



Osiris Therapeutics Initiates Phase II Clinical Trial Evaluating Prochymal™ for Type 1 Diabetes

Juvenile Diabetes Research Foundation Provides \$4 Million in Funding to Support Clinical Development of Leading Cell Therapy

COLUMBIA, Maryland – October 25, 2007 – Osiris Therapeutics, Inc. (NASDAQ:OSIR) today announced the initiation of a Phase II clinical trial evaluating Prochymal, a stem cell therapy, as a treatment for type 1 diabetes. Through a partnership with the Juvenile Diabetes Research Foundation (JDRF), the organization has provided \$4 million in funding to support the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus.

Type 1 diabetes, commonly known as juvenile diabetes or insulin-dependent diabetes, is an autoimmune disorder that attacks and destroys insulin producing islet cells in the pancreas causing glucose accumulation in the blood. As a result, those suffering from type 1 diabetes must take insulin to regulate blood sugar levels. Over time, poorly controlled diabetes can lead to serious health conditions, including heart disease, stroke, blindness, amputations, kidney disease and nerve damage. Currently, there are no preventative measures for type 1 diabetes. In preclinical research, both animal and human bone marrow-derived mesenchymal stem cells (MSCs) were shown to preserve beta cell function in animal models of diabetes.

"A critical unmet need in the treatment of type 1 diabetes, which currently affects as many as 3 million people in the country, is addressing the autoimmune attack that causes the disease," said Richard Insel, M.D., Executive Vice President of Research at JDRF. "The development of an immunomodulatory cell therapy that could address the underlying inflammatory and immunological dysregulation and preserve islet cell function would be groundbreaking. The safety and efficacy data for Prochymal warrants further evaluation in type 1 diabetes. We look forward to working with Osiris to develop new treatment options for patients with this debilitating disease."

"While improvements in diabetes management and the use of newer formulations of insulin have certainly improved the lifestyle and potentially the outlook for those with type 1 diabetes, those efforts still do not represent a cure," said Dr. Mark Atkinson, an Eminent Scholar for Diabetes Research at the University of Florida. "We are excited by the promising research that has been conducted by Osiris in this new field of stem cell therapy, and are hopeful that safe and more effective treatment options will ultimately result from this effort, one that will truly lead to a cure for this disease."

This marks the fifth indication for which the therapy has been granted approval to proceed into the clinical stages of testing. Osiris recently announced FDA clearance to begin a Phase III clinical trial evaluating Prochymal as a treatment for acute Graft versus Host Disease (GVHD), a life threatening reaction of the immune system for which there is no treatment. In the Phase II trial for acute GVHD, Prochymal was well tolerated and demonstrated a 77 percent complete remission rate.

"Prochymal has shown promise in Phase II clinical trials as a therapy for severe immune mediated conditions including Crohn's Disease and GVHD, and as a result has advanced into Phase III pivotal trials," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "It is appropriate to evaluate related conditions such as type 1 diabetes, where data indicates Prochymal may also be of therapeutic benefit. We are honored that JDRF has selected Prochymal as a promising new therapy for evaluation."

"As a person living with type 1 diabetes since childhood, the opportunity to help develop a stem cell therapy for the disease is very exciting," said Sharron McCulloch, the Osiris study coordinator for the type 1 diabetes trial. "Proper control of blood glucose with insulin injections can be difficult. With this trial, we hope to build upon the exciting pre-clinical research that has shown MSCs can delay or prevent the need for insulin therapy."

About the Phase II Type 1 Diabetes Trial

The Phase II trial will evaluate the safety and efficacy of Prochymal in conjunction with standard of care in preserving insulin production in patients recently diagnosed with type 1 diabetes mellitus. The design will be a double-blind, placebo-controlled trial with a target enrollment of 60 patients. The primary endpoint of the



trial will be the measurement of C-peptide produced during a Mixed Meal Tolerance Test in patients treated with Prochymal, compared to those receiving placebo. This test is frequently used in diabetic patients to determine how much insulin is being produced by the pancreas in response to glucose stimulation.

About Prochymal

Prochymal is a preparation of mesenchymal stem cells specially formulated for intravenous infusion. The stem cells are obtained from the bone marrow of healthy adult donors. Prochymal is currently being evaluated in two separate, double-blind, placebo-controlled Phase III pivotal trials for the treatment of GVHD. Each Phase III study for GVHD serves as a stand alone trial before the product is submitted to FDA, Canadian and European regulatory agencies for full approval. Prochymal is also being studied in Phase III trials for the treatment of moderate to severe treatment refractory Crohn's Disease. Prochymal has been granted Fast Track status by FDA for both GVHD and Crohn's Disease. Prochymal also obtained Orphan Drug status by FDA and EMEA for steroid refractory GVHD. FDA established the Fast Track program to accelerate the development of drugs that show promise for treating life-threatening conditions. Orphan Drug designation provides incentives to companies that develop drugs for underserved patient populations.

Cell mediated inflammatory diseases result in high levels of pro-inflammatory chemical signals called cytokines. These cytokines cause the unbalanced activation of certain immune cells that result in tissue damage. Delivered intravenously, Prochymal is able to target areas of active inflammation. Published data indicates that Prochymal is able to down-regulate the production of pro-inflammatory cytokines, including tumor necrosis factor-alpha or TNF-alpha and interferon-gamma. Additionally, Prochymal up-regulates the production of beneficial anti-inflammatory cytokines, specifically interleukin-4 and interleukin-10. When the stem cells found in Prochymal are delivered into an inflammatory environment, they appear to change the course of the disease by altering the cytokine secretion profile of the dendritic and T cell subsets, thereby resulting in a shift from a pro-inflammatory to an anti-inflammatory state and arresting disease progression. Furthermore, data indicates Prochymal may also promote the regeneration of tissue structures damaged in the inflammatory process.

About JDRF

JDRF was founded in 1970 by the parents of children with juvenile diabetes—a disease that strikes children suddenly, makes them insulin dependent for life, and carries the constant threat of devastating complications. Since inception, JDRF has provided more than \$1.2 billion to diabetes research worldwide. More than 80 percent of JDRF's expenditures directly support research and education about research. JDRF's mission is constant: to find a cure for diabetes and its complications through the support of research. For more information about JDRF, please visit www.jdrf.org.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Osiris currently markets and sells Osteocel® for regenerating bone in orthopedic indications. Prochymal™ is in Phase III clinical trials for both Graft versus Host Disease and Crohn's disease and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris has also partnered with Genzyme Corporation to develop Prochymal™ as a medical countermeasure to nuclear terrorism and other radiological emergencies. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for arthritis in the knee, and Provacel™, for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. Osiris has developed an extensive intellectual property portfolio to protect the company's technology in the United States and a number of foreign countries including 47 U.S. and 211 foreign patents owned or licensed. More information can be found on the company's website, www.Osiris.com. (OSIR-G)



Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for MSCs and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding our facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled "Risk Factors" in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission. Accordingly, you should not unduly rely on these forward-looking statements. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this press release or to reflect the occurrence of unanticipated events.

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