



Press release

BioArctic: U.S. Food and Drug Administration Approves Investigational New Drug Application for ABBV-0805

- ABBV-0805 is being evaluated as a potential disease modifying treatment for Parkinson's Disease

Stockholm, Sweden, February 11, 2019 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that AbbVie has received approval from the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for ABBV-0805. This is a requirement to start clinical trials in the U.S.

ABBV-0805, previously named BAN0805, is the most advanced within the portfolio of alpha-synuclein targeting antibodies in-licensed by AbbVie from BioArctic in December 2018. The antibody is being evaluated as a disease modifying treatment for Parkinson's disease. The first clinical study is planned to start in 2019.

ABBV-0805 is a result of a strategic research alliance between BioArctic and AbbVie focused on the development of a potential immunotherapy for Parkinson's disease. AbbVie is responsible for the clinical development of ABBV-0805.

Parkinson's disease is the second most common neurodegenerative disease in the world and is expected to grow from approximately 6.2 million patients to 12.9 million by 2040¹. Mutations in the alpha-synuclein gene are strongly linked to the development of Parkinson's disease in a small number of patients with an inherited form of the disease. Alpha-synuclein accumulation in the form of toxic aggregates and intracellular deposits (Lewy bodies) is a key neuropathological feature of the more common sporadic Parkinson's disease.

"I am very pleased that AbbVie has received FDA approval of the IND for ABBV-0805. I see this as a result of the successful partnership and an acknowledgement of the high-quality deliveries from BioArctic. Our aim is that ABBV-0805 can continue to develop into a therapy with the potential to provide meaning advances for patients with Parkinson's disease," said Gunilla Osswald, Ph.D., CEO, BioArctic.



For more information, please contact:

Gunilla Osswald, PhD, CEO, BioArctic AB

E-mail: gunilla.osswald@bioarctic.se

Telephone: + 46 8 695 69 30

Christina Astrén, IR & Communications Director, BioArctic AB

E-mail: christina.astren@bioarctic.se

Telephone: + 46 70 835 43 36

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 persons above, at 05.00 p.m. CET on February 11, 2019.

Notes to editors

About Parkinson's disease

Parkinson's disease is a progressive disease of the nervous system that is associated with reduced levels of dopamine in the brain. Tremor and movement disturbances are the pathological hallmarks of the disease, but it is also characterized by dementia, depression, sleep disturbance and other symptoms. As the second most common neurodegenerative disease, after Alzheimer's disease, Parkinson's disease affects a large number of individuals and their families. Many who fall ill are still at working age resulting in considerable financial consequences for the individual and society. Patients with Parkinson's disease suffer from an extensive loss of nerve cells in a part of the brain associated with movement. These nerve cells contain the so-called Lewy bodies consisting of aggregated misfolded alpha-synuclein that are associated with cell loss. Alpha-synuclein aggregates can also be released from the cells and travel to neighboring cells, whereby the disease is spread from one area of the brain to another. Research has shown that mutations in the alpha-synuclein gene lead to Parkinson's disease.

- 1) Dorsey and Bloem, JAMA Neurology 2018;75:9-10

About BioArctic AB

BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. The company also develops a potential treatment for Complete Spinal Cord Injury. 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 our strategically important global partners in the Alzheimer (Eisai) and Parkinson



(AbbVie) projects. 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 B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

For more information about BioArctic, please visit www.bioarctic.com.