



Osiris Achieves Milestone Payment for Progress Developing Stem Cell Therapy for Type 1 Diabetes

Review of Safety Data Leads to Expansion of Clinical Trial to Include Pediatric Patients

COLUMBIA, Md., Jul 28, 2009 (BUSINESS WIRE) -- [Osiris Therapeutics, Inc.](#) (NASDAQ:OSIR) today announced that it has achieved a \$750,000 milestone payment from the [Juvenile Diabetes Research Foundation \(JDRF\)](#) for progress made on a Phase II clinical trial evaluating Prochymal, an adult mesenchymal stem cell (MSC) therapy, as a treatment for patients recently diagnosed with type 1 diabetes. The payment was triggered after one-half of the patients in the 60-participant study were enrolled, a milestone in the funding agreement with the JDRF. The trial is also being expanded to include pediatric patients, opening enrollment to patients between 12 and 35 years of age. Osiris and the JDRF entered into a [partnership](#) in 2007 for the development of Prochymal as a therapy for newly diagnosed type 1 diabetes mellitus.

The change to the entry criteria will help ensure that the study includes the population most likely to benefit from a therapy designed to intervene in the early stages of the disease. To support expanding the age range in the trial, early, blinded data from the ongoing type 1 diabetes trial was submitted to the Food and Drug Administration (FDA) for review. Additionally, updated safety information on Prochymal from experience with pediatric patients in other indications, including the pediatric expanded access program for graft vs. host disease (GvHD), was submitted.

"We are proud to be working alongside the JDRF in this landmark trial to evaluate the role of mesenchymal stem cells in patients with type 1 diabetes," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. "Caring for kids with limited medical options is a very special part of life at Osiris and we take that responsibility seriously. The progress we are making in this clinical program is remarkable and would not be possible without our patients, clinical teams, and the FDA's thoughtful and responsive assistance."

In [type 1 diabetes](#), the patient's own immune system attacks and destroys insulin-producing islet cells in the pancreas, resulting in the loss of blood-sugar control. Currently, there are no approved treatments for altering the rate of destruction of these critical islet cells, called beta cells. Preclinical studies first conducted by researchers at Genzyme found that MSCs may have the ability to delay the progression of type 1 diabetes by preserving beta cell function. In clinical trials, Prochymal has already shown promise for treating GvHD, a severe immune-mediated disease. Prochymal is currently in Phase III trials for acute and steroid-refractory GvHD, indications that have been granted Fast Track status by the FDA.

For more information about the trial and how to participate, please visit the Osiris Web site at www.Osiris.com.

About the Phase II Type 1 Diabetes Trial

The Phase II trial is evaluating the safety and efficacy of Prochymal in preserving insulin production in patients 12 to 35 years old recently diagnosed with type 1 diabetes. To be eligible, candidates must be diagnosed two to twenty weeks prior to participation in the study. The design is a double-blind, placebo-controlled trial at 20 U.S. medical centers with a target enrollment of 60 patients. The primary endpoint of the trial will be the measurement of C-peptide produced after glucose stimulation. This test is frequently used in diabetic patients to assess the pancreas' ability to produce insulin. Patients will be followed for safety and efficacy for a total of two years.

About Prochymal

Prochymal is a preparation of mesenchymal stem cells specially formulated for intravenous infusion. These adult stem cells are obtained from the bone marrow of healthy adult donors, avoiding the controversy surrounding embryonic and fetal cell sources. Prochymal is currently being evaluated in three, double-blind, placebo-controlled Phase III studies, including steroid refractory GvHD, acute GvHD, and Crohn's disease. Prochymal has been granted Fast Track status by FDA for all three of these indications. Prochymal also obtained Orphan Drug status by FDA and the European Medicines Agency for GvHD. Prochymal is also being studied in Phase II trials for the treatment of acute myocardial infarction, COPD and type 1 diabetes. Additionally, the Department of Defense awarded Osiris a contract to develop Prochymal as a treatment for acute radiation syndrome.

About Juvenile Diabetes Research Foundation

JDRF is a leader in setting the agenda for diabetes research worldwide, and is the largest charitable funder and advocate of

type 1 research. The mission of JDRF is to find a cure for diabetes and its complications through the support of research. Type 1 diabetes is a disease which strikes children and adults suddenly and requires multiple injections of insulin daily or a continuous infusion of insulin through a pump. Insulin, however, is not a cure for diabetes, nor does it prevent its eventual and devastating complications which may include kidney failure, blindness, heart disease, stroke, and amputation.

Since its founding in 1970 by parents of children with type 1 diabetes, JDRF has awarded more than \$1.3 billion to diabetes research, including more than \$100 million in FY2009, including centers, grants and fellowships in more than 20 countries.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is the leading stem cell therapeutic company focused on developing products to treat serious medical conditions in the inflammatory, orthopedic and cardiovascular areas. The Company's pipeline of internally developed biologic drug candidates under evaluation includes Prochymal for inflammatory, autoimmune, and cardiovascular indications, as well as Chondrogen for arthritis in the knee. Osiris is a fully integrated company, with capabilities in research, development, manufacturing, and distribution of stem cell products. Osiris has developed an extensive intellectual property portfolio to protect the company's technology including 49 U.S. patents each having one or more foreign counterparts. Osiris, Prochymal and Chondrogen are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

In November 2008, Osiris and Genzyme announced a strategic alliance for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, Osiris retains commercialization rights to Prochymal and Chondrogen in the United States and Canada, with Genzyme having these rights in all other countries.

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 and the ability to successfully navigate these 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 Prochymal, Chondrogen and our other MSC and biologic drug candidates; our cash needs; patents and proprietary rights; the safety and ability of our potential products to treat disease and the results of our scientific research; 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. Risks and uncertainties related to the sale of our Osteocel assets and related transactions include typical business transactional risks, the risk of changing relationships with customers, suppliers or employees; and the risk that we may not be able to fully perform or generate or receive milestone payments. Risks and uncertainties related to our Collaboration Agreement with Genzyme for the development and commercialization of Prochymal and Chondrogen include, among others: typical business transactional risks; risks related to product development and clinical trial design, performance and completion; uncertainty of the success of Prochymal and Chondrogen in clinical trials and their ability to treat disease; Genzyme's early termination and opt-out rights; the ability of Osiris and Genzyme to successfully navigate regulatory requirements and to manufacture and commercialize products; and the uncertainty as to our ability to successfully perform under the collaborative arrangement and earn milestone and royalty payments thereunder. 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 and other Periodic Reports filed on Form 10-Q, 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.

SOURCE: Osiris Therapeutics, Inc.

Osiris Therapeutics, Inc.
Erica Elchin, 443-545-1834
OsirisPR@Osiris.com

or

Media Contacts:

Schwartz Communications

Stacey Holifield/Andrew Law
781-684-0770
Osiris@schwartz-pr.com

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