we look forward to initiating two Phase 2b studies during the first half of 2027, one in Mild Cognitive Impairment (MCI) or mild dementia due to Parkinson's disease or Dementia with Lewy Bodies, and one in Multiple System Atrophy," said Johanna Fälting, Chief R&D Officer at BioArctic.

BioArctic is planning to present more data from the EXIST study at an upcoming scientific conference.

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.

The information was released for public disclosure, through the agency of the contact person below, on November 23, 2026, at 08:00 am CET.

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About Exidavnemab
Exidavnemab (BAN0805) 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 slows the progression of alpha-synucleinopathies e.g. Parkinson's disease and MSA. 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 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 therapies 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.com.