

GERON TO PROCEED WITH FIRST HUMAN CLINICAL TRIAL OF EMBRYONIC STEM CELL-BASED THERAPY

Geron to Study GRNOPC1 in Patients with Acute Spinal Cord Injury

MENLO PARK, Calif., July 30, 2010 – Geron Corporation (Nasdaq: GERN) announced today that the U.S. Food and Drug Administration (FDA) has notified the company that the clinical hold placed on Geron's Investigational New Drug (IND) application has been lifted and the company's Phase I clinical trial of GRNOPC1 in patients with acute spinal cord injury may proceed.



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

"We are pleased with the FDA's decision to allow our planned clinical trial of GRNOPC1 in spinal cord injury to proceed," said Thomas B. Okarma, Ph.D., M.D., Geron's president and CEO. "Our goals for the application of GRNOPC1 in subacute spinal cord injury are unchanged – 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. Additionally, we are now formally exploring the utility of GRNOPC1 in other degenerative CNS disorders including Alzheimer's, multiple sclerosis and Canavan disease."

The clinical hold was placed following results from a single preclinical animal study in which Geron observed a higher frequency of small cysts within the injury site in the spinal cord of animals injected with GRNOPC1 than had previously been noted in numerous foregoing studies. In response to those results, Geron developed new markers and assays as additional release specifications for GRNOPC1. The company completed an additional confirmatory preclinical animal study to test the new markers and assays, and subsequently submitted a request to the FDA for the clinical hold to be lifted.

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 ready to begin the clinical testing of 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. "We know that 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 found to be 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

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agree to have GRNOPC1 injected into the lesion sites between seven and 14 days after injury.



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, 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 Impairment Scale 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.

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.

Other Potential Neurological Indications for GRNOPC1

In addition to spinal cord injury, GRNOPC1 may have therapeutic utility for other central nervous system indications. Geron has established a number of collaborations with academic groups to test GRNOPC1 in selected animal models of human disease for which there is a strong rationale for the approach.

Alzheimer's Disease: Alzheimer's disease is a progressive, fatal, degenerative disorder that attacks the neurons in the brain, resulting in loss of memory, cognitive function such as reasoning and language, and behavioral changes. According to the Alzheimer's Association an estimated five million people in the United States have Alzheimer's disease. GRNOPC1 is being evaluated in animal models of Alzheimer's disease in collaboration with Professor Frank M. LaFerla, Director of the Institute for Memory Impairments and Neurological Disorders (UCI MIND) at the University of California, Irvine.

Multiple Sclerosis (MS): MS is an autoimmune disease that causes demyelination of nerve axons in the brain and spinal cord often progressing to physical and cognitive disability. There is currently no known cure for the disease. According to the National Multiple Sclerosis Society there are about 400,000 people in the United States with MS. GRNOPC1 is being tested in a non-human primate model of MS in collaboration with Professor Jeffery D. Kocsis of the Departments of Neurology and Neurobiology at Yale University School of Medicine and the Department of Veterans Affairs.

Canavan Disease: Canavan disease is a fatal neurological disorder that belongs to a group of genetic disorders called leukodystrophies, characterized by the abnormal development or degeneration of myelin. Symptoms of Canavan disease present in the first six months of life and death usually occurs at 3 – 10 years of age. GRNOPC1 is being tested in a rodent model of Canavan disease in collaboration with Dr. Paola Leone, Director of the Cell and Gene Therapy Center, at the University of Medicine and Dentistry of New Jersey.

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Background on GRNOPC1

Additional information on Geron's hESC programs and GRNOPC1 is available at Geron's website www.geron.com.



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 in different cancers. 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 protection 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 March 31, 2010.

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BACKGROUND

July 30, 2010



Human Embryonic Stem Cells

Human embryonic stem cells (hESCs) are nature's master stem cells. They are a self-renewing source for the scalable manufacturing of functional replacement cells for every tissue and organ in the body. The hESCs with which Geron works were derived from surplus *in vitro* fertilized embryos originally created as part of an *in vitro* fertilization (IVF) procedure. The embryos, which would otherwise have been destroyed, were donated for research by the parental donors under informed consent. The hESC line that is used to produce GRNOPC1 is the H1 line. 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.

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hESCs have two characteristics that make them different from other naturally occurring stem cells. First, they are immortal – they express the enzyme telomerase that enables the cells to divide endlessly in tissue culture. This allows scalable manufacturing of therapeutic cells derived from a master cell bank. Second, hESCs have the ability to differentiate into any of the more than 200 functional, specialized cells that make up the tissues and organs of the human body. Geron scientists have learned how to grow undifferentiated hESCs under carefully defined conditions, enabling them to be numerically expanded to form large cell banks (hundreds of vials of frozen undifferentiated hESCs) that serve as uniform starting material for manufacturing procedures that convert the undifferentiated hESCs into functional therapeutic cells. Geron scientists have learned how to manufacture seven different types of functional cells from hESCs:

- neural cells to treat chronic degenerative diseases of the nervous system;
- cardiomyocytes for the treatment of congestive heart failure and myocardial infarction;
- islets for the treatment of diabetes;
- chondrocytes for the treatment of osteoarthritis;
- hepatocytes for ADME drug testing;
- dendritic cells for immunotherapy for cancer and infectious diseases; and
- osteoblasts for the treatment of osteoporosis and bone fractures.

These functional cells are produced from hESCs by specific processes in which the frozen, banked hESCs are thawed, numerically expanded in their undifferentiated state and then treated with specific biologicals and growth factors to induce them to differentiate into specific functional cell types for therapeutic use. Each cell type requires a unique manufacturing "recipe." All of the differentiated cells produced by the manufacturing process are normal, healthy cells that have not been genetically modified and which have characteristics similar to the equivalent "natural" cell type present in the body.

Geron's hESC-derived Oligodendrocyte Progenitor Cells - GRNOPC1

Geron's first product manufactured from hESCs to enter clinical testing is GRNOPC1. GRNOPC1 is a population of living cells containing precursors to oligodendrocytes, otherwise known as oligodendrocyte progenitor cells (OPC). Oligodendrocytes are naturally occurring cells in the nervous system that have several functions. Oligodendrocytes produce myelin (insulating layers of cell membrane) that wraps around the axons of neurons to enable them to conduct electrical impulses. Myelin enables efficient conduction of nerve impulses in the same manner as insulation prevents short circuits in an electrical wire. Without myelin, many of the nerves in the brain and spinal cord cannot function properly. Oligodendrocytes also produce neurotrophic factors (biologicals that enhance neuronal survival and function) to support the maintenance of nerve cells. Oligodendrocytes are lost in spinal cord injury, resulting in myelin and neuronal loss that cause paralysis in many patients with spinal cord injuries.



In preclinical studies, GRNOPC1, when injected into the injury site of spinal cord-injured animals, migrate throughout the lesion site and mature into functional oligodendrocytes that remyelinate axons and produce neurotrophic factors (*Stem Cells and Development*, Vol. 15, 2006), resulting in improved locomotion in the treated animals.

The ultimate goal for the use of GRNOPC1 in man is to achieve spinal cord repair by injecting these cells directly into the spinal cord lesion.

The Pathology of Acute Spinal Cord Injury

Most human spinal cord injuries are due to contusions (bruises), rather than to a severing of the spinal cord. Most automobile, sports or industrial accidents cause a displacement or crush of the vertebral bodies in the cervical or thoracic spine that results in a contusion within the spinal cord, damaging the delicate nerve fibers at the site of the fracture. Spinal cord injuries cause severe inflammation within the spinal cord at the site of the fracture that is particularly toxic to the oligodendrocytes in the spinal cord.

GRNOPC1 Restores Locomotion in Rodent Models of Spinal Cord Injury

Geron scientists, in collaboration with Dr. Hans Keirstead's laboratory at the University of California, Irvine, developed a method to produce oligodendrocyte progenitor cells from hESCs. These cells were tested in a validated rodent model of acute spinal cord injury. Under anesthesia, animals were given a spinal cord contusion injury, mimicking what occurs in humans who suffer traumatic injury to the spinal cord. The lesions resulted in loss of truncal muscle function, bladder control and hind limb function. The injured animals received either no treatment, control cells or media, or one injection of GRNOPC1 within seven days after injury. Animals were then carefully followed and observed for locomotor recovery after the injury.

Injured animals treated with GRNOPC1 displayed significant improvement in a variety of functional parameters compared to control groups. GRNOPC1-treated animals had improved hind limb locomotor control. Paw placement, stride length and paw rotation all significantly improved compared to controls. When the GRNOPC1-treated animals were examined histologically, increased remyelination of axons in the injury site was observed compared to that in the control animals. An increased

number of axons were also observed in the vicinity of the injection within the injury. These animal results were published in the *Journal of Neuroscience*, Vol. 25, May 2005. In additional studies, the lesion site of animals nine months after injury and injection of GRNOPC1 was observed to be essentially filled with GRNOPC1 and myelinated rat axons crossing the lesion. These animal observations serve as the rationale for the use of GRNOPC1 in treating spinal cord injuries in man.

Animal Toxicology Testing of GRNOPC1

Geron has developed a manufacturing process to produce GRNOPC1 to standards required to begin human clinical trials. GRNOPC1 produced by this process was subjected to extensive toxicology testing to support the IND (Investigational New Drug) application and begin human clinical trials.

Absence of Teratoma Formation

A major concern for hESC-based therapies is the possible formation of teratomas (benign growths of unwanted cells) that may result from the injection of the therapeutic cells. Teratomas are thought to arise from contaminating, live, undifferentiated hESCs that may reside in the population of therapeutic cells.

Twelve-month in-life teratoma studies were undertaken to determine if clinical grade GRNOPC1 preparations could form teratomas *in vivo*. Uninjured and spinal cord-injured animals were maintained for up to 12 months after a single injection of clinical grade GRNOPC1. After sacrifice, animals were carefully examined histologically by trained neuropathologists for the presence of teratomas within the spinal cord. No teratomas were found in any animal injected in the spinal cord with clinical grade GRNOPC1. Positive control animals in which teratomas were found included animals that received pure, undifferentiated hESCs or GRNOPC1 preparations that were intentionally contaminated with at least 5% of live, undifferentiated hESCs. These data demonstrate the absence of teratoma formation one year after the injection of clinical grade GRNOPC1.

Cysts

In a very low number of animals, small cysts were observed in the regenerating injury site when examined histologically. These cysts were confined to the injury site, were smaller than the injury cavity and did not lead to any adverse consequences to the animals. A single animal study performed last year showed a higher frequency of these cysts than had been previously seen in the numerous foregoing animal studies that were submitted as part of the original IND. These new findings prompted the company to develop new molecular markers and release assays, which have been shown in animal studies to minimize the likelihood of cyst formation.

Absence of Significant Acute or Chronic Systemic Toxicity and Absence of Systemic Migration of GRNOPC1 Outside the Nervous System

A standard panel of acute and chronic toxicology studies was performed in rats and mice receiving injections of GRNOPC1. These studies examined both the GRNOPC1 product and the effects of its delivery to the injured spinal cord. Multiple hematology, clinical chemistry, urinalysis, and gross and microscopic pathology tests were performed on the spinal cord-injured rats that received GRNOPC1. No significant systemic toxicity was found. GRNOPC1 was not detected outside of the central nervous system in spinal cord-injected animals.

Absence of Allodynia

Injured rats injected with GRNOPC1 were tested for allodynia (pain induced by normally non-noxious stimuli). In these studies, control and GRNOPC1-treated animals were tested for abnormal behavioral responses to cold and mechanical stimuli placed at, above or below the area of injury. No evidence for allodynia was detected.

Absence of Direct Allogeneic Immune Response to GRNOPC1

GRNOPC1 is intended for implantation in the lesion site after spinal cord injury and will be an allograft in human subjects. Because of the potential for allograft rejection, studies were performed to determine the ability of GRNOPC1 to stimulate or be the target for humoral or cell-mediated immune responses. *In vitro* studies were performed to test human allogeneic antibody, T cell and NK cell responses to GRNOPC1. In these studies, GRNOPC1 was incubated with serum and cell samples from normal healthy volunteers and analyzed for either GRNOPC1 lysis or T cell proliferation (*Journal of Neuroimmunology*, Vol. 192, 2007). The collective *in vitro* immunological data suggest that GRNOPC1 does not have major susceptibility to direct humoral or cell-mediated alloimmune attack. These results serve as the rationale for short-term administration of low-dose immunosuppression in the clinical protocol.

The Clinical Program

The FDA-approved clinical study is a Phase I multi-center trial designed to assess the safety and tolerability of GRNOPC1 in patients with complete ASIA (American Spinal Injury Association) Impairment Scale grade A thoracic spinal cord injuries. Spinal cord injuries are graded in severity according to the ASIA Impairment Scale (AIS) – grade A being the most severe with complete loss of locomotor and sensory activity below the site of the injury. Most such patients do not recover function or respond significantly to physical therapy. The first subjects to receive GRNOPC1 under the clinical protocol will be AIS grade A injured patients with a thoracic injury resulting in a neurological level of T₃ to T₁₀. The therapeutic protocol is also limited to subjects with subacute injuries – injuries that can be treated with GRNOPC1 within seven to 14 days after the injury. Animal studies have demonstrated that GRNOPC1 injections are ineffective if administered more than three months after the injury due to the scarring that occurs in the injured cord as part of the inflammatory response to spinal cord injury.

GRNOPC1 will be injected by qualified, trained spine surgeons seven to 14 days post-injury to patients who give informed consent and also have appropriate laboratory, physical and radiographic characteristics that verify the location and severity of the injury. Because the injection of GRNOPC1 must be precisely controlled, Geron has developed a syringe positioning device that attaches to the frame of the operating room table and enables the spine surgeon to precisely control the needle placement and penetration into the lesion site. All participating spine surgeons will be trained in the use of this device as part of the clinical trial site initiation protocol.

The primary endpoint of the study is safety. Standardized physical examinations and neurological testing will be administered before and after the injection of GRNOPC1 at specified time points for one year after the injection to monitor safety parameters. The secondary endpoint of efficacy will use similar testing for evidence of any return

of sensory function or lower extremity motor function for one year after injection of GRNOPC1. Subjects will be immune-suppressed from the time of injection with low-dose tacrolimus for 46 days, at which time the immune suppression will be tapered and withdrawn at 60 days. Subjects will be monitored for a total of 15 years after administration of GRNOPC1.

Geron has selected seven U.S. medical centers as candidates to participate in this study and in the planned protocol extensions. The sites are leading referral centers for neurotrauma with experienced, board-certified spine surgeons who will perform the GRNOPC1 injections. Each of the participating medical centers is affiliated with a qualified long-term rehabilitation center where the long-term assessment for safety and efficacy for each treated patient will take place using standard tests administered by trained rehabilitation specialists.



After safety is demonstrated in the initial group of subjects, Geron plans to seek FDA approval to extend the study to increase the dose of GRNOPC1, enroll patients with complete cervical injuries, and, ultimately, expand the trial to include patients with severe, incomplete (AIS grade B or C) injuries to test the safety and utility of GRNOPC1 in as broad a range of severe spinal cord-injured patients as medically appropriate.

Production and Qualification of GRNOPC1

GRNOPC1 is a cryopreserved cell population containing a mixture of oligodendrocyte progenitor cells and other characterized cell types that are produced by a specific differentiation protocol from a master cell bank of H1 undifferentiated hESCs that has been qualified for human use. GRNOPC1 is produced under current Good Manufacturing Practices (cGMP) in Geron's qualified manufacturing facilities. The GRNOPC1 manufacturing process in Geron's clean room suites has been inspected and licensed by the state of California.

The manufacturing process consists of three stages: 1) numerical expansion of undifferentiated hESCs obtained from the qualified H1 hESC master cell bank, 2) differentiation of the expanded hESCs into GRNOPC1, and 3) harvest, formulation, fill and cryopreservation of the GRNOPC1 drug product. The manufacturing protocol specifies the sequential addition of biologicals and growth factors to induce the expansion and progressive differentiation of undifferentiated hESCs into the GRNOPC1 drug product. A significant portion of each manufacturing run of GRNOPC1 is retained and subjected to extensive quality control testing to ensure the identity, sterility, viability and cellular composition of each manufacturing run before the product is released to the sites for clinical use.

Intellectual Property

The production and commercialization of GRNOPC1 is protected by three separate patent estates owned by or exclusively licensed to Geron. Geron funded the work at the University of Wisconsin-Madison that led to the original derivation of hESCs. Accordingly, Geron maintains an exclusive license to the issued fundamental WARF patents covering hESCs for the production of neural cells, cardiomyocytes and pancreatic islets for therapeutic applications. Additionally, GRNOPC1 is protected by an exclusive license to Geron from the University of California covering technology developed in a research collaboration between Geron and the University of California scientists that led to the discovery of the method to produce oligodendrocyte progenitors from hESCs. Finally, GRNOPC1 is protected by an expanding patent

estate of pending and issued patents owned by Geron covering novel technologies for undifferentiated hESC expansion, scalable cell manufacturing methods and the production of specific therapeutic cell preparations.

About Geron

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