



Osiris Therapeutics Initiates Phase II Clinical Trial Evaluating Prochymal™ for Chronic Obstructive Pulmonary Disease

First-in-class stem cell therapy now being evaluated to treat fourth leading cause of death

COLUMBIA, Maryland – May 21, 2008 – Osiris Therapeutics, Inc. (NASDAQ:OSIR) today announced the treatment of the first patients in a new Phase II clinical trial evaluating Prochymal, a mesenchymal stem cell (MSC) therapy, for moderate to severe Chronic Obstructive Pulmonary Disease (COPD). This trial marks the sixth indication for which Prochymal has been advanced into Phase II or later-stage clinical trials.

COPD, a form of lung disease characterized by limitation or obstruction of airflow in the airway, encompasses both emphysema and chronic bronchitis. COPD is the fourth leading cause of death in the U.S. with an estimated 12 million Americans diagnosed with the disease. COPD has no known cure, thus current therapeutic intervention is aimed at providing relief of symptoms. Preclinical and clinical data suggest that Prochymal's unique mechanism of action may provide a first-in-class treatment option with the ability to reverse the underlying disease.

"Our COPD program serves as another example of how quickly and efficiently we can now work towards developing this first-in-class stem cell therapy," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. "With the early testing completed, the clinical development and regulatory pathways are significantly streamlined for future indications. This supports our strategy to seek initial approval for the world's first stem cell drug in relatively small underserved diseases, such as GvHD and resistant Crohn's disease, and promptly expand the technology to include blockbuster markets for which the technology also holds great promise."

"Studies that we and others have conducted provide convincing evidence that MSCs have the potential to be effective in addressing selected lung diseases, including COPD," said Daniel Weiss, M.D., Ph.D., Associate Professor of Medicine at the University of Vermont College of Medicine and an expert in research using stem cells to treat lung diseases. "These mesenchymal stem cells are particularly suited for treating pulmonary disease due to their inherent trafficking pathway through the lungs when delivered intravenously and their ability to remain in the lungs when inflammatory molecules are present. With their demonstrated ability to both reduce inflammation and reverse tissue damage, we have reason for optimism about Prochymal's use in this devastating disease."

A recent Osiris study evaluating Prochymal as a treatment for myocardial infarction demonstrated a statistically significant improvement in lung function as compared to placebo. Specifically, patients treated with Prochymal showed a 17 point improvement in FEV₁ % predicted, a measure of pulmonary function, versus only a 6 point improvement in patients treated with placebo (p < 0.05). Prochymal has also demonstrated clinical benefit in trials evaluating patients with inflammatory conditions including graft-versus-host disease (GvHD) and Crohn's disease, both of which are in Phase III programs and have Food and Drug Administration (FDA) Fast Track status.

"This landmark study is very exciting for the entire field and we are honored to have been able to enroll and treat the first patients," said Charles Fogarty, M.D., Medical Director of Spartanburg Medical Research. "We look forward to the results of this trial, which may have long-term implications for improvements in disease progression and remodeling of the lung."

About the Phase II Chronic Obstructive Pulmonary Disease Trial

The Phase II trial will evaluate 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 conducted at multiple sites with a target enrollment of 60 patients. Patients will be randomized to either Prochymal or placebo at a 1:1 ratio. Pulmonary function tests, exercise capability, and quality of life are some of the measurements being used to detect potential improvements in subjects treated with Prochymal. 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. 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. FDA established the Fast Track program to accelerate the development of drugs that show promise for treating life-threatening conditions. Orphan Drug designation provides incentives to companies that develop drugs for underserved patient populations. Prochymal is also being studied in Phase II trials for the treatment of acute myocardial infarction, type 1 diabetes, and COPD. Additionally, the Department of Defense recently awarded Osiris a \$224.7 million contract to develop Prochymal for acute radiation syndrome.

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, 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, 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 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 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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