



Osiris Completes Enrollment in Stem Cell Trial to Treat Cardiac Disease

April 5, 2006 – Baltimore, Maryland - Osiris Therapeutics, Inc. announced today that it has completed enrollment in a human clinical trial designed to evaluate the safety and preliminary effectiveness of its universal adult stem cell drug candidate Provacel™, being developed to treat patients suffering from heart attacks. A total of 53 patients were enrolled in the Phase I trial at ten leading heart centers across the country.

“The potential to repair heart damage using stem cells is one of the most exciting areas in cardiology,” said Cardiologist Jay Traverse, M.D., Assistant Professor of Medicine at the University of Minnesota. Dr. Traverse is an investigator in the Provacel trial at Abbott Northwestern Hospital and is involved in several other trials evaluating stem cell therapies for myocardial repair. “What is really significant here is the opportunity to treat patients with a universal stem cell.”

The adult stem cell products being developed by Osiris are unique in that they do not require patient-specific matching. The stem cells are mass-produced in the Company’s Baltimore headquarters, frozen, and shipped to hospitals around the country where they are stored until needed. “Having a stem cell product readily available would give us the ability to treat patients in the acute setting,” said Dr. Traverse.

“At Osiris, patient safety comes first. Establishing an excellent safety profile is an essential step in the responsible development of our universal stem cell technology,” said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. “The company continues to gain momentum as it executes on its plans to make stem cell therapies available to patients.”

Provacel is a formulation of adult stem cells being developed to repair damaged heart tissue. A key feature of Provacel is that it is given to patients through a standard IV line. In pre-clinical studies the cells responded to chemical signals given off by the heart following injury. These signals attracted the cells specifically to the area of injury, where they participated in repair.

“If this cell based therapy is proven to be safe and effective in human trials, it could represent a major advancement in the treatment of heart attack patients,” said lead investigator Dr. Joshua Hare, Director of Heart Failure and Cardiac Transplantation at Johns Hopkins University. Dr. Hare was the first investigator to treat patients in the study. “The universal nature of the product combined with its ease-of-use would make it possible for cardiologists to treat patients in almost any setting.”

The trial is a double blind, placebo controlled Phase I study 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 stem cells obtained from healthy, unrelated adult donors. In accordance with the design of the trial, an independent safety monitoring board conducted two formal reviews of the data while the trial was in progress. During the reviews, the board evaluated safety data of patients treated with the drug as compared to those receiving placebo. Based on predetermined criteria for the severity and number of treatment related adverse events, the board twice unanimously concluded that the trial should proceed.

“We want to thank the outstanding physicians and health care professionals who participated in this trial,” said Michael Archambault, Program Director for Provacel. “We look forward to continuing to work with this team in capturing and evaluating the data.”

Osiris is developing Provacel as part of a strategic alliance with Boston Scientific Corporation (NYSE: BSX) for development and commercialization of Osiris’ mesenchymal stem cell technology in the cardiac field. “Completion of enrollment certainly reinforces our excitement about Osiris’ potential to provide a new stem cell therapy for heart attack patients,” said Jim Barry, Boston Scientific Vice President for Corporate Research and Advanced Technology Development.



The Provacel trial is one of five Osiris stem cell clinical trials currently active in the U.S. In addition, the company has two Phase II trials for Graft vs. Host Disease, a life threatening complication of bone marrow transplantation, a Phase II trial for Crohn's Disease, and a Phase I/II trial for the regeneration of cartilage in the knee.

About Osiris Therapeutics

Osiris® Therapeutics, Inc. is a 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 thousands of patients. These cells have been used in patients unrelated to the donor, without rejection, eliminating the need for donor matching and recipient immune suppression. Once transplanted, the cells have been shown to 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 cancer, to treat Crohn's Disease, to repair damage following a heart attack or congestive heart failure, and to prevent and treat arthritis.

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