



## Osiris Receives Approval for Prochymal Expanded Access Program in Canada

**COLUMBIA, Maryland – December 5, 2008** - Osiris Therapeutics, Inc. (NASDAQ:OSIR) today announced it has received approval from Health Canada to initiate a pediatric expanded access treatment program for Prochymal, making the investigational stem cell product more readily available to children with life-threatening Graft vs. Host Disease (GvHD). Earlier this year the U.S. Food and Drug Administration became the first regulatory agency to take this action, making Prochymal available to children in the United States.

To learn more, pediatric transplant physicians are invited to meet with members of the Prochymal expanded access team December 6-8 at the 50<sup>th</sup> American Society of Hematology Annual Meeting and Exposition (Booth 385).

Prochymal is a formulation of adult mesenchymal stem cells designed to provide therapeutic benefit by controlling inflammation, promoting tissue regeneration, and preventing scar formation. Prochymal recently completed a Phase III trial for steroid refractory GvHD and is currently enrolling patients in a Phase III trial for Crohn's Disease. Late last year Osiris reported data evaluating Prochymal as a rescue therapy in pediatric patients with severe GvHD. In that study, the drug completely resolved life-threatening GvHD in 58% of children who had otherwise exhausted available treatment options.

"The results for Prochymal in pediatric patients with severe GvHD have thus far been very encouraging, and as a participating principal investigator in the Phase III trial for steroid-refractory GvHD, my experience treating patients with Prochymal has been a positive one," said Andrew Daly, M.D., Clinical Professor, Department of Medicine and Oncology at the University of Calgary, Canada. "With the implementation of this expanded access program, Osiris confirms its global commitment to the field of GvHD, a disease which is a significant unmet medical need."

Under the expanded access program, children 2 months to 17 years in age inclusive with Grades B-D acute GvHD not responsive to steroids are eligible for treatment. For further eligibility criteria or information e-mail [prochymal@osiris.com](mailto:prochymal@osiris.com).

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 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. Prochymal is also being studied in Phase II trials for the treatment of COPD, type 1 diabetes, and acute myocardial infarction.

### 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 treatment of 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.

### **For additional information, please contact:**

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