

Osiris Therapeutics Announces Cardiac Stem Cell Therapy Presentation at BMT Tandem Meeting

Joshua Hare, M.D. to Present Recently Published Data Demonstrating the Safety and Effectiveness of Prochymal for Acute Myocardial Infarction

COLUMBIA, Md. - February 24, 2010 – [Osiris Therapeutics, Inc.](#) (NASDAQ:OSIR) today announced that data from a 53-patient double-blind, placebo controlled trial studying the treatment of heart attack patients with Prochymal, a proprietary formulation of mesenchymal stem cells (MSCs), as well as research on the underlying mechanism of action of MSCs for cardiac repair, will be presented at the [2010 BMT Tandem Meeting](#). Joshua M. Hare, M.D., Louis Lemberg Professor of Medicine (Cardiology) and Director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine, will present the data during a session entitled “Cardiac Stem Cell Therapy” on Thursday, February 25. Results from the study were recently published in the *Journal of the American College of Cardiology* (JACC).

“Patients receiving Prochymal did better than those receiving only standard-of-care,” said Dr. Hare, lead author of the JACC publication. “They had fewer side effects and significant improvements in heart, lung and global function compared to the placebo group. The efficacy seen in this well-controlled trial represents an important step forward in the search for stem cell treatments for heart disease. With a strong safety profile that now includes more than 1,000 patients studied in clinical trials, mesenchymal stem cells are in a position to make significant advances in the field of cardiology.”

The study demonstrates that treatment with [Prochymal](#) was safe in cardiac patients with recent heart attacks. Additionally, Prochymal significantly improved cardiac function and patient global symptom score, and reduced cardiac arrhythmias (irregular heartbeat), compared to placebo. The [abstract](#) and full-length manuscript are available online at the JACC’s website. Based on these positive findings, a larger Phase II study in patients who have recently experienced severe acute myocardial infarction is underway.

About the Ongoing Acute Myocardial Infarction Trial

The Phase II double-blind, placebo-controlled trial will evaluate the safety and efficacy of Prochymal in conjunction with standard of care to improve heart function in patients who experienced a first heart attack. The trial will be conducted at leading institutions and academic research centers in the United States and Canada. This trial involves patients who have suffered a severe myocardial infarction, defined as left ventricular ejection fraction, or LVEF, between 20% and 45% at baseline. LVEF, which reflects the fraction of blood pumped out of a ventricle with each heart beat, is a common measurement of overall heart function and typically declines after a heart attack. The target enrollment is 220 patients, and patients will be randomized to Prochymal or placebo at 1:1. Efficacy endpoints determined from cardiac MRI include end systolic volume, LVEF and the ability of Prochymal to preserve functional heart tissue, or limit scar formation following a heart attack. In addition, functional and quality-of-life assessments will be performed.

About Prochymal

Prochymal is a preparation of mesenchymal stem cells (MSCs) formulated for intravenous infusion. The MSCs utilized in Prochymal are isolated from the bone marrow of healthy young adult donors, avoiding the controversy surrounding embryonic and fetal cell sources. They are grown in culture, permitting large-scale production. Because the cells can be expanded, thousands of doses can be produced from a single donation. Studies suggest MSCs are able to safely facilitate tissue repair through a number of mechanisms. Specifically, these studies indicate that MSCs are able to down-regulate severe inflammation and work at the cellular level to rebuild damaged tissue through the coordinated release of tissue-specific growth factors.

Prochymal is being evaluated in Phase III programs for steroid-refractory graft vs. host disease (GvHD), acute GvHD and Crohn’s disease. Prochymal has been granted Fast Track status by the FDA for GvHD and Crohn’s disease, and is the first stem cell product to receive FDA expanded access approval, making the product available now to patients with life-threatening GvHD. Prochymal obtained Orphan Drug status for GvHD from the FDA and the European Medicines Agency. This stem cell therapy is also being studied in Phase II trials for the treatment of acute myocardial infarction, pulmonary disease and type 1 diabetes.

About Osiris Therapeutics



[Osiris Therapeutics, Inc.](http://www.Osiris.com) 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 holding 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 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.

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