Neuroplast successfully completes patient inclusion of Phase II clinical trial for Traumatic Spinal Cord Injury

- 16 patients have been enrolled in a multicenter international, randomized, placebo-controlled, double-blinded Phase II clinical trial
- Goal: to determine the effect size of Neuro-Cells®, a stem-cell treatment for Traumatic Spinal Cord Injury (TSCI)
- Confirmed excellent safety and tolerability of Neuro-Cells®
- Preclinical evidence showcases Neuro-Cells® potential in other indications, including traumatic brain injury
- Primary outcomes expected in February 2024, full study completion projected in August 2024

Geleen, The Netherlands, 7 September 2023 – Neuroplast, a Dutch clinical-stage biotech, focusing on cell-based treatments for neurodegenerative diseases, has successfully completed patient inclusion of its Phase II randomized placebo-controlled double-blinded clinical trial to evaluate the effect size of Neuro-Cells® for Traumatic Spinal Cord Injury (TSCI). Preliminary data indicate an excellent safety profile due to the complete absence of product related adverse events. Furthermore, patient feedback confirms excellent tolerability. The trial is conducted in collaboration with Hospital Nacional de Parapléjicos in Toledo, Spain, and Rigshospitalet in Copenhagen, Denmark.

The Neuro-Cells® technology platform uses the patient's own bone marrow to create a stem cell treatment that modulates inflammation and improves regeneration potential in the central nervous system. Neuro-Cells® are administered intrathecally to patients in the sub-acute stage. This autologous treatment aims to preserve and restore function, mobility, and therefore independence.

Double-blinded, randomized, placebo-controlled multi-center study

The trial was conducted by Principal Investigators Antonio Oliviero, MD, PhD and Prof. Jörg Mey from Hospital Parapléjicos in Toledo, Spain, as well as Professor Fin Biering-Sørensen and MD, PhD Claus Andersen from Rigshospitalet in Copenhagen, Denmark.

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

measurements. Next to the absence of product related adverse events, the patients describe the intervention as easy and feasible as it does not require significant changes in daily living or medication intake.

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

> *"In our collaboration with Neuroplast to establish the role of cell transplantation in the recovery of individuals with spinal cord injury, it is great to hear that patients are pleased with the treatment that they experience as easy, feasible and safe."*

Fin Biering-Sørensen, MD, PhD, Principal investigator at Rigshospitalet, Denmark, adds :

> *"For decades we have been seeking a cure for spinal cord injury. This project may be one step on that road, which is very exciting, due to the fact that so far, we have only been able to treat the symptoms and complications caused by the spinal cord injury."*

In total, the trial involves 16 patients that were included six to ten weeks after sustaining trauma to the spinal cord.

The trial is conducted under official approval from the Spanish and Danish medical ethical committees and competent authorities.

Neuroplast CEO Johannes de Munter concludes:

> *"This milestone takes us one step closer to offering an effective treatment for patients suffering from traumatic spinal cord injury. We are especially glad to see further confirmation of the excellent tolerability and safety of our Neuro-Cells® product"*

Potential relevance to other neurological conditions

Preclinical evidence suggests that the Neuro-Cells® treatment may have broader applications in addressing various neurodegenerative diseases. Neuroplast has obtained orphan disease designations for traumatic spinal cord injury and frontotemporal dementia. Ongoing research efforts are actively exploring additional potential applications.

Neuroplast is open to discussing investment opportunities aimed at advancing the clinical pathways for addressing a broader range of conditions affecting the central nervous system, including traumatic brain injury.

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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 platform treatment under GMP. It contains a non-substantially manipulated bone marrow-derived integrated mixture of stem cells including 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 in The Netherlands.

For more information, please visit www.neuroplast.com

About Hospital de Parapléjicos, Toledo, Spain

Hospital Nacional de Parapléjicos 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 Rigshospitalet, Copenhagen, Spain

Rigshospitalet is one of the two Danish national centers offering highly specialized treatment, rehabilitation and care of individuals with spinal cord lesions.

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 50 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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