neuroplast
STEM CELL TECHNOLOGY

PRESS RELEASE

__NEUROPLAST__, a Dutch medical BioTech company in the growing field of regenerative medicine stem cell-based therapeutics, today 01-05-2019 announced that the __European Medicines Agency (EMA)__ has granted Orphan Drug Designation to __Neuro-Cells__, the Company's autologous therapy for the treatment of __Traumatic Spinal Cord Injury. Orphan Drug Designation (ODD)__ can be granted for a product that is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union. With the ODD status Neuroplast takes advantage of potential incentives from the European Union such as protocol assistance, reduced fees, funding from the European Commission for clinical trials, and 10 years of market exclusivity.

ABOUT SPINAL CORD INJURY

A spinal cord injury (SCI) is damage or trauma to the spinal cord which interrupts communication of the brain with body regions below the site of injury. Spinal cord injuries are mainly caused by accidents and, in most of the cases, result in life-long loss of control of motor functions and sensation. After the primary injury to the spinal cord, a cascade of events leads to progressive loss of tissue which may further deteriorate the patient's prognosis. Current treatment approaches for neurodegenerative disorders as SCI are only symptomatic, leaving the underlying pathophysiology unaffected.

ABOUT NEURO-CELLS

Neuro-Cells represents a non-substantially manipulated tissue engineered product manufactured from patient's own bone-marrow, intended to treat patients suffering from traumatic SCI. Based on these mechanisms Neuroplast focuses to develop a stem cell therapy, which can inhibit the inflammatory processes following damaged/dying neural tissue cells and sees its Neuro-Cells as a disease modifying therapy (DMT). DMT's are defined as treatments or interventions that affect the underlying pathophysiology of the disease and have a beneficial outcome on the course of several neurodegenerative diseases such as SCI and Amyotrophic Lateral Sclerosis (ALS).

ABOUT NEUROPLAST

As a Dutch medical biotechnology company willing to take an innovative forerunner role in the personalized regenerative medicine arena, Neuroplast dedicates not only to its product Neuro-Cells but also to its manufacturing process. An autologous stem cell product under GMP is a combination of manufacturing tools, quality monitoring and final release of a safe treatment. The manufacturing feature to process bone marrow to Neuro-Cells is the Rapid Interventional Stem Cell Platform (RISP) with the customized disposable Neurokit, enabling decentralized manufacturing and centralized batch release. Neuroplast is currently in the process of applying an international multi-center, double-blind, randomized, placebo-controlled, delayed-start phase II/III study to assess the efficacy and safety of Neuro-Cells in (sub)acute spinal cord injury patients which will start in the third quarter of 2019.

DISCLAIMER

All statements other than statements of historical facts, including the statements about the clinical and therapeutic potential and future clinical milestones of Neuro-Cells, including the initiation of Phase II/III clinical trials, the potential for Neuro-Cells to capture any expected benefits from Orphan Drug Designation, the indications we intend to pursue and our possible clinical or other business strategies, and the timing of these events, are forward-looking statements. Forward-looking statements can be identified by terms such as "believes", "expects", "plans", "potential", "would" or similar expressions and the negative of those terms. These forward-looking statements are based on our management's current beliefs and assumptions about future events and on information currently available to management. Neuroplast BV does not make any representation or warranty, express or implied, as to the improper use of this article, accuracy, completeness or updated status of above-mentioned statements. Therefore, in no case whatsoever will Neuroplast BV be legally liable or liable to anyone for any decision made or action taken in conjunction with the information and/or statements in this press release or for any related damages.

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