



Osiris Therapeutics Reports Positive Phase II Results Using PROCHYMAL™ for the Treatment of Acute Graft vs. Host Disease

Stem cell therapy resulted in a 74% complete response rate in a life threatening disease that currently has no approved treatment

BALTIMORE, Maryland – November 9, 2006 – Osiris Therapeutics, Inc. (NASDAQ:OSIR) announced positive results from a 32 patient Phase II study using PROCHYMAL for the treatment of acute Graft vs. Host Disease or GVHD. In the study, 29 of 31, or 94% of evaluable patients responded after receiving two infusions of PROCHYMAL. More significantly, 23 patients, or 74% achieved a complete response, meaning the patients had experienced total clinical resolution of the disease. Currently, PROCHYMAL is being evaluated in a Phase III trial for the treatment of steroid refractory GVHD.

Graft vs. Host Disease or GVHD is a life threatening immunological reaction that occurs in certain patients who have received a bone marrow transplant. GVHD is a form of rejection in which immune cells from the donated bone marrow attack the recipient's own organs and tissues. There are no approved treatments for GVHD. As a result, it is one of the leading causes of death in bone marrow transplant patients.

"The results of this trial were promising", said Dr. Partow Kebriaei of the MD Anderson Cancer. Dr Kebriaei was a lead investigator in the Phase II trial and is participating in the Phase III trial for PROCHYMAL. "The utility of stem cells for the treatment of GVHD is becoming clear. We look forward to the Phase III data with renewed confidence and anticipation in light of this new information. More importantly, we look forward to the introduction of an effective therapy for GVHD."

About the Trial

The trial was a randomized, prospective, open label trial, conducted at 16 leading cancer centers within the US. In addition to standard care including steroids, patients were given two infusions of PROCHYMAL three days apart at the onset of moderate to severe (grades II-IV) GVHD. Patients were divided into two groups and received either low dose (2 million cells per kilogram) or high dose (8 million cells per kilogram) of PROCHYMAL. Endpoints of the study included response of GVHD to treatment with PROCHYMAL and the safety and tolerability of the drug at the two different dose levels.

A total of 32 patients were enrolled in the trial with 31 available for evaluation. The study population consisted of 22 men and 10 women, with a median age of 52 years. Complete response, defined as having complete resolution of all clinical symptoms of GVHD within the 28 day evaluation period, was observed in 23 patients. An additional 6 patients experienced a partial response, defined as achieving improvement in at least 1 affected organ. The overall response rate was 94%.

The gastrointestinal GVHD patient population is particularly difficult to treat and is associated with high rates of morbidity and mortality. In this study, 18 of 31 had gastrointestinal involvement. Of significance, 12 of 18 or 67% of patients with gastrointestinal involvement experienced a complete response. In this group, the overall response rate was 16 of 18 or 89%. In October, Osiris reported positive Phase II results using PROCHYMAL for the treatment of Crohn's Disease, another highly debilitating inflammatory disease of the intestines. In that study, PROCHYMAL was shown to be effective at reducing the severity of Crohn's disease after just one week of treatment.

Thirteen of the 31 subjects experienced the skin form of GVHD. In this sub-population, 85% of the patients experienced a complete response, and the overall response rate to PROCHYMAL was 100%.



PROCHYMAL continued to demonstrate a strong safety profile as the drug was well tolerated at both dose levels. Specifically, no patients experienced infusional toxicity and all patients tolerated the repeat dosing without incident. All patients were given full body CT scans to monitor for unexpected tissue formation, and no evidence of ectopic tissue formation was noted in any of the 31 patients. Additionally, there were no serious adverse events that were deemed to be likely related to the product.

"As a physician treating patients with GVHD, the response rate coupled with the safety profile is what is exciting to me," said Dr Joseph Uberti, Director, Blood and Marrow Stem Cell Transplantation Program, Karmanos Cancer Institute. "After we initiate steroids for GVHD no other treatment is considered standard. Our only option has been to borrow drugs used in other diseases which have immunosuppressive activity. Unfortunately, these drugs often add toxicity with no proven benefit in treatment. A drug with proven efficacy in the treatment of GVHD with a good safety profile would be a huge benefit in our patients."

"The evidence supporting PROCHYMAL continues to build," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "When evaluating the PROCHYMAL trials in total, we are seeing what could be the emergence of a new class of therapeutic agent for the treatment of a wide range of inflammatory and immune mediated diseases."

GVHD and Crohn's disease are T-cell mediated inflammatory processes that result in high levels of pro-inflammatory chemical signals called cytokines. These cytokines cause the unbalanced activation of certain immune cells that results in tissue damage. Delivered intravenously, PROCHYMAL is able to target areas of active inflammation. Laboratory data indicates that PROCHYMAL is able to down regulate the production of pro-inflammatory cytokines, including tumor necrosis factor-alpha or TNF-alpha and interferon-gamma. Additional data indicates that PROCHYMAL up-regulates the production of beneficial anti-inflammatory cytokines, specifically interleukin-10 and interleukin-4. Taken together, when the stem cells found in PROCHYMAL are delivered into an inflammatory environment, they appear to change the course of the disease by altering the cytokine secretion profile of the dendritic and T cell subsets, thereby resulting in a shift from a pro-inflammatory to an anti-inflammatory state and arresting disease progression. Furthermore, it is believed that PROCHYMAL facilitates the repair of previously damaged tissue through the secretion of growth factors that promote tissue regeneration.

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 a double-blind, placebo controlled Phase III study for the treatment of GVHD. The ongoing Phase III study for GVHD is anticipated to be the final trial before the product is submitted to FDA, Canadian and European regulatory agencies for full approval. PROCHYMAL has been granted both Fast Track and Orphan Drug status by FDA for GVHD. FDA established the Fast Track program to accelerate the development of drugs that show promise for treating life-threatening conditions. Orphan Drug designation provides incentives to companies that develop drugs for underserved patient populations. PROCHYMAL is also being evaluated for the treatment of Crohn's Disease and has completed a Phase II trial, which demonstrated positive results, including a significant reduction in the Crohn's Disease Activity Index of 105 points. Preparations for further studies for Crohn's Disease are currently underway.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Osiris currently markets and sells Osteocel[®] for regenerating bone in orthopedic indications. Prochymal[™] is in Phase 3 clinical trials and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen[™] for regenerating cartilage in the knee, and Provacel[™], for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed stem cell capabilities in research and development,



manufacturing, marketing and distribution. Osiris has developed an extensive intellectual property portfolio to protect the company's technology in the United States and a number of foreign countries including 46 U.S. and 164 foreign patents owned or licensed. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. 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; 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 MSCs and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; 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. 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 Registration Statement on Form S-1, File No: 333-134037, as filed with the United States Securities and Exchange Commission and declared effective on August 3, 2006. 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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