

# Osiris Launches the First Trial Using Adult Universal Stem Cells in Cardiac Patients

## Landmark Study Focuses on Promising Therapy for the Treatment of Heart Disease

BALTIMORE -- March 31, 2005 -- Osiris Therapeutics, Inc. announced today that it has begun a multi-center, randomized clinical trial with Provacel(TM), a novel therapeutic based on adult mesenchymal stem cells (MSCs). "We are extremely enthusiastic about this study which represents the first use of an allogeneic adult stem cell to treat the consequences of heart attack in humans. The trial design is supported by an extensive series of preclinical studies performed in animal models that demonstrate that MSCs safely and effectively reduce the damage caused by heart attack," said lead investigator Dr. Joshua Hare, Director of Heart Failure and Cardiac Transplantation and the Cardiobiology Section of the Institute for Cell Engineering at Johns Hopkins University School of Medicine.

Enrollment in the Phase I study began March 24. It is being conducted in accordance with U.S. Food and Drug Administration guidelines, and is designed to evaluate safety and investigate the therapeutic benefits of treatment with allogeneic adult MSCs.

"Our investigators, hospitals, and team have worked exceptionally well together to advance the trial to this point," said C. Randal Mills, PhD, President and CEO of Osiris Therapeutics. "We remain committed to bringing this and other revolutionary treatments to patients who need them, while making every effort to ensure their safety by conducting tightly controlled clinical studies."

Osiris is evaluating Provacel with pioneers in the cardiac research field at leading U.S. institutions. "We are investigating an exciting new approach to address the unmet needs of cardiac patients," said Dr. Nabil Dib, Chief of Cardiovascular Research at the Arizona Heart Institute, another investigator in the trial. "According to the American Heart Association, about two thirds of heart attack patients never completely recover. This is due to the fact that heart cells can't repair themselves, so we have to try innovative ways to treat the damage that occurs at the time of heart attack. If the research conducted to date is any indication, mesenchymal stem cells may be the answer."

Provacel is a formulation of MSCs shown to repair damaged tissue. A unique benefit of the product is that it is given to patients through a standard IV line. The delivered cells, responding to the body's own signals, migrate to the area of injury. Osiris recently became the first company to receive Fast Track designation from FDA for a similar stem cell product, Prochymal(TM), for the treatment of graft versus host disease in cancer patients.

*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 includes the use of adult stem cells to improve outcomes in bone marrow recipients being treated for leukemia, to promote cardiac repair resulting from a heart attack or congestive heart failure, and to prevent arthritis.*