

Investigators Present Phase III Data for Prochymal in Steroid-Refractory Graft vs. Host Disease

Stem Cell Study is First to Show Significant Improvement in Difficult-to-Treat GvHD

COLUMBIA, Md. - February 24, 2010 – [Osiris Therapeutics, Inc.](#) (NASDAQ:OSIR) today announced that results from the Phase III trial evaluating [Prochymal](#) for the treatment of steroid-refractory acute graft vs. host disease (GvHD) will be presented by Paul Martin, M.D., of the Fred Hutchinson Cancer Research Center and Paul Szabolcs, M.D., of Duke University Medical Center at the [2010 BMT Tandem Meeting](#). The meeting is being held February 24-28 in Orlando, Florida.

“Refractory GvHD is a devastating disease for which there have been no well-controlled studies demonstrating the safety and effectiveness of any therapeutic agent beyond steroids,” said Paul Martin, M.D. of the Fred Hutchinson Cancer Research Center, Professor of Medicine at the University of Washington and principal investigator for the steroid-refractory GvHD trial. “This rigorous study shows significant improvements in gut and liver GvHD above and beyond standard of care, and without additive toxicity. We now have clear evidence demonstrating the benefits of mesenchymal stem cell therapy in the two most deadly and difficult-to-treat forms of the disease.”

Steroid-Refractory Gastrointestinal and Liver GvHD

Dr. Martin will give a presentation entitled, “Prochymal Improves Response Rates in Patients with Steroid-Refractory Acute Graft versus Host Disease (SR-GvHD) Involving the Liver and Gut: Results of a Randomized, Placebo-Controlled, Multicenter Phase III trial in GvHD” ([Abstract #41](#)) on Thursday, February 25th. Highlights from the abstract and presentation include:

- Prochymal significantly improved response in steroid-refractory liver (76% vs. 47%, $p=0.03$) and gastrointestinal GvHD (82% vs. 68%, $p=0.03$).
- In the sickest patients - those with GvHD affecting all three organs, skin, liver and gastrointestinal tract - treatment with Prochymal resulted in a 63% overall response rate, while none of the placebo-treated patients responded ($p<0.05$).
- Patients treated with Prochymal had significantly less progression of liver GvHD compared to placebo (37% vs. 65%, $p=0.05$).
- Prochymal demonstrated a positive safety profile relative to placebo for key safety outcomes of interest, including recurrent malignancy (8% vs. 10%), infusional toxicity (2% vs. 2%) and discontinuation of study due to an adverse event (1% vs. 5%).

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

Pediatric Steroid Refractory GvHD

Dr. Szabolcs, Associate Professor, Pediatric Blood and Marrow Transplant Program at Duke University Medical Center, will present an abstract entitled “Treatment of Steroid-Refractory Acute GvHD with Mesenchymal Stem Cells Improves Outcomes in Pediatric Patients; Results of the Pediatric Subset in a Phase III Randomized, Placebo-Controlled Study” ([Abstract #381](#)) on February 27th. Highlights from the abstract include:

- Children receiving Prochymal had an overall response rate of 64% compared to 36% in patients receiving placebo.
- Prochymal more than doubled complete response rates (64% vs. 29%) and reduced disease progression by half (21% vs. 43%).
- Treatment with Prochymal resulted in a 30 point improvement in 100 day survival compared to placebo (79% vs. 50%).
- There was no infusional toxicity reported, no evidence of Prochymal leading to ectopic tissue and no adverse events leading to discontinuation of therapy.



GvHD, a frequent complication of bone marrow transplantation, is the leading cause of morbidity and mortality for patients receiving allogeneic hematopoietic stem cell (bone marrow) transplants. Currently there is no approved treatment for acute GvHD.

About the Phase III Steroid-Refractory Acute GvHD Trial (Protocol 280)

The Phase III trial evaluated the safety and efficacy of Prochymal in conjunction with standard of care for treatment of patients who had failed to respond to corticosteroid treatment for acute GvHD. The clinical trial is a double-blinded, placebo-controlled study. Patients were randomized to receive Prochymal or placebo at a 2:1 ratio in addition to standard of care. GvHD assessments were performed according to the International Bone Marrow Transplant Registry (IBMTR) grading scale. The trial enrolled 260 patients and treated 244 patients from 72 leading bone-marrow transplant centers across the United States, 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. (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.

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