



Osiris Therapeutics Receives FDA Clearance to Initiate Phase III Pivotal Trial for Prochymal™ as a First Line Treatment for Acute Graft vs. Host Disease

Strong Data from Phase II Trial Supports Remission and Survival Endpoints in Life Threatening Condition

COLUMBIA, Maryland – October 17, 2007 – Osiris Therapeutics, Inc. (NASDAQ:OSIR) announced the initiation of a Phase III pivotal trial evaluating Prochymal as a first line agent in the treatment of acute Graft vs. Host Disease (GVHD), a life threatening complication of bone marrow transplantation that currently has no approved treatment.

This trial marks the third indication for which Prochymal has advanced into Phase III testing. The primary endpoint of this pivotal trial includes remission rates and increased patient survival. These endpoints are supported by data from the company's Phase II trial for the same indication. Highlights from the 32 patient Phase II trial include:

- 77% of patients experienced complete remission of GVHD within 28 days when treated with Prochymal.
- At six months, 61% of patients treated with Prochymal still had a durable response requiring no additional immunosuppressive therapy, clinical intervention, or increased steroid use.
- 95% of patients achieving a durable response were alive at six months. This compared favorably to patients receiving additional immunosuppressive therapy where survival was only 25%.
- There were no serious adverse events attributed to Prochymal through the six month evaluation period.

"These data are very impressive. What is really significant for the transplant community is the high proportion of patients that completely resolved their GVHD without the need for potentially lethal immunosuppressants," said Joseph Uberti, M.D., Ph.D., Co-Director of the Blood and Marrow Stem Cell Transplant Program at the Barbara Ann Karmanos Cancer Institute. "We know that if we can minimize immunosuppression, patients do better. Ultimately, the study demonstrated that Prochymal has the potential to double the complete response rate we typically see in patients suffering from GVHD, and as a result, appears to significantly reduce mortality."

After review of the Phase II data, Osiris reached agreement with FDA on the design and endpoints of a standalone pivotal trial for first line treatment of acute GVHD. Patient characteristics, inclusion and exclusion criteria, and onset of treatment will be similar to the Phase II trial. The primary endpoint of the pivotal trial is the proportion of patients that achieve a complete response and are alive at day 90 when Prochymal is added to standard steroid therapy compared to steroid therapy alone. In the Phase II study, 61% of patients met these criteria. Previously published data indicate less than 35% of patients achieve this endpoint when treated with steroids alone.

"The strength of the Phase II data enabled us to work closely with FDA to design and power a pivotal trial for acute GVHD that maximizes our opportunity for success," said Lode Debrabandere, Pharm.D., Ph.D., Vice President and General Manager of Inflammatory Diseases at Osiris. "We are grateful for the Agency's ongoing cooperation in the development of a trial to address this significant unmet medical need." Dr. Debrabandere continued, "The timing of this trial allows us to efficiently utilize existing infrastructure from our ongoing steroid refractory GVHD pivotal trial."



About the Phase III Acute GVHD Trial

The Phase III trial will evaluate the safety and efficacy of Prochymal in conjunction with steroid therapy in treating patients with newly diagnosed acute GVHD, grades B-D. The trial design will be a double-blind, placebo controlled trial with target enrollment of 180 patients. The primary endpoint of the trial will be the proportion of patients surviving at least 90 days that achieve a complete response when Prochymal alone is added to steroid therapy as compared to those receiving steroids alone. Patients will be considered treatment failures if they do not achieve a complete response within 28 days of initiating treatment, if the steroid dose is increased or other immunosuppressive agents are added, or if the patient does not survive the 90 day evaluation period.

About the Phase II Acute GVHD Trial

The Phase II trial is a randomized, prospective, open label trial, conducted at 16 leading cancer centers in the U.S. In addition to standard of care including steroids, patients were given two infusions of Prochymal, three days apart at the onset of moderate to severe (grades II-IV) GVHD. Endpoints of the study include response rates of GVHD to treatment with Prochymal, survival, and the safety and tolerability of the drug.

A total of 32 patients were enrolled in the trial with 31 available for evaluation. As previously reported, 29 of 31, or 94% responded after receiving two infusions of PROCHYMAL, with 24 patients, or 77% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. The 28 day complete response rate was adjusted upward by one patient following an audit of the source data at the clinical sites. Five patients, or 16% had a partial response and 2 patients, or 6% did not respond. These response rates are approximately twice as high as the results of a large study previously published in *Biology of Blood and Marrow Transplantation* (MacMillan et al, 2002) evaluating 443 patients with acute GVHD, grades I-IV. This study found that only 35% of patients had a complete response to steroids only. Of importance, the GVHD of patients enrolled in the Prochymal Phase II study was more severe than the GVHD described in the MacMillan manuscript. The study further demonstrated Prochymal's excellent safety profile as there were no severe adverse events attributed to the administration of Prochymal.

About GVHD

GVHD is a T-cell mediated inflammatory process that results in high levels of pro-inflammatory chemical signals called cytokines. These cytokines cause the unbalanced activation of certain immune cells that result in tissue damage. Delivered intravenously, Prochymal is able to target areas of active inflammation. Published 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. Additionally, Prochymal up-regulates the production of beneficial anti-inflammatory cytokines, specifically interleukin-10 and interleukin-4. 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, data indicates Prochymal may also promote the regeneration of tissue structures damaged by GVHD.



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 a global, double-blind, placebo controlled Phase III study for the treatment of steroid refractory 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 Fast Track status by FDA for both GVHD and Crohn's Disease. Prochymal also obtained Orphan Drug status by FDA and EMEA 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 studied in Phase III trials for the treatment of moderate to severe treatment refractory Crohn's Disease.

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 III clinical trials for both Graft versus Host Disease and Crohn's disease and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris has also partnered with Genzyme Corporation to develop Prochymal™ as a medical countermeasure to nuclear terrorism and other radiological emergencies. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for arthritis in the knee, and Provacel™, for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. 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 47 U.S. and 211 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 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 Annual Report on Form 10-K filed 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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