



## Dutch stem cell biotech Neuroplast announces successful clinical Phase I trial with its Neuro-Cells® stem cell treatment for Traumatic Spinal Cord Injury

- Positive safety profile and well tolerated, without product-related adverse effects
- Demonstrated clinical feasibility to collect, manufacture and treat Spanish patients from its Dutch GMP production facility
- Preparation for randomized, placebo-controlled, international multi-center Phase II study in sub-acute patients
- Orientation on additional funding to expand clinical trials to other geographies

[Geleen, The Netherlands and Toledo, Spain, 9 November 2021](#) – Dutch clinical phase biotech company Neuroplast and Hospital Nacional de Paraplégicos de Toledo in Spain, today announced positive clinical Phase I results after analysis of ten patients suffering from Traumatic Spinal Cord Injury (TSCI). Data demonstrate that Neuroplast’s investigational stem cell treatment Neuro-Cells® appears to be safe and well tolerated, without product-related adverse events. The transformative treatment uses the patient’s own stem cells to prevent (further) loss of function after sustaining TSCI, to potentially limit loss of mobility and independence of otherwise life-long impairment.

The Phase I study evaluated the safety and tolerability of the Neuro-Cells® stem cell preparation for intrathecal application (injection into the spinal canal). Ten patients with spinal cord injury, who sustained the trauma between one and five years ago and suffered either an incomplete or a complete lesion, received the Neuro-Cells® treatment, manufactured from the patient’s own bone marrow, led by principal investigators Antonio Oliviero, MD, PhD and Prof. Dr. Jörg Mey.

The safety study started in November 2020 and reached its primary endpoint in October 2021. No serious safety concerns or product-related adverse events have occurred during the study.

In addition, Neuroplast demonstrated clinical feasibility to collect, manufacture and treat patients in Spain with a fresh autologous stem cell preparation derived from bone marrow, from its GMP (Good Manufacturing Practice) production facility in the Netherlands, within 48 hours.

[Antonio Oliviero, MD, PhD, Hospital Nacional de Paraplégicos, Toledo, Spain and principal investigator in the Phase I study, comments:](#)

*“I’m really enthusiastic about the prospects of this therapy and what it means for the future treatment of patients with TSCI. Neuro-Cells® might be a game-changer.”*

[Neuroplast CEO Johannes de Munter, adds:](#)

*“Proving the safety of our autologous Neuro-Cells® treatment is an important step in the development of a treatment for acute TSCI patients, as the absence of product-related adverse events in the clinical phase I study highlights its inherent safety. The functional, psychological, and financial impacts of traumatic spinal cord injury are broad, and we are committed to advance our treatment for patients worldwide as soon as possible.”*

With the completion of the Phase I safety trial, Neuroplast will finalize preparation for the start of a randomized, placebo-controlled, international multi-center Phase II study. This study will evaluate the efficacy and safety of treatment in sub-acute patients.

The current study is focused on Europe. Neuroplast is seeking additional funding to expand clinical trials for TSCI to other geographies.

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### About Traumatic Spinal Cord Injury

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, hospital systems and societies at large.

### About Neuro-Cells®

Neuro-Cells® is a transformative treatment under GMP in the crucial first phase after sustaining TSCI, during which the irreversible impact of TSCI can be radically reduced. 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 Hospital Nacional de Paraplégicos

The Hospital Nacional de Paraplégicos de Toledo (HNP) is the reference public hospital in Spain for the treatment of spinal cord injury (number two center in Spain).

### About Neuroplast

Neuroplast is a Dutch stem cell technology company focusing on fast-track development programs using autologous cell products for treatment of primarily inflammation-driven neurological disorders, 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 investors are Lumana Invest, Brightlands Venture Partners and LIOF. Neuroplast is located in Brightlands Chemelot Campus in The Netherlands.

### 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 BVP Fund IV 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 Chemelot Ventures, Brightlands Agrifood Fund and Limburg Ventures. BVP Fund IV focuses on sustainability and health and is the successor fund of the 2014 vintage Chemelot Ventures; 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.

### 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<sup>®</sup>, 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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