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ASIA EDITION

International Stem Cell Corporation completes enrollment in its Parkinson's Disease clinical trial

April 30, 2019 | News

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.



International Stem Cell Corporation, a California-based clinical stage biotechnology company developing stem cell-based therapies and biomedical products has announced 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 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 Questionnair-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.

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 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.

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.