



Press release

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

Stockholm, Sweden, March 21, 2018 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the company has received approval by the Norwegian Medicines Agency (NOMA) departments for medicinal products and medical device and the local ethics committee for inclusion of Norwegian 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.

The Norwegian patients will undergo treatment with SC0806 at the Karolinska University Hospital in Stockholm, Sweden, followed by an 18-months training period in the study to enhance the patients’ motor ability in the paralyzed part of the body. The rehabilitation will initially take place in Sweden and will then continue in Norway, which will be the third country with regulatory approval participating in the study, together with Sweden and Estonia.

“Our ambition is to develop SC0806 to improve the quality of life for patients with complete spinal cord injury since there is no effective treatment available for these patients today,” 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 March 21, 2018, at 01:00 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 at Karolinska University Hospital, Sweden. 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 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. 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.