



Press release

BioArctic receives European patent protection for a medical device for treatment of patients with Complete Spinal Cord Injury

Stockholm, Sweden, October 3, 2018 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the European Patent Office (EPO) has issued a decision to grant the company's patent application in Europe, EP12815796.3, for a medical device, which is one of the main components in the product candidate SC0806. The product candidate is a combination of a medical device (implant) and a medicinal product (FGF1) for patients with complete spinal cord injury. The decision states that the European patent, EP 2 787 900 B1, will enter into force on October 24, 2018.

The patent will provide important protection for medical for treatment of patients with complete spinal cord injury. A corresponding patent has previously been granted in China and during 2018 in Australia, the US and Japan. BioArctic has an active patent strategy covering all major geographic markets, including the US, Japan, China and Europe.

"The patent protection in Europe is in line with the company's strategy to protect important products through patents. A clinical Phase 1/2 study with the product candidate SC0806 for patients with complete spinal cord injury is currently ongoing. These patients lack effective treatment today. Our ambition is to develop SC0806 and thus improve the patients' quality of life," 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 October 3, 2018, at 02.30 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 ongoing. 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.

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. 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.