



Prochymal™ Demonstrates Lasting Benefit in Heart Attack Patients; Osiris Receives FDA Clearance to Start Phase II Trial

One Year Results of Phase I Trial Continue to Demonstrate Safety and Persistent Cardiac Improvement

COLUMBIA, Maryland – February 26, 2008 – Osiris Therapeutics, Inc. (NASDAQ: OSIR) today announced that interim results at the one year time point for the Company's Phase I trial evaluating Prochymal™ for the treatment of heart attack patients continued to demonstrate a strong safety profile and statistically significant improvement in heart function. Based upon the positive results from this 53-patient, double-blind, placebo-controlled trial, the Company has received approval from the Food and Drug Administration (FDA) to initiate a Phase II trial.

"This early stage trial exceeded our expectations for both safety and efficacy," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "These data support our pre-clinical results and suggest that in acute myocardial infarction, early treatment with Prochymal can alter the course of disease. Based on this encouraging data, we look forward to promptly advancing Prochymal in this exciting, multi-billion dollar market."

Prochymal for Heart Attack Patients: An Interim Analysis at One Year

The trial collected one-year magnetic resonance imaging (MRI) data on left ventricular ejection fraction (LVEF), which reflects the fraction of blood pumped out of a ventricle with each heart beat. This is a commonly used measurement of overall heart function and typically declines after injury to the heart, as often occurs in heart attack patients. Patients with significantly compromised LVEF progress to heart failure.

Key results include:

- The Prochymal treatment group achieved a statistically significant 5.2 point increase in LVEF over baseline (P = 0.021). The placebo group experienced a 1.8 point improvement in LVEF over baseline, which was not statistically significant.
- Patients with more severe myocardial infarction, defined as a baseline LVEF of 45 or less, demonstrated even greater effects. The Prochymal-treatment group showed a 6.5 point improvement one-year post-treatment, compared to a 1.9 point increase in the placebo group.
- Prochymal treated patients continued to experience fewer adverse events, at a rate of 6.1 per patient, compared to 8.0 per placebo-group patient.
- No serious adverse events were attributed to Prochymal.

"First and foremost, the safety data generated in this trial were outstanding and add to the growing body of evidence demonstrating that Prochymal can be used to treat patients in the acute setting," said Joshua Hare, M.D., lead investigator for the Prochymal cardiac study. Dr. Hare is the Louis Lemberg Professor of Medicine at the Miller School of Medicine, University of Miami; Chief of the Cardiovascular Division; and Director of the School's Interdisciplinary Stem Cell Institute. "The data further suggest that the greater the cardiac damage, the greater the potential benefit from Prochymal. We are very excited about advancing Prochymal into Phase II, and the prospect of ushering in a new era in the treatment of myocardial infarction."

The one year interim analysis was performed as part of the full two year follow-up period to the trial, and as a result, contains only limited data. A more comprehensive data set will be available at the two year time-point, which marks the conclusion of the trial.

Prochymal, a patented formulation of adult stem cells, is currently in Phase III clinical trials for the treatment of Graft vs. Host Disease and Crohn's Disease and is in a Phase II trial for type 1 diabetes. Osiris was recently awarded a \$224.7 million contract for the development and stockpile of Prochymal by the Defense Department for the treatment of acute radiation syndrome. The Company recently regained exclusive world-wide rights to cardiovascular indications for the product and as a result, discontinued using the cardiac specific brand name Provacel.



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 being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also Crohn's disease, and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris also has partnered with Genzyme Corporation to develop Prochymal™ as a medical countermeasure to nuclear terrorism and other radiological emergencies. Prochymal is also being developed for the repair of heart tissue following a heart attack and for the protection of pancreatic islet cells in patients with type 1 diabetes. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for arthritis in the knee. 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 253 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 mesenchymal stem cells 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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