International Stem Cell Corporation Announces Positive Results of Primate Parkinson's Study

The Associated Press

International Stem Cell Corporation (OTCQB: ISCO) (www.internationalstemcell.com), a California-based biotechnology company focused on the therapeutic applications of human parthenogenetic stem cells, announced today safety and encouraging efficacy of stem cell therapy in rodent and non-human primate models of Parkinson's disease.

"This pilot study represents a first essential step in bringing cell-based therapies for Parkinson's disease to clinical trials," commented co-author of the study Evan Y. Snyder, MD, PhD, Director of Stem Cells and Regenerative Biology Program at Sanford Burnham Medical Research Institute.

These placebo-controlled studies were designed to demonstrate the viability, fate and functional efficacy of the stem cell derived neural cells after implantation to the brain. Highly pure populations of neuronal cells were differentiated from human parthenogenetic stem cells (hpSC) according to the protocol developed by International Stem Cell Corporation and recently published in the Nature Publishing Group's Scientific Reports.

The studies employ MPTP-lesioned African Green monkeys and 6-OHDA-lesioned rats, the principle models used to study Parkinson's disease. The duration of the primate study was four months and the rodent study six months. In the non-human primate model, behavioral endpoints were assessed with parkinsonian scores. These scores, based on a standardized rating scale, were recorded by observers blinded to whether the primates were in the treatment or control group. Observations were done twice per day, five days per week. In the rodent model, behavioral improvement was assessed using the cylinder test, amphetamine and apomorphine induced rotation tests. Cell engraftment, viability and phenotype of the implanted cells were determined histologically at the end of the studies. Tumorigenicity and safety of the therapy was assessed at the end of both the rodent and primate studies by gross necropsy, and brain histology.

The primate study consisted of eight asymptomatic monkeys which have the pathology of the disease, low levels of dopamine induced by bilateral injections of the neurotoxin MPTP, and lack clinical symptoms. Four of the monkeys were transplanted with hpSC-derived neuronal cells, two monkeys sham transplanted with an equivalent volume of cell-less media thus serving as the placebo control group and two healthy monkeys serving as a positive control. Behavioral endpoints were recorded to evaluate possible adverse effects.

Subsequent to implantation of the neuronal cells, all monkeys in the treatment group had higher levels of dopamine in the brain compared with the control group.

Additionally, the rats in the treatment group showed gradual improvements in motor symptoms consistent with cells survival, engraftment and dopamine release. No adverse events, including dyskinesia, deformations, tumors or overgrowth, were observed in the rat or monkey treatment groups. Overall, these results provide evidence to support the hypothesis that hpSC-derived neuronal cells can be safe and have a disease modifying effect. These results, although preliminary, are a strong indication that our approach to Parkinson's disease can succeed.

"These results are pivotal for our pre-clinical Parkinson's program showing, as they do, that the hpSC-derived neuronal cells can potentially ameliorate the behavioral symptoms without triggering dyskinesias. This data forms the foundation of our discussions with the FDA as we move towards our IND in 2013," said Dr. Ruslan Semechkin, Principal Investigator of this study, head of R&D for International Stem Cell Corporation and Member of the American Academy of Neurology.

These results will be presented and discussed at the 65th American Academy of Neurology Annual Meeting, one of the world's most important annual events for neurologists and neuroscience professionals and the largest such international meeting of its kind with more than 12,000 attendees at last year's meeting.

Location: San Diego Convention Center, 111 W Harbor Dr., San Diego, CA 92101Session: Movement Disorders; Parkinson's Disease Therapeutics Date and time: March 20th, 2012 at 3:30 PM PDT

Parkinson's disease (PD) is a debilitating neurodegenerative disorder characterized by a progressive degeneration of dopamine-producing neurons in the central nervous system. Approximately 60,000 American's are diagnosed with PD every year, world-wide there are thought to be as many as ten million sufferers. Current PD treatments, including small molecule such as Levadopa which replaces the lost dopamine, are useful in the relatively early stage of the disease. As symptoms grow worse, the efficacy of such therapies declines, leaving many patients severely disabled.

About International Stem Cell CorporationInternational Stem Cell Corporation 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) hence avoiding 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.

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