Press release

BioArctic receives regulatory approval in Finland for a clinical study in patients with Complete Spinal Cord Injury

Stockholm, Sweden, July 10, 2018 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the company has received approval by Fimea, the Finnish Medicines Agency, and Valvira, the Finnish authority for medical device, as well as the local ethics committee for inclusion of Finnish patients in BioArctic's ongoing clinical Phase 1/2 study with SC0806. The candidate product is a combination of a medical device (implant) and a medicinal product (FGF1) for patients with complete spinal cord injury. This approval means that BioArctic has received approvals in all the countries planned to participate in the study, i.e. Sweden, Estonia, Norway and now Finland.

The Finnish patients will undergo treatment with SC0806 in Sweden followed by an 18-months rehabilitation period in Finland to enhance the patients' motor ability in the paralyzed part of the body. The treated patients will also be offered 12 month's further participation in an extension study.

"Today there is no effective treatment available for patients suffering from complete spinal cord injury. In April of this year, the inclusion of patients with complete spinal cord injury was completed in the first panel of BioArctic's ongoing Phase 1/2 study. We are pleased to be able to include patients from Sweden, Estonia, Norway and now also Finland to participate in the study's next panel. Our ambition is to develop SC0806 to improve the quality of life for these patients," 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, on July 10, 2018, at 00.30 p.m. CET.

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. 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 inclusion of patients with complete spinal cord injury in the first panel of BioArctic's ongoing study was completed in April 2018. Due to the novelty of the treatment, patients have been included sequentially, in order to monitor the effect and safety. The last patient in the first panel has now received the treatment with SC0806, which completes the inclusion of patients into the first panel of three. The initiation of the next panel is being prepared. 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 of 12 months additional participation in an extension study.

SC0806 obtained orphan drug designation in 2010 in EU and in 2011 in the US, which gives 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
A Spinal Cord Injury (SCI) occurs when trauma or disease damages the spinal cord and results in partial or complete paralysis. 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. The estimated lifetime cost is approximately 3 MUSD for one patient.[3)]

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 (STO:BIOA B). **www.bioarctic.com**

1) Datamonitor, Stakeholder Opinions: Spinal Cord Injury, 2010.
2) NSCISC Annual Statistics report 2010.
3) Krueger et al., 2013.