

# International Stem Cell Corporation Announces Commencement of Enrollment of Phase I Trial of ISC-hpNSC

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## Melbourne Health Ethics Committee Approves Phase I Clinical Trial for Treatment of Parkinson's Disease

CARLSBAD, CA--(Marketwired - March 07, 2016) - [International Stem Cell Corporation](#) (OTCQB: ISCO), a clinical stage biotechnology company developing novel stem cell-based therapies, announced today that it is enrolling patients in the Phase I trial of ISC-hpNSC<sup>®</sup>, human parthenogenetic stem cell-derived neural stem cells for the treatment of moderate to severe Parkinson's disease. The Melbourne Health Human Research Ethics Committee (HREC) granted its approval of the Phase I clinical trial in patients with moderate to severe Parkinson's disease. This approval clears the study's initiation at the Royal Melbourne Hospital. Parkinson's disease has no cure and is the second most common neurodegenerative disease affecting over 7 million people worldwide.

Russell Kern, PhD, executive vice president and chief scientific officer of ISCO, said, "Enrollment in this trial is an important milestone. Promising preclinical results support our expectation that ISC-hpNSC will bring a long-needed solution for patients suffering from Parkinson's disease. The ability of our approach to replace and protect dopaminergic neurons and restore neural function offers significant potential benefit to patients. We look forward to preliminary clinical data in Q4 2016."

### About the clinical study

The Phase I clinical study is a dose escalation safety and preliminary efficacy study of ISC-hpNSC<sup>®</sup>, intracranially transplanted into patients with moderate to severe Parkinson's disease. The open-label, single center, uncontrolled clinical trial will evaluate three different dose regimens of 30,000,000 to 70,000,000 neural cells. A total of 12 participants with moderate to severe Parkinson's disease will be treated. Following transplantation, the patients will be monitored for 12 months at specified intervals, to evaluate the safety and biologic activity of ISC-hpNSC<sup>®</sup>. PET scan will be performed at baseline, as part of the screening assessment, and at 6 and 12 months after surgical intervention. Clinical responses compared to baseline after the administration of ISC-hpNSC<sup>®</sup> will be evaluated using various neurological assessments such as Unified Parkinson Disease Rating Scale (UPDRS), Hoehn and Yahr and other rating scales.

The study will be performed at Royal Melbourne Hospital in Australia. The study's submission is being overseen by ISCO subsidiary, Cyto Therapeutics Pty Ltd.

### About Parkinson's disease

Parkinson's disease (PD) 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, and depression is the most common psychiatric symptom. Parkinson's disease is more common in older people, with most cases occurring after the age of 50.

Currently, medications typically used in the treatment of Parkinson's, L-DOPA 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. In 2013 PD resulted in about 103,000 deaths globally, up from 44,000 deaths in 1990.

### About ISC-hpNSC<sup>®</sup>

International Stem Cell Corporation's proprietary ISC-hpNSC<sup>®</sup> consists of a highly pure population of neural stem cells derived from human parthenogenetic stem cells. ISC-hpNSC<sup>®</sup> is a suspension of clinical grade cells manufactured under cGMP conditions that have undergone stringent quality control measures and are clear 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<sup>®</sup>. ISC-hpNSC<sup>®</sup> provides neurotrophic support and cell replacement to the dying dopaminergic neurons of the recipient PD brain. Additionally, ISC-hpNSC<sup>®</sup> are safe, well tolerated and do not cause adverse events such as dyskinesia, systemic toxicity or tumors in preclinical models. International Stem Cell Corporation believes that ISC-hpNSC<sup>®</sup> 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](http://www.lifelinecelltech.com)), and stem cell-based skin care products through its subsidiary Lifeline Skin Care ([www.lifelineskincare.com](http://www.lifelineskincare.com)). More information is available at [www.internationalstemcell.com](http://www.internationalstemcell.com).

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#### **Safe harbor statement**

Statements pertaining to anticipated developments, expected results and timing of clinical studies, potential applications of ISC-hpNSC® to other diseases, progress of research and development initiatives, 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.