Press release

BioArctic's product candidate SC0806 for treatment of patients with complete spinal cord injury is now in Phase 2

Stockholm, Sweden, February 13, 2019 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the first patient in the second panel of the Phase 1/2 study now has been treated with SC0806. This means that the study with the product candidate SC0806 for complete spinal cord injury has progressed into Phase 2.

BioArctic develops a new innovative treatment for patients with complete spinal cord injury. The product candidate SC0806 is a combination of a biodegradable medical device and a drug substance (FGF1). SC0806 is designed to support nerve regeneration across the injured area in the spinal cord. Due to the novelty of the treatment, patients have been included sequentially, in order to monitor the effect and safety. A safety evaluation of all the patients in the first panel has been performed and provided support to start the next panel. The first patient in the second panel has now received treatment with SC0806 and hereby the Phase 2 part of the study has been initiated. The inclusion of patients to the second of the three panels in the study is on-going.

Each panel consists of six patients receiving SC0806 and three control patients. The treatment with SC0806 includes a surgical procedure. The surgery is followed by 18 months of intensive training in a robotic system to support nerve regeneration and muscle rebuilding in the part of the body affected by the paralysis. Patients receiving SC0806 are also given the option to participate in a 12 months extension study. An interim analysis of safety and efficacy of SC0806 in the first panel at 18 months is planned Q4 2019/Q1 2020.

”Today there is no effective treatment for patients with complete spinal cord injury. The initiation of the second panel was depending on a positive safety evaluation of the patients in the first panel. I am pleased that the study with SC0806 now has progressed into Phase 2 and we are looking forward to the important activities ahead of us within this therapeutic area,” said Gunilla Osswald, CEO of BioArctic.

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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 08.00 a.m. CET on February 13, 2019.

About SC0806
SC0806 is a novel product under development for the treatment for patients with complete spinal cord injury. The product candidate is currently in an ongoing Phase 1/2 clinical trial. The first patient was treated in 2016. BioArctic has obtained approvals from the regulatory authorities and ethics committees to recruit patients in Sweden, Estonia, Finland and Norway to the study. The product candidate is a combination of a biodegradable medical device and a drug substance (FGF1) designed to support nerve regeneration across the injured area in the spinal cord.

The product obtained orphan drug designation in 2010 in EU and in 2011 in the US, which may give the company 10 and 7 years of market exclusivity in Europe and the US, respectively.

BioArctic has received funding from the European Union's Horizon 2020 Research and Innovation Program under Grant Agreement No. 643853 to perform a clinical study with SC0806.

About Spinal Cord Injury
Spinal Cord Injuries (SCI) occur when trauma or disease damages the spinal cord and results in partial or complete paralysis. A complete spinal cord injury is defined as an injury where the patient cannot provide any voluntary movement or has any sensory feedback below the injury. A spinal cord injury causes degeneration of the nerve fibers below the site of the injury, as nerve cells do not regenerate. The incidence ranges between 12.7 and 44.3 per million inhabitants depending on country.[1] Some 40% of these patients are estimated to have chronic complete spinal cord injury.[2] Patients with complete spinal cord injury require life-long therapy and care, which means high costs for the healthcare system. The victims are usually young people. The injury has little effect on life expectancy, but leads to major challenges to maintain an acceptable quality of life. Following complete injury, the patient faces a permanent loss of function below the site of injury, with devastating consequences for the patient's quality of life. Today there is no effective treatment available for the patients.

[1)] Datamonitor, Stakeholder Opinions: Spinal Cord Injury, 2010.
[2)] NSCISC Annual Statistics report 2010.

About BioArctic

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 us at www.bioarctic.com**.**