



## Osiris Therapeutics Provides Update on Groundbreaking Stem Cell Trial for Type 1 Diabetes

**COLUMBIA, Md. – January 3, 2012** - [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), today provided an update on its Phase 2 trial evaluating Prochymal, a formulation of adult mesenchymal stem cells (MSCs), in patients with newly diagnosed type 1 diabetes. This first-of-its kind trial, conducted in partnership with JDRF, is testing MSCs from unrelated adult donors in 63 pediatric and adult patients to assess the safety of MSCs in this population and whether the treatment shows signs of slowing progression of the disease. Participants were randomly assigned to receive either Prochymal or placebo, and both the physicians and patients remain blinded as to which patients received stem cells.

The interim assessment at one year showed that systemic infusions of Prochymal were well-tolerated in this unique population. There were no differences in adverse event rates between the Prochymal and placebo groups. Importantly, no patients experienced a reaction to the infusions despite the cells being unrelated to the recipient, unmatched, and used without immunosuppression. No significant differences in the rates of disease progression, as measured by stimulated C-peptide levels at the one year time point, have been observed. However there was a trend towards fewer hypoglycemic events for patients treated with Prochymal as compared to controls. The patients will be followed for another year (for a total of two years), after which time a complete analysis of the data will be conducted.

"This groundbreaking study is an important first step in the use of stem cells to potentially alter the course of type 1 diabetes," said Jay S. Skyler, M.D., Professor of Medicine and Deputy Director of the Diabetes Research Institute at the University of Miami Miller School of Medicine. "The ability to safely use stem cells from unrelated donors is an important finding of this study and provides new possibilities for further development of stem cell therapies for type 1 diabetes."

Prochymal is designed to provide therapeutic benefit by controlling inflammation, promoting tissue regeneration, and preventing scar formation. 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.

### About Osiris Therapeutics

Osiris Therapeutics, Inc. is the leading stem cell company focused on developing and marketing products to treat medical conditions in inflammatory and cardiovascular disease areas and wound healing. Osiris currently markets and sells Grafix and Ovation for tissue repair. 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 46 U.S. and 144 foreign patents.

Osiris formed a strategic alliance with Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, Osiris has commercialization rights to Prochymal and Chondrogen in the United States and Canada. Genzyme holds these rights in all other countries except Japan, where JCR Pharmaceuticals holds rights to Prochymal for the treatment of patients with hematological malignancies.



Osiris, Prochymal, Graftix and Ovation are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, [www.Osiris.com](http://www.Osiris.com). (OSIR-G)

### **About JDRF**

JDRF is the leading global organization focused on type 1 diabetes (T1D) research. Driven by passionate, grassroots volunteers connected to children, adolescents, and adults with this disease, JDRF is now the largest charitable supporter of T1D research. The goal of JDRF research is to improve the lives of every person affected by T1D by accelerating progress on the most promising opportunities for curing, better treating, and preventing T1D. JDRF collaborates with a wide spectrum of partners who share this goal. Since its founding in 1970, JDRF has awarded more than \$1.6 billion to diabetes research. Past JDRF efforts have helped to significantly advance the care of people with this disease, and have expanded the critical scientific understanding of T1D. JDRF will not rest until T1D is fully conquered. More than 80 percent of JDRF's expenditures directly support research and research-related education.

For more information, please visit [www.jdrf.org](http://www.jdrf.org).

### **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 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.

**For additional information, please contact:**

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