



Osiris Therapeutics Receives FDA Fast Track Status for Prochymal™ as First-Line Treatment for Acute GvHD

Third Fast Track Designation Obtained for Leading Stem Cell Therapy

COLUMBIA, Maryland – December 7, 2007 – Osiris Therapeutics, Inc. (NASDAQ: OSIR) announced today that Prochymal™ has received Fast Track designation from the U.S. Food and Drug Administration (FDA), expediting development of the stem cell therapy as a first-line agent for acute Graft versus Host Disease (GvHD). A Phase III pivotal study for this indication was initiated in November and is now actively enrolling patients.

This is the third indication for which Osiris has obtained Fast Track status and has advanced into Phase III trials. Osiris was the first company to receive Fast Track status for a ready-to-use stem cell treatment, when in 2005, FDA granted Prochymal Fast Track status for the treatment of steroid refractory acute GvHD. In 2006, Prochymal was granted Fast Track status for the treatment of Crohn's disease. Both these programs are enrolling patients in Phase III registration trials.

Osiris recently reported positive Phase II trial results evaluating Prochymal as a first-line therapy for acute GvHD. Of particular interest in this Phase II study was the increased survival rate in those patients that achieved a complete response 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. Previously published data in similar patients indicate less than 35% of patients achieve this composite endpoint when treated with steroids alone.

"The Phase II trial data is encouraging for GvHD patients, who today have very limited treatment options," said Partow Kebriaei, M.D., Assistant Professor Stem Cell Transplantation at MD Anderson Cancer Center. "Incorporating knowledge and feedback from the previous research efforts, the Phase III study has been well designed to measure patient response durability, the trial's composite endpoint and the most effective way to assess clinical benefit. We are optimistic that Prochymal's unique mechanism of action, which combines fast-onset anti-inflammatory activity followed by long-term tissue-repairing capabilities, will continue to demonstrate clinical efficacy for this devastating, often-fatal disease."

"The decision by FDA to grant Fast Track status to another indication of Prochymal underscores the leadership position that Osiris has developed in the emerging field of cellular therapeutics," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "It serves to further validate the considerable scientific, clinical, and regulatory strength the company has developed, and provides us with a clear regulatory path to market approval for Prochymal, now as a first-line treatment for patients with acute GVHD. We thank the FDA for their efforts and look forward to continuing our productive working relationship."

FDA established Fast Track to facilitate the development and accelerate the pre-market review of treatments for serious and life-threatening conditions, so that these products can reach approval more rapidly. To receive Fast Track designation, the product must address a serious unmet medical condition, and be supported by strong results from preclinical or clinical testing demonstrating the product potential. The FDA reached their decision to grant Osiris Fast Track for first-line treatment of acute GvHD after reviewing the accumulation of clinical trial data submitted by the Company, along with a detailed plan for the Phase III evaluation of the drug.

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 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 days following initial treatment.

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 215 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 mesenchymal stem cells 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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