**Press release**

# BioArctic announces results from interim analysis of the Phase 1/2 study of SC0806 in patients with complete spinal cord injury

**Stockholm, Sweden, November 18, 2019 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today the results of an interim analysis of a Phase 1/2 study of SC0806 in patients with complete spinal cord injury. In this analysis, none of the patients showed an effect as measured by electrical impulses passing through the injured area after treatment. Electrical impulse passage is considered a prerequisite to restore motor function. This means that the study did not meet the primary efficacy endpoint. In addition, the results did not show convincing efficacy on secondary endpoints regarding motor function, other functions or quality of life. Based on these results BioArctic has decided to stop the inclusion of patients in the ongoing Phase 1/2 study. The company has also decided not to further develop the complete spinal cord injury project after the final patient has completed the training program. These decisions do not impact BioArctic's research and development of novel drugs targeting Alzheimer's, Parkinson's and other diseases in the central nervous system.**

BioArctic's treatment concept, SC0806, is a biodegradable medical device surgically implanted into the injured spinal cord with the goal to restore function. The implant contains the growth factor FGF1 and is designed to support nerve regeneration. The channels in the implanted device guide nerve fibers across the injured area in the spinal cord. Preclinical studies with SC0806 showed nerve regeneration, restored electrophysiology and improved motor function. These groundbreaking preclinical results were the basis for the decision by the company to start a clinical Phase 1/2 study of SC0806 in patients with complete spinal cord injury.

The Phase 1/2 study was designed to include three panels with nine patients in each, with six patients receiving SC0806 and three control patients. Patients treated with SC0806 received the implant through a surgical procedure followed by at least 18 months of intensive training in a robotic system to support nerve regeneration and rebuilding of muscle affected by the paralysis. Control patients received training only. Safety and tolerability of the treatment have been measured in the study. The primary efficacy endpoint is measured by MEP (Motor Evoked Potential) that shows the occurrence of electrical impulses passing through the injured area. Secondary efficacy endpoints include sensory and motor function as measured by AIS (American Spinal Injury Association Impairment Scale), other physical function measures and a number of clinician and self-assessed parameters.

After a favorable safety assessment of the first panel, a pre-specified interim analysis of the efficacy and safety has been made, evaluating the first nine patients who completed the 18 months rehabilitation. Electrical impulses passing the injured area (MEP) were not detected in any patient, which is considered a prerequisite to restore motor function. In addition, there was no improvement in sensory or motor function as measured by AIS. Results from the self-assessment questionnaires showed that there was a tendency to some temporary improvements in pain in patients treated with SC0806. There were no consistent benefits shown by other measurements. The treatment and surgical method showed an acceptable safety profile in the study.

Based on these results BioArctic has decided to terminate the ongoing Phase 1/2 study of SC0806 and no more patients will be included in the study. The patient that has had a surgical procedure in the second panel of the study will be allowed to complete the 18 months training program.

”Groundbreaking research at Karolinska Institutet and Karolinska University Hospital has led to the first attempt in the world to try a wholly new treatment concept in complete spinal cord injury. Despite some positive effects, none of the patients have regained their sensory or motor function. I want to thank all of the patients and personnel participating in the study for their commitment that made this study of growth factor and nerve implantation possible. We will continue to analyse and evaluate which learnings will be of use for further research in the future”, comments Professor Mikael Svensson, Principal Investigator for the clinical study with SC0806.

BioArctic has also decided that the whole SC0806 project will be terminated after the last patient has completed the training program. The company will continue to focus on the core business of research and development of novel drugs targeting Alzheimer’s, Parkinson’s and other diseases of the central nervous system.

“Although it is disheartening that the SC0806 treatment did not have a similar effect to that indicated by preclinical studies, the study has contributed to increased knowledge about patients with spinal cord injuries. We will close the study in a controlled and responsible manner and ensure that valuable knowledge gathered is made accessible to researchers globally”, comments Gunilla Osswald, CEO, BioArctic.

The study results are planned to be submitted for publication in a scientific journal at a later date.

The Phase 1/2 clinical study has received funding from the European Union's Horizon2020 Research and Innovation Program under Grant Agreement No. 643853.

**For further information, please contact:**
Gunilla Osswald, CEO, BioArctic AB
E-mail: **gunilla.osswald@bioarctic.se**
Phone: +46 8 695 69 30

*This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons above, at 10:30 PM CET on November 18, 2019*

**About Spinal Cord Injuries**
Spinal cord injuries are mainly caused by traumatic events resulting in partial or complete paralysis. After a complete spinal cord injury, the patient does not have any sensation and cannot create any voluntary movement below the injury. Apart from paralysis, patients suffering from complete spinal cord injury can have other serious symptoms such as neuropathic pain, incontinence, pressure sores and sexual dysfunction. The injury results in a significantly reduced quality of life and no treatments are currently available. A spinal cord injury causes degeneration of the nerve fibers below the site of the injury, which render them unusable.

**About BioArctic**
BioArctic (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. 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 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**.