Milestone: Neuroplast reports halfway patient inclusion in Phase II clinical trial for Traumatic Spinal Cord Injury

- 8 out of 16 patients enrolled
- None of the included patients reported serious adverse events so far
- The randomized, placebo-controlled, Phase II clinical trial aims to determine efficacy for treatment of Traumatic Spinal Cord Injury (TSCI)
- Further applications of Neuro-Cells® are being explored, with targets on both the chronic- and the trauma-induced spectrum.
- Neuroplast holds an orphan disease designation for its Neuro-Cells® technology for both traumatic spinal cord injury and frontotemporal dementia

Geleen, The Netherlands, 29 September 2022 – Neuroplast, a Dutch clinical stage biotech, focusing on cell-based treatments for neurodegenerative diseases, has included 8 of the 16 required patients in a Phase II clinical trial to evaluate efficacy of Neuro-Cells® for Traumatic Spinal Cord Injury (TSCI). No serious adverse events have been reported so far. The trial is conducted in collaboration with Hospital Nacional de Parapléjicos in Toledo, Spain.

The Neuro-Cells® technology platform uses the patient's own bone marrow to develop a stem cell treatment that modulates inflammation of damaged cells in the central nervous system, after sustaining acute injury to the spinal cord. This autologous treatment aims to prevent (further) impairment, to preserve function, mobility and independence.

The goal of the Phase II clinical trial is to determine efficacy of the technology for traumatic spinal cord injury. With patient inclusion half completed, no serious adverse events have been reported to date.

Randomized, placebo-controlled multi-center study

The trial is conducted by Principal Investigators Antonio Oliviero, MD, PhD and Prof. Jörg Mey from Hospital Parapléjicos in Toledo, Spain.

The study is a randomized and placebo-controlled trial, with an early and late intervention cross-over design. The intervention group receives Neuro-Cells® in the sub-acute phase after sustaining trauma, with six months follow-up to their primary endpoints. The placebo group receives a placebo at first but will be treated with Neuro-Cells® after the initial six-month follow-up period. The multi-facetted follow-up for both groups include standardized and validated outcome measures on motor and sensory function and multiple blood and cerebrospinal fluid measurements.

Antonio Oliviero, MD, PhD, Principal Investigator at Hospital Nacional de Parapléjicos de Toledo, Spain:

> *"After having worked in the field of Spinal Cord Injury for almost twenty years, I'm happy to contribute to establishing the role of cell transplantation in the functional recovery of individuals with Spinal Cord Injury. I am excited to be a part of this new step in research, together with Neuroplast."*

In total, the trial involves 16 patients that will be included six to eight weeks after sustaining trauma to the spinal cord.

The trial is conducted under official approval from the Spanish medical ethical committee Comité de Ética de la Investigación con medicamentos (CEIm) and the competent authority Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). These authorities approved a combined Phase II/III approach. This enables a faster path towards the market due to savings in time and a reduced number of required patients to study.

Neuroplast CEO Johannes de Munter concludes:

> *"Our mission is to bring back perspective to people who suffer from neurodegenerative diseases for which no effective treatments are available. Our progress in this Phase II clinical trial means that we are one step closer to realizing that mission for Traumatic Spinal Cord Injury."*

Potential applicability to both acute and chronic neurological disorders

This halfway milestone follows shortly after the news that Neuroplast received an orphan disease designation for frontotemporal dementia, highlighting the potential applicability of Neuro-Cells® to both acute and chronic neurological disorders. Other therapeutical areas under exploration include traumatic brain injury, ALS, Alzheimer's and Parkinson's disease.

Neuroplast is open to discuss investor opportunities to effectuate the clinical pathways to a wider scope of neurological conditions.

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About Traumatic Spinal Cord Injury (TSCI)

Acute TSCI causes incurable impairment to the spinal cord, affecting approximately 12,000 people across Europe and 17,000 across the USA annually. The damage or trauma interrupts communication of the brain with the 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 sensations. 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 TSCI are only symptomatic, leaving the underlying pathophysiology unchanged.

TSCI has a serious impact on the quality of life of patients, with severe implications on mobility and loss of independence. In addition, TSCI creates a lifetime financial burden for patients, payors, healthcare systems and societies at large.

About Neuro-Cells®

Neuro-Cells® is a transformative treatment under GMP. It contains non-substantially manipulated bone marrow-derived hematopoietic and mesenchymal stem cells, manufactured from a patient's own bone marrow (donor and receiver are the same person). Inflammatory inducing components and pathogens are removed during this process.

About Neuroplast

Neuroplast is a Dutch stem cell technology company focusing on fast-track development programs using autologous cell products for treatment of neurodegenerative diseases, with the aim of giving back perspective to people who suffer from those conditions.

The company was founded in August 2014 by physician Johannes de Munter and neurologist Erik Wolters. Current funders are Lumana Invest, Brightlands Venture Partners, LIOF and the Netherlands Enterprise Agency. Neuroplast is located at Brightlands Chemelot Campus in The Netherlands.

For more information, please visit www.neuroplast.com

About Hospital de Parapléjicos, Toledo, Spain

Hospital Nacional de Parapléjicos de Toledo is the reference public hospital in Spain for the treatment of spinal cord injury, recognized by the Ministry of Health of the Government of Spain.

About Lumana Invest

Investment company Lumana was established by entrepreneurs and unique due to not having a predetermined investment horizon. The Lumana founders showcase strong commitment to their portfolio companies by actively supporting management in strategic decision making.

About Brightlands Venture Partners

Brightlands Venture Partners (BVP) is the fund manager of Chemelot Ventures and is a so-called ecosystem investor. BVP invests in companies benefiting from and contributing to the Brightlands campuses in the south of The Netherlands. Other funds under management are BVP Fund IV, Brightlands Agrifood Fund and Limburg Ventures. The funds of BVP focus on sustainability and health; together the funds have made over 40 investments.

About LIOF

LIOF is the regional development agency for Limburg and supports innovative entrepreneurs with advice, network and financing. Together with entrepreneurs and partners, LIOF is working towards a smarter, more sustainable and healthier Limburg by focusing on the transitions of energy, circularity, health and digitalization.

About The Netherlands Enterprise Agency

The Netherlands Enterprise Agency operates under the auspices of the Dutch Ministry of Economic Affairs and Climate Policy. It facilitates entrepreneurship, improves collaborations, strengthens positions and helps realize national and international ambitions with funding, networking, know-how and compliance with laws and regulations.

Forward looking statements

All statements other than statements of historical facts, including the statements about the clinical and therapeutic potential and future clinical milestones of Neuro-Cells®, 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 B.V. 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 B.V. 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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