



Osiris Reports Positive Two-Year Data on Stem Cell Treatment for Acute Myocardial Infarction

Prochymal Shows Lasting Clinical Benefit in Heart Attack Patients

COLUMBIA, Maryland – February 12, 2009 – Osiris Therapeutics, Inc. (NASDAQ: OSIR) today announced the final two-year results for the Company's trial evaluating Prochymal[®] for the treatment of acute myocardial infarction. Prochymal is a proprietary formulation of adult stem cells designed to provide therapeutic benefit by controlling inflammation, promoting tissue regeneration, and preventing scar formation. This double-blind, placebo-controlled study of 53 patients, which evaluated safety and preliminary efficacy, found heart attack patients receiving the intravenous therapy had lower rates of adverse events and significantly improved heart function.

Important Findings Include:

- The trial met its primary endpoint demonstrating safety of Prochymal in the acute MI setting.
- Patients receiving Prochymal had fewer adverse events compared to placebo.
- A lower percentage of patients treated with Prochymal required repeat hospitalization.
- Patients receiving Prochymal had reduced incidence of cardiac arrhythmia.
- Patients receiving Prochymal had a significant and durable improvement in cardiac function.

"This study adds convincing long-term data to the excellent safety profile of Prochymal, having now treated hundreds of patients in trials over the past decade," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "We are excited that Prochymal demonstrated strong evidence of efficacy beyond the best cardiac care available today. We are now advancing this program into a larger Phase II trial, focusing on patients with more severe heart damage."

Recently, Osiris completed enrollment in a Phase III trial of Prochymal for the treatment of steroid-refractory acute graft versus host disease (GvHD). In January, clearance from U.S. Food and Drug Administration (FDA) was received to broaden the expanded access program for Prochymal, now making the investigational stem cell product available to adults, as well as pediatric patients, with life-threatening GvHD. In 2008, Osiris and Genzyme Corp. announced a strategic alliance for the development and commercialization of Prochymal. Under the terms of the agreement, Osiris will commercialize Prochymal in the United States and Canada, and Genzyme will commercialize the treatment in all other countries.

Final Safety Data

Throughout the two-year trial Prochymal demonstrated a favorable safety profile. In this fully-immunocompetent patient population, there were no signs of adverse immune response or infusional toxicities. The adverse events rate experienced by Prochymal patients was lower than that of placebo patients (8 versus 11 per patient). Notably in the class of chest pain events, there were fewer cases in the Prochymal group than placebo (24.2% vs. 63.2%, $p=0.008$). No serious adverse events were attributed to Prochymal, and all-cause hospitalizations trended lower in the Prochymal group (38.2%) as compared to the placebo group (47.4%).

Performance Data

Data from this trial strongly suggests that Prochymal is able to attenuate adverse effects typically associated with acute myocardial infarction by blocking scar formation and pathological remodeling. This was evident in cardiac performance measures of both electrical and mechanical function of the heart.

During the trial patients receiving Prochymal experienced fewer arrhythmias. This effect was maintained for the duration of the study, with 47.4% of placebo patients experiencing cardiac arrhythmia compared to only



11.8% of Prochymal patients ($p=0.006$). Ventricular arrhythmias are associated tissue damage and scar formation in the heart resulting from infarction and can be a sign of poorer prognosis.

Along with the conduction effects seen, the mechanical performance data collected from magnetic resonance imaging (MRI) data on a subset of patients showed functional recovery that was maintained through the two-year study.

Left ventricular ejection fraction (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. Patients with significantly compromised LVEF progress to heart failure. Two-year MRI data demonstrates there was statistically significant improvement in LVEF over baseline, 6.6 point in Prochymal relative to a 3.9 point improvement in placebo. For patients with more severe myocardial infarction, defined as a baseline LVEF of 45% or less, even greater effects were observed. The Prochymal group showed a significant 9.5 point improvement over baseline two years post-treatment ($p < 0.05$). This compares favorably to the 3.1 point increase observed for the placebo group (NS).

"This placebo controlled study was truly first of its kind and the data produced is promising," said Timothy Henry, M.D., Director of Research at the Minneapolis Heart Institute Foundation at Abbott Northwestern. "It clearly suggests that allogeneic adult stem cells have significant potential to improve recovery following a heart attack and can prevent long term adverse effects. Given the fact that we can administer this drug through a standard IV in an acute setting, Prochymal could become an integral part of standard of care for treatment of heart attacks everywhere."

About the Phase II 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 for improving heart function in patients who experienced a first heart attack. This trial focuses on patients who have suffered a severe myocardial infarction, defined as LVEF between 30% and 45% at baseline. The target enrollment is 220 patients. Patients will be randomized to either 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 specially formulated for intravenous infusion. The stem cells are obtained from the bone marrow of healthy adult donors. Prochymal is currently being evaluated in Phase III trials for 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 being studied in Phase II trials for the treatment of COPD, type 1 diabetes, and acute myocardial infarction. Additionally, the Department of Defense recently awarded Osiris a contract to develop Prochymal as a treatment for acute radiation syndrome.

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 a partnership with Genzyme Corp. for the development and commercialization of Prochymal and Chondrogen in countries outside the United States and Canada. Osiris has developed an extensive intellectual property portfolio to protect the company's technology including 47 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)



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 Collaboration Agreement with Genzyme 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 the ability of the parties to successfully perform under the collaborative arrangement and for Osiris to 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 Quarterly 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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