



Osiris Completes Enrollment of Stem Cell Trial to Treat Pulmonary Disease

COLUMBIA, Maryland – September 23, 2008 – Osiris Therapeutics, Inc. (NASDAQ:OSIR) announced today that it has completed enrollment in a human clinical trial designed to evaluate Prochymal, the Company's proprietary formulation of adult mesenchymal stem cells, for the treatment of moderate to severe Chronic Obstructive Pulmonary Disease (COPD). A total of 62 patients were enrolled in the Phase II trial at six sites throughout the United States.

"These stem cells have qualities that make them naturally well suited for the repair of lung tissue, and early clinical data are so far very encouraging," said Michelle LeRoux Williams, Ph.D., Vice President of Development at Osiris Therapeutics. "We are excited to learn more about the therapeutic utility of these cells in the lungs, not only for the treatment of COPD, but for other pulmonary conditions as well. This study will provide for us the necessary base for further rapid development of this remarkable stem cell technology in what could ultimately prove to be a broad spectrum of lung diseases."

Mesenchymal stem cells have been shown to be effective in treating numerous lung diseases in pre-clinical animal models. The ability of the stem cells to reduce inflammation, block fibrosis or scarring and repair tissue damage suggests that they may be effective in reversing or preventing the progression of COPD. In an earlier human trial for heart disease, infusions of Prochymal were shown to improve lung function by a statistically significant margin compared to patients receiving placebo.

"We would like to thank our participating physicians and their teams for the remarkable job they did enrolling this study so quickly," said Robin Flannery, who coordinated the trial at Osiris. "But most of all, we would like to recognize and offer our sincere thanks to the patients who are participating in this historic trial. It is only with their cooperation that we seek to usher in a new era in the treatment of lung disease."

Osiris is investigating Prochymal in patients with COPD, the fourth leading cause of death in the United States. Over 12 million Americans have been diagnosed with the disease, and it is estimated that an additional 14 million Americans have the disease and have not yet been diagnosed.

About the Phase II Chronic Obstructive Pulmonary Disease Trial

The Phase II trial is evaluating the safety and efficacy of Prochymal in conjunction with standard of care for improving pulmonary function in patients with moderate to severe COPD. The clinical trial is a double-blind, placebo-controlled study. Patients were randomized to either Prochymal or placebo at a 1:1 ratio. Measurements used in the trial to detect potential improvements in subjects treated with Prochymal include pulmonary function tests, exercise capability, and quality of life assessments. In addition, exacerbations and hospitalizations due to COPD will be monitored for both safety and efficacy. Patients will be evaluated over the course of two years following initial Prochymal or placebo infusion.

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, 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 and type 1 diabetes. Additionally, the Department of Defense recently awarded Osiris a \$224.7 million contract to develop Prochymal as a treatment for acute radiation syndrome.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. 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. Furthermore, Prochymal is being developed for the repair of heart tissue following a heart attack, the protection of pancreatic islet cells in patients with type 1 diabetes, and the repair of lung tissue in patients with chronic obstructive pulmonary disease. 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, and distribution of stem cell products. 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; 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 MSCs 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 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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