

## Osiris Therapeutics Reports Interim Data for COPD Stem Cell Study

**COLUMBIA, Maryland – June 23, 2009** – Osiris Therapeutics, Inc. (NASDAQ:OSIR) today announced six-month interim data from a Phase II clinical trial evaluating Prochymal, the Company's proprietary formulation of adult mesenchymal stem cells, for the treatment of chronic obstructive pulmonary disease (COPD). Sixty-two patients were enrolled and are being followed for two years in the placebo-controlled study. At the six-month time-point, the data revealed several important findings.

### Important Findings:

- The trial met its primary goal of demonstrating the safety of Prochymal in patients with compromised pulmonary function at the six-month evaluation point.
- Prochymal significantly decreased systemic inflammation in patients when compared to those receiving placebo, as determined by C-reactive protein (CRP).
- Despite the reduction in inflammation, pulmonary function in patients receiving Prochymal was not significantly improved compared to those receiving placebo.

"We are very pleased with the interim outcome of this study and that the data continues to support the strong safety profile of this therapy, particularly given the severity of these patients' pulmonary disease," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "Importantly, we are gratified to obtain clear, objective data that helps bolster our understanding of the anti-inflammatory effects of these remarkable cells. Short-term, these anti-inflammatory effects did not appear to improve pulmonary function in patients with advanced destructive changes of the lung. Collectively however, these findings add to our confidence about the safety and effectiveness of the drug."

### Six-Month Interim Data

Prochymal was evaluated in a total of 62 patients, 58% of them male. The patients ranged in age from 47 to 80 years and suffered from moderate (n=23) to severe (n=39) COPD. Patients had been suffering with COPD for an average of 7.8 years. Patients with asthma were excluded from the trial.

All patients in the trial completed the planned course of four infusions without any evidence of infusional toxicity. Oxygen saturation levels were measured throughout each infusion and showed no adverse effects of the infusion. Adverse event rates were comparable for patients receiving Prochymal and placebo. There were no signs of adverse immune reaction after any of the four infusions and no differences in the reported incidence of infection of any kind.

Prochymal significantly decreased the levels of CRP compared to placebo in those patients with elevated CRP (>4 mg/L) at the time of study entry (p<0.05). The difference from placebo was evident at ten days post initial infusion, and was maintained throughout the treatment and follow-up period. CRP is a protein found in the blood in response to inflammation and is often elevated in inflammatory diseases such as GvHD and Crohn's disease, and has been found to correlate with clinical parameters of disease activity. Although there is substantial preclinical evidence, this study provides the first well-controlled objective data confirming the systemic anti-inflammatory effects of Prochymal in humans.

Pulmonary function tests such as FEV1 and DLCO or carbon monoxide diffusing capacity of the lung were not improved over placebo following treatment with Prochymal at six months. FEV1 or forced expiratory volume is the amount of air that can forcibly be blown out of the lungs in the first second of exhalation. Although not reaching statistical significance, treatment with Prochymal did produce positive trends in exploratory functional endpoints such as the six-minute walk test and certain cardiac related parameters, particularly in patients with less established COPD.

The trial will continue as planned and patients will be followed for the balance of the two-year evaluation period.



## **About the Phase II Chronic Obstructive Pulmonary Disease Trial**

The Phase II trial is evaluating the safety of Prochymal in conjunction with standard of care in patients with moderate to severe COPD. The clinical trial is a double-blind, placebo-controlled study. A total of 62 patients were randomized to either Prochymal or placebo at a 1:1 ratio. In order to explore potential improvements in pulmonary function, several evaluations including pulmonary function tests, exercise capability, and quality of life assessments are being conducted. 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 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 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](http://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 having 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 the sale of our Osteocel assets



and related transactions include typical business transactional risks, the risk of changing relationships with customers, suppliers or employees; and the risk that we may not be able to fully perform or generate or receive milestone payments. 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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