

International Stem Cell Corporation Completes Enrollment and Dosing in its Parkinson's Disease Clinical Trial

Release: 4/29/2019 8:30:00 AM

CARLSBAD, Calif., April 29, 2019 (GLOBE NEWSWIRE) -- International Stem Cell Corporation (OTCQX: ISCO) (www.internationalstemcell.com) ("ISCO" or "the Company"), a California-based clinical stage biotechnology company developing stem cell-based therapies and biomedical products, announced today the completion of subject enrollment in its phase 1 clinical trial of ISC-hpNSC® for the treatment of Parkinson's disease. The fourth subject of the third cohort, who was the twelfth and final subject of the phase 1 clinical study, was successfully transplanted with the highest dose of ISC-hpNSC® cells. This clinical trial, which involved 12 patients with Parkinson's disease, was conducted in collaboration with investigators from Royal Melbourne Hospital, a leading medical institution with an international reputation for excellence.

"We are excited to announce the completion of enrollment of the world's first approved human pluripotent stem cell-based clinical trial for the treatment of Parkinson's disease. This is a major milestone for the Company and we expect to announce complete clinical results of this phase 1 clinical trial in the first half of 2020," commented ISCO's Co-Chairman and CEO Andrey Semechkin, PhD.

"In addition, now that we have completed the most expensive stage of the phase 1 clinical trial, ISCO will have more resources available to invest in growing and developing its commercial business, where we have recently made significant progress," he continued.

The goal of this study is to assess the safety and incidence of treatment-emergent adverse events after intracerebral transplantation of 30 million, 50 million, and 70 million ISC-hpNSC® cells into the substantia nigra and striatum of patients with Parkinson's disease. Thus far there have been no serious adverse events related to the transplanted ISC-hpNSC®, which is a very significant achievement due to the invasive nature of the transplantation procedure. Preliminary efficacy is also evaluated through secondary endpoints, although no definitive conclusions can be drawn due to the fact that this is a clinical study with no placebo control group. Secondary endpoints assess the change from baseline in different neurological scales such as Unified Parkinson's Disease Rating Scale, Parkinson's Disease Quality of Life Questionnaire-39, and Patient motor diary. After transplantation, patients are evaluated for 12 months (active phase of the study) with an additional 5-year observational follow-up period to assess the safety of ISC-hpNSC®. Eight patients have already completed the 12-month study and entered the follow-up phase.

Interim results of this study will be presented at the upcoming 2019 American Academy of Neurology 71st Annual Meeting in Philadelphia, PA on May 5th, 2019.

About Parkinson's disease

Parkinson's disease is a degenerative disorder of the central nervous system mainly affecting the motor system. The motor symptoms of Parkinson's disease result from the death of dopamine-generating cells in the substantia nigra, a region of the midbrain. Early in the course of the disease, the most obvious symptoms are movement-related. These symptoms include shaking, rigidity, slowness of movement and difficulty with walking and gait. Later, thinking and behavioral problems may arise, with dementia commonly occurring in the advanced stages of the disease. Depression is the most common psychiatric symptom. Parkinson's disease is more common in people over the age of 50.

There are no approved treatments that restore the damaged dopaminergic neurons. Medications typically used in the treatment of Parkinson's disease, levodopa and dopamine agonists, improve the early symptoms of the disease. As the disease progresses and dopaminergic neurons continue to be lost, the drugs eventually become ineffective, while at the same time frequently producing a complication marked by involuntary writhing movements. There are over 10 million people afflicted with Parkinson's disease, worldwide. In 2013 Parkinson's disease resulted in about 103,000 deaths, globally. In 1990, the death toll recorded was 44,000.

About ISC-hpNSC®

International Stem Cell Corporation's proprietary ISC-hpNSC® consists of a highly pure population of neural stem cells derived from human parthenogenetic stem cells. ISC-hpNSC® is a suspension of clinical grade cells manufactured under cGMP conditions that have undergone stringent quality control measures and are free of any microbial and viral contaminants. Preclinical studies in rodents and non-human primates have shown improvement in Parkinson's disease symptoms and increase in brain dopamine levels following the intracranial administration of ISC-hpNSC®. ISC-hpNSC® provides neurotrophic support and neuroregeneration to the dying dopaminergic neurons of the recipient Parkinson's disease brain. Additionally, ISC-hpNSC® is safe, well tolerated and has shown not to cause adverse events such as dyskinesia, systemic toxicity or tumors in preclinical models. International Stem Cell Corporation believes that ISC-hpNSC® may have broad therapeutic applications for many neurological diseases affecting the brain, the spinal cord and the eye.

About International Stem Cell Corporation

International Stem Cell Corporation (ISCO) is focused on the therapeutic applications of human parthenogenetic stem cells (hpSCs) and the development and commercialization of cell-based research and cosmetic products. ISCO's core technology, parthenogenesis, results in the creation of pluripotent human stem cells from unfertilized oocytes (eggs). hpSCs avoid ethical issues associated with the use or destruction of viable human embryos. ISCO scientists have created the first parthenogenetic, homozygous stem cell line that can be a source of therapeutic cells for hundreds of millions of individuals of differing genders, ages and racial background with minimal immune rejection after transplantation. hpSCs offer the potential to create the first true stem cell bank, UniStemCell™. ISCO also produces and markets specialized cells and growth media for therapeutic research worldwide, through its subsidiary Lifeline Cell Technology (www.lifelinecelltech.com), and stem cell-based skin care products through its subsidiary Lifeline Skin Care (www.lifelineskincare.com). More information is available at www.internationalstemcell.com.

To subscribe to receive ongoing corporate communications, please click on the following link: <http://www.b2i.us/irpass.asp?BzID=1468&to=ea&s=0>

To like our Facebook page or follow us on Twitter for company updates and industry related news, visit: www.facebook.com/InternationalStemCellCorporation and www.twitter.com/intlstemcell

Safe harbor statement

Statements pertaining to anticipated developments, clinical studies expectations (including timing), resource availability, progress of research and development, and other opportunities for the Company and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates,") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, regulatory approvals, need and ability to obtain future capital, application of capital resources among competing uses, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the company's business, particularly those mentioned in the cautionary statements found in the Company's Securities and Exchange Commission filings. The Company disclaims any intent or obligation to update forward-

looking statements.

Contacts

International Stem Cell Corporation

Russell Kern, PhD

Executive Vice President, Chief Scientific Officer

ir@intlstemcell.com

Joe Green

Investor Relations

Edison Inc.

jgreen@edisongroup.com

+1 (646) 653-7030

