

## New Study Demonstrates Effectiveness of Prochymal as a Rescue Therapy for Pediatric Patients with Severe Graft vs. Host Disease

*Data Presented at the 2010 Tandem Meeting of the Center for International Blood and Marrow Transplant Research and the American Society of Blood and Marrow Transplantation*

**COLUMBIA, Md. - February 24, 2010** – [Osiris Therapeutics, Inc.](#) (NASDAQ:OSIR) today reported that a new study shows Prochymal achieved an overall response rate of 63% when used as a rescue therapy in children suffering from severe treatment resistant graft vs. host disease (GvHD). Furthermore, the study demonstrates that response to Prochymal significantly improved survival. The data are being presented at the [2010 BMT Tandem Meeting](#) by the study's lead author, Joanne Kurtzberg, M.D., Professor of Pediatrics and Pathology and Director of the Pediatric Blood and Marrow Transplant Program at Duke University Medical Center ([Abstract #40](#)).

"Treatment-resistant GvHD remains a significant challenge in transplantation and results in poor outcomes and high mortality," said Dr. Kurtzberg. "We are encouraged to see high response rates and improved survival in children with disease unresponsive to other treatments. Because of its excellent risk-benefit profile, Prochymal should be considered in pediatric patients with GvHD that does not respond to steroids."

### Highlights from the Study

The study (Protocol 275) evaluated Prochymal as a rescue therapy in 59 pediatric patients with severe, treatment resistant GvHD. Patients were evaluated for response to Prochymal at day 28 of therapy and survival through day 100.

The children in this study had severe, refractory GvHD:

- At study entry, six patients (10%) had Grade B, 18 patients (31%) had Grade C and 35 patients (59%) had Grade D GvHD. Grades C and D represent the most severe forms of GvHD.
- Prior to treatment with Prochymal, patients had GvHD that was unresponsive to an average of three lines of therapy for an average of 46 days.

Response to treatment with Prochymal was prompt and clinically meaningful:

- Overall response to treatment with Prochymal at 28 days was 63%.
- Response to Prochymal at day 28 significantly improved survival over patients who progressed (78% vs. 9%,  $p < 0.05$ ).

Prochymal also continued to demonstrate a strong safety profile. Prochymal infusions were well tolerated and no serious adverse events were attributed to treatment with the stem cells.

The full study results are included in a February supplement issue of the peer-reviewed journal, *Biology of Blood and Marrow Transplantation*.

### About Protocol 275

Pediatric patients with Grades B to D acute GvHD who had failed steroids and other immunosuppressive agents were eligible for enrollment in Protocol 275. As defined in the protocol, patients received two infusions of Prochymal per week for four weeks. Patients who experienced a partial response by day 28 were eligible for continued treatment. GvHD assessments performed according to the International Bone Marrow Transplant Registry (IBMTR) were used in the study to detect improvements in subjects treated with Prochymal. A total of 59 patients from were treated at 33 pediatric transplant centers across the U.S., Canada, Europe and Australia.



## About Prochymal

Prochymal is a preparation of mesenchymal stem cells (MSCs) formulated for intravenous infusion. The MSCs utilized in Prochymal are isolated from the bone marrow of healthy young adult donors, avoiding the controversy surrounding embryonic and fetal cell sources. They are grown in culture, permitting large-scale production. Because the cells can be expanded, thousands of doses can be produced from a single donation. Studies suggest MSCs are able to safely facilitate tissue repair through a number of mechanisms. Specifically, these studies indicate that MSCs are able to down-regulate severe inflammation and work at the cellular level to rebuild damaged tissue through the coordinated release of tissue-specific growth factors.

Prochymal is being evaluated in Phase III programs for steroid-refractory GvHD, acute GvHD and Crohn's disease. Prochymal has been granted Fast Track status by the FDA for GvHD and Crohn's disease, and is the first stem cell product to receive FDA expanded access approval, making the product available now to patients with life-threatening GvHD. Prochymal obtained Orphan Drug status for GvHD from the FDA and the European Medicines Agency. This stem cell therapy is also being studied in Phase II trials for the treatment of acute myocardial infarction, pulmonary disease and type 1 diabetes.

## About Osiris Therapeutics

[Osiris Therapeutics, Inc.](http://www.Osiris.com) 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 holding 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 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.

**For additional information, please contact:**

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

**Media Contacts:**  
**Andrew Law/Rachel Gross**  
**Schwartz Communications**  
**(781) 684-0770**  
**Osiris@schwartz-pr.com**