



OSIRIS THERAPEUTICS, INC.

Osiris Cleared by FDA to Begin Stem Cell Trial for Knee Repair

The announcement marks the third adult stem cell product that Osiris has in human clinical trials.

Baltimore, MD, April 1, 2005 – Osiris Therapeutics, Inc. announced today that it has received clearance from the U.S. Food and Drug Administration to begin enrollment in the first human clinical trial for a stem cell therapy targeted at injured tissue in knee surgery patients. Chondrogen™, a formulation of adult mesenchymal stem cells, will be evaluated in a forty-eight patient, randomized trial to be conducted at the University of Southern California's University Hospital. The Phase I/II study will evaluate the safety and efficacy of the stem cell treatment for the regeneration of meniscus.

“Given the complexity of considerations involved in a stem cell clinical trial, I am proud that our team has been able to once again provide the FDA with the data necessary to move a product into the clinic,” said C. Randal Mills, Ph.D., President and CEO of Osiris. “They did an excellent job conducting and compiling a large amount of research. Our focus now turns to executing the clinical trial.” Chondrogen joins Prochymal™ and Provacel™ in the family of stem cell products under human clinical testing by Osiris.

In the U.S. alone, approximately 800,000 people each year have surgery to remove a portion of damaged meniscus, a cartilage-like tissue in the knee that acts as a shock absorber. In several large animal studies, Chondrogen has demonstrated the potential to regenerate the excised meniscus, as well as prevent the typical progression to osteoarthritis associated with this procedure.

“Patients who require removal of their damaged meniscus are at a much higher risk of developing arthritis,” said C. Thomas Vangsness, MD, Professor of Orthopedic Surgery at USC's Keck School of Medicine and Chief of Sports Medicine at University Hospital. “To provide my patients the opportunity to regrow their own, naturally functioning meniscus would be revolutionary for the treatment of knee injuries and for the practice of sports medicine.” Dr. Vangsness will serve as the Principal Investigator in the trial.

Regarding the relationship with USC, Mills said, “We are honored to be working with an institution of such high caliber. With their clinical expertise and Osiris' technology and resources, this study will be the foundation for a future pivotal trial and eventual product launch.”

Chondrogen, which has been in development at Osiris since 1999, has shown encouraging preclinical results that served as the basis for FDA's decision to allow the first human treatments with the therapy. “The evidence suggests that a simple injection of MSCs into the knee has the potential to regenerate healthy meniscus,” said Dr. Vangsness. “If these results are confirmed in humans, the impact will be enormous.”

Osiris Therapeutics, Inc. is the leader in adult stem cell therapy. The stem cells produced by Osiris are obtained from adult volunteer donors, avoiding the technical problems and controversy surrounding other stem cell technologies. Using proprietary methods, these cells are grown in culture to very high numbers, allowing a single donor's cells to treat hundreds of patients. These cells are universal in that they can be used in patients unrelated to the donor, without rejection, eliminating the need for donor matching and recipient immune suppression. Once transplanted, the cells promote healing of damaged or diseased tissues. The Company's current focus is the use of adult stem cells to improve outcomes in bone marrow recipients being treated for leukemia, to promote cardiac repair following a heart attack or congestive heart failure, and to prevent arthritis.

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