



## **Osiris Receives FDA Clearance to Broaden Prochymal Expanded Access Program**

### **Access to Treatment Now Available to Patients of All Ages Suffering from Life Threatening GvHD**

**COLUMBIA, Maryland – January 15, 2009** – Osiris Therapeutics, Inc. (NASDAQ: OSIR) today announced U.S. Food and Drug Administration (FDA) clearance to broaden its expanded access program (EAP) for Prochymal, now making the investigational stem cell product available to adults with life-threatening Graft vs. Host Disease (GvHD). In May of 2008, FDA approved the first Prochymal EAP for the treatment of pediatric GvHD patients.

Congress and the FDA created the expanded access program to facilitate the availability of promising new drugs to desperately ill patients before general marketing begins. The program allows for investigational drugs to be made available to patients under certain circumstances during evaluation in late stage clinical trials when no satisfactory alternative therapy is available. For expanded access, the FDA must determine that the available scientific evidence, taken as a whole, demonstrates that the drug may be effective and would not expose the patients to unreasonable risks. Additionally, the FDA permits companies meeting certain criteria to charge for the investigational product. Expanded access to Prochymal was initially restricted to only pediatric patients suffering from steroid refractory GvHD until patient enrollment in the Phase III pivotal trial was completed.

Prochymal, a formulation of adult mesenchymal stem cells designed to provide therapeutic benefit by controlling inflammation, promoting tissue regeneration, and preventing scar formation, is in phase III clinical trials for GvHD and Crohn's disease. Enrollment in the Phase III pivotal trial for steroid-refractory GvHD was recently completed. Enrollment is ongoing in another Phase III trial for acute GvHD and in a Phase III trial for Crohn's disease.

"As a transplant physician who has used Prochymal, I have seen first hand the power of this promising therapy to reverse otherwise non-responsive GvHD," said Dr. Hans Klingemann, Director, Bone Marrow and Hematopoietic Stem Cell Transplantation Program at Tufts-New England Medical Center. "This is a disease that is so devastating that survival is often measured in days. This action by FDA is significant because it now enables us to provide all of our critically ill GvHD patients with faster and more reliable access to Prochymal."

GvHD is a life-threatening immune reaction that can occur in patients following bone marrow transplantation. Steroids are typically used to control symptoms of the disease, although they are only effective in approximately 35% of patients. Mortality can exceed 85% for patients with GvHD that do not respond to steroids.

Under the EAP, patients two months to 70 years of age, inclusive, who have been diagnosed with GvHD that is unresponsive to steroid therapy, are eligible to receive Prochymal. For consideration and further eligibility criteria please email [prochymal@osiris.com](mailto:prochymal@osiris.com).

In November 2008, Osiris and Genzyme 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 Phase III trials for 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 being studied in Phase II trials for the treatment of COPD, type 1 diabetes, and acute myocardial infarction. Additionally, the Department of Defense recently 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 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:**

**Erica Elchin**  
**Osiris Therapeutics, Inc.**  
**(443) 545-1834**  
**OsirisPR@Osiris.com**

**Media Contacts:**  
**Stacey Holifield/Andrew Law**  
**Schwartz Communications**



**(781) 684-0770**  
**Osiris@schwartz-pr.com**