



## Osiris Completes Enrollment in First Worldwide Phase III Stem Cell Trial

**COLUMBIA, Maryland – December 4, 2008** - [Osiris Therapeutics, Inc.](#) (NASDAQ:OSIR) announced today that it has completed patient enrollment in its Phase III pivotal trial evaluating Prochymal for the treatment of steroid-refractory acute Graft versus Host Disease (GvHD), a life threatening complication of bone marrow transplantation. [Prochymal](#) is a proprietary formulation of adult mesenchymal stem cells (MSCs) designed to provide therapeutic benefit by controlling inflammation, promoting tissue regeneration, and preventing scar formation.

This double-blinded, placebo controlled trial will assess safety and efficacy of Prochymal over a six-month period. A total of 244 patients were enrolled at 72 leading bone marrow transplant centers across the United States, Canada, United Kingdom, Spain, Italy, Australia, Germany and Switzerland. The three top enrolling sites in the study were the Fred Hutchinson Cancer Research Center in Seattle, Washington, the M.D. Anderson Cancer Center in Houston, Texas, and the Karmanos Cancer Institute in Detroit, Michigan.

"Completion of this study's enrollment represents an outstanding accomplishment for the transplantation field," said Paul Martin, M.D., of the Fred Hutchinson Cancer Research Center, Professor at the University of Washington and lead investigator for the trial. "Steroid-refractory acute Graft versus Host disease poses one of the most serious and difficult-to-treat complications that can occur after bone marrow transplantation. Previous studies have not identified reliably effective treatments, and no drugs have been approved for this devastating disease. Transplant clinicians throughout the world now eagerly await results of this rigorous multicenter study."

In total, 168 patients were treated in the United States, 31 in Canada, 27 in Europe, and 18 in Australia. A total of 27 pediatric patients were enrolled. The last patient is expected to complete the trial by May 29<sup>th</sup>, 2009.

MSCs have been reported as an effective agent in the treatment of GvHD by a number of medical centers. In a recent *Lancet* publication, Le Blanc et al. reported a 55% complete response rate when using MSCs in the treatment of steroid-resistant GvHD. Additional Phase II studies performed by Osiris corroborate these findings. Prochymal was shown to induce a 58% complete response in pediatric patients suffering from end-stage GvHD. Studies also have shown an increase in response rates when patients are treated earlier in the course of disease. In a Phase II trial evaluating Prochymal as a first-line agent for GvHD in adults, 77% achieved complete resolution.

"On behalf of everyone at Osiris, I would like to offer our sincere appreciation to the patients, their families, and all of the outstanding healthcare professionals who participated in this historic event," said Moya Daniels, study director for the steroid-refractory GvHD program at Osiris Therapeutics. "We look forward with great anticipation to the results of this landmark stem cell trial and the opportunity to make a positive difference in the care of transplant patients everywhere."

In November, 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.

### About the Phase III Steroid-Refractory Trial

The Phase III trial is evaluating the safety and efficacy of Prochymal in conjunction with standard of care for treatment of patients who have failed to respond to corticosteroid treatment for acute GvHD. The clinical trial is a double-blind, placebo-controlled study. Patients were randomized to either Prochymal or placebo at a 2:1 ratio. GvHD assessments performed according to the International Bone Marrow Transplant Registry (IBMTR) were used in the trial to detect improvements in subjects treated with Prochymal. The key endpoints of this trial are complete response, and both 100-day and 180-day survival.

Osiris is also investigating the use of Prochymal as a first line agent for acute GvHD in a 184-patient Phase III trial and as a treatment for Crohn's disease in a 270-patient Phase III trial.

### 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. 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 also formed 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](http://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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