



Press release

Inclusion completed of patients with complete spinal cord injury in the first panel of BioArctic's ongoing study

Stockholm, Sweden, April 25, 2018 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the inclusion of patients with complete spinal cord injury in the first panel has been completed in the company's ongoing clinical Phase 1/2 study.

BioArctic develops a new innovative treatment for patients with complete spinal cord injury. The product candidate, SC0806, is a combination of a medical device and a drug.

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 now 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.

“Today there is no effective treatment available for patients with complete spinal cord injury. We are looking forward to the important upcoming activities in this therapy area as well as the 18 months interim results from the first panel in the Phase 1/2 study with SC0806,” 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 April 25, 2018, at 11.00 a.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 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

Spinal cord injuries are usually caused by traumatic events resulting in partial or complete paralysis. A complete spinal cord injury is defined as an injury where the patient can accomplish no voluntary movement or 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.

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 (Nasdaq Stockholm: BIOA B).

www.bioarctic.com

¹⁾ Datamonitor, Stakeholder Opinions: Spinal Cord Injury, 2010.

²⁾ NSCISC Annual Statistics report 2010.