Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy

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Geron to Study GRNOPC1 in Patients with Acute Spinal Cord Injury

MENLO PARK, Calif., January 23, 2009 - Geron Corporation (Nasdaq: GERN) announced today that the U.S. Food and Drug Administration (FDA) has granted clearance of the company's Investigational New Drug (IND) application for the clinical trial of GRNOPC1 in patients with acute spinal cord injury.

The clearance enables Geron to move forward with the world's first study of a human embryonic stem cell (hESC)-based therapy in man. Geron plans to initiate a Phase I multi-center trial that is designed to establish the safety of GRNOPC1 in patients with "complete" American Spinal Injury Association (ASIA) grade A subacute thoracic spinal cord injuries.

"The FDA's clearance of our GRNOPC1 IND is one of Geron's most significant accomplishments to date," said Thomas Okarma, Ph.D., M.D., Geron's president and CEO. "This marks the beginning of what is potentially a new chapter in medical therapeutics - one that reaches beyond pills to a new level of healing: the restoration of organ and tissue function achieved by the injection of healthy replacement cells. The ultimate goal for the use of GRNOPC1 is to achieve restoration of spinal cord function by the injection of hESC-derived oligodendrocyte progenitor cells directly into the lesion site of the patient's injured spinal cord."

GRNOPC1, Geron's lead hESC-based therapeutic candidate, contains hESC-derived oligodendrocyte progenitor cells that have demonstrated remyelinating and nerve growth stimulating properties leading to restoration of function in animal models of acute spinal cord injury (*Journal of Neuroscience*, Vol. 25, 2005).

"The neurosurgical community is very excited by this new approach to treating devastating spinal cord injury," said Richard Fessler, M.D., Ph.D., professor of neurological surgery at the Feinberg School of Medicine at Northwestern University. "Demyelination is central to the pathology of the injury, and its reversal by means of injecting oligodendrocyte progenitor cells would be revolutionary for the field. If safe and effective, the therapy would provide a viable treatment option for thousands of patients who suffer severe spinal cord injuries each year."

The GRNOPC1 Clinical Program

Patients eligible for the Phase I trial must have documented evidence of functionally complete spinal cord injury with a neurological level of T3 to T10 spinal segments and agree to have GRNOPC1 injected into the lesion sites between seven and 14 days after injury. Geron has selected up to seven U.S. medical centers as candidates to participate in this study and in planned protocol extensions. The sites will be identified as they come online and are ready to enroll subjects into the study.

Although the primary endpoint of the trial is safety, the protocol includes secondary endpoints to assess efficacy, such as improved neuromuscular control or sensation in the trunk or lower extremities. Once safety in this patient population has been established and the FDA reviews clinical data in conjunction with additional data from ongoing animal studies, Geron plans to seek FDA approval to extend the study to increase the dose of GRNOPC1, enroll subjects with complete cervical injuries and expand the trial to include patients with severe incomplete (ASIA grade B or C) injuries to enable access to the therapy for as broad a population of severe spinal cord-injured patients as is medically appropriate.

Preclinical Evidence of Safety, Tolerability and Efficacy

Geron submitted evidence of the safety, tolerability and efficacy of GRNOPC1 to the FDA in a 21,000-page IND application that described 24 separate animal studies requiring the production of more than five billion GRNOPC1 cells. Included in the safety package were studies that showed no evidence of teratoma formation 12 months after injection of clinical grade GRNOPC1 into the injured spinal cord of rats and mice. Other studies documented the absence of significant migration of the injected cells outside the spinal cord, allodynia induction (increased neuropathic pain due to the injected cells), systemic toxicity or increased mortality in animals receiving GRNOPC1.

In vitro studies have shown that GRNOPC1 is minimally recognized by the human immune system. GRNOPC1 is not recognized *in vitro* by allogeneic sera, NK cells or T cells (*Journal of Neuroimmunology*, Vol. 192, 2007). These immune-privileged characteristics of the hESC-derived cells allow a clinical trial design that incorporates a limited course of low-dose immunosuppression and provide the rationale for an off-the-shelf, allogeneic cell therapy.

Also included in the IND application were published studies supporting the utility of GRNOPC1 for the treatment of spinal cord injury. Those studies showed that administration of GRNOPC1 significantly improved locomotor activity and kinematic scores of animals with spinal cord injuries when injected seven days after the injury (*Journal of Neuroscience*, Vol. 25, 2005). Histological

examination of the injured spinal cords treated with GRNOPC1 showed improved axon survival and extensive remyelination surrounding the rat axons. These effects of GRNOPC1 were present nine months after a single injection of cells. In these nine-month studies, the cells were shown to migrate and fill the lesion cavity, with bundles of myelinated axons crossing the injury site.

Production and Qualification of GRNOPC1

GRNOPC1 is produced using current Good Manufacturing Practices (cGMP) in Geron's manufacturing facilities. Geron's GRNOPC1 production process and clean-room suites have been inspected and licensed by the state of California. The cells are derived from the H1 human embryonic stem cell line, which was created before August 9, 2001. Studies using this line qualify for U.S. federal research funding, although no federal funding was received for the development of the product or to support the clinical trial.

Geron's H1 hESC master cell bank is fully qualified for human use and was shown to be karyotypically normal and free of measurable contaminants of human or animal origin. Production of GRNOPC1 from undifferentiated hESCs in the master cell bank uses qualified reagents and a standardized protocol developed at Geron over the past three years. Each manufacturing run of GRNOPC1 is subjected to standardized quality control testing to ensure viability, sterility and appropriate cellular composition before release for clinical use. GRNOPC1 product that has passed all such specifications and has been released is available for the approved clinical trial. The current production scale can supply product needs through pivotal clinical trials. The existing master cell bank could potentially supply sufficient starting material for GRNOPC1 to commercially supply the U.S. acute spinal cord injury market for more than 20 years.

Intellectual Property

The production and commercialization of GRNOPC1 is protected by a portfolio of patent rights owned by or exclusively licensed to Geron. Patent rights owned by Geron protect key technologies developed at Geron for the scalable manufacturing of hESCs, as well as the production of neural cells by differentiation of hESCs. The fundamental patents covering hESCs are exclusively licensed to Geron from the Wisconsin Alumni Research Foundation (WARF) for the production of neural cells, cardiomyocytes and pancreatic islets for therapeutic applications. The validity of these patents was recently confirmed by the U.S. Patent and Trademark Office in a re-examination proceeding. Geron funded the original research at the University of Wisconsin-Madison that led to the first isolation of hESCs. The production of oligodendrocytes from hESCs is covered by patent rights exclusively licensed to Geron from the University of California. These patent rights cover technology developed in a research collaboration between Geron and University of California scientists.

Conference Call and Video Webcast

Thomas B. Okarma, Ph.D., M.D., will host a conference call and video Webcast presentation for investors and the media at 6:00 a.m. PST/9:00 a.m. EST today. Participants can access the conference call via telephone by dialing 866-783-2145 (U.S.) or 857-350-1604 (international). The passcode is 89631672. The video Webcast presentation is available at http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=67323&eventID=2077348. All participants are encouraged to view Dr. Okarma's presentation on the Internet. The video Webcast will also be accessible through a link that is posted on the home page of Geron's Web site at www.geron.com. Participants are encouraged to log on at least 15 minutes prior to the beginning of the presentation in order to download any necessary software. The video Webcast will be available for replay through February 23, 2009.

About Geron

Geron is developing first-in-class biopharmaceuticals for the treatment of cancer and chronic degenerative diseases, including spinal cord injury, heart failure and diabetes. The company is advancing an anti-cancer drug and a cancer vaccine that target the enzyme telomerase through multiple clinical trials. Geron is also the world leader in the development of human embryonic stem (hESC) cell-based therapeutics. The company has received FDA clearance to begin the world's first human clinical trial of a hESC-based therapy: GRNOPC1 for acute spinal cord injury. For more information, visit www.geron.com.

This news release may contain forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that statements in this press release regarding potential applications of Geron's human embryonic stem cell technology constitute forward-looking statements that involve risks and uncertainties, including, without limitation, risks inherent in the development and commercialization of potential products, uncertainty of clinical trial results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of our intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in Geron's periodic reports, including the quarterly report on Form 10-Q for the quarter ended September 30, 2008.

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