



Osiris Receives Approval for Use of Prochymal™ Under FDA Expanded Access Treatment Program

Decision makes investigational stem cell treatment available to critically ill children

COLUMBIA, Maryland – May 8, 2008 – Osiris Therapeutics, Inc. (NASDAQ: OSIR) today announced it has been given clearance by the U.S. Food and Drug Administration (FDA) to initiate an expanded access treatment program for Prochymal, making the investigational stem cell product available to children with life-threatening Graft vs. Host Disease (GvHD). Prochymal, a formulation of adult mesenchymal stem cells administered through a standard intravenous line, is currently in Phase III clinical trials, the final stage of clinical testing before submission to FDA for marketing approval.

Congress and FDA created the expanded access program to facilitate the availability of promising new drugs to desperately ill patients before general marketing begins. The program allows for investigational drugs to be made available to patients under certain circumstances during evaluation in late stage clinical trials when no satisfactory alternative therapy is available. For expanded access, FDA must determine that the available scientific evidence, taken as a whole, demonstrates that the drug may be effective for its intended use or would not expose the patients to unreasonable and significant additional risk of illness or injury. Additionally, FDA permits companies meeting certain criteria to charge for the investigational product.

"Prochymal has had a profound positive impact on the children that we have treated, all of whom had exhausted available therapeutic options," said Paul Szabolcs, M.D., Pediatric Blood and Marrow Transplant Program at Duke University. "Since there are no approved treatments for GvHD and mortality is so high, gaining faster and more reliable access to Prochymal will be very helpful to the families we serve."

GvHD is a life-threatening immune reaction that can occur in patients following bone marrow transplantation. Steroids are typically used to control the disease, however they are often ineffective. In patients that fail to respond to steroids, mortality can reach 85%.

In support of the expanded access treatment program, Osiris submitted summary safety and efficacy data to FDA. Prochymal was evaluated in pediatric patients suffering from severe GvHD that had failed, on average, three lines of therapy prior to entry into the trial. All patients (12 of 12) experienced an objective clinical response to therapy, and 58% achieved complete resolution of their GvHD. In a Phase II randomized, prospective trial evaluating Prochymal for acute GvHD in adults, 94% (29 of 31) responded after receiving two infusions of Prochymal, with 74% achieving complete resolution of their disease. There were no infusional toxicities associated with the administration of Prochymal in either trial.

"More kids' lives will be saved thanks to adult stem cells and the FDA's prompt action," said U.S. Senator Sam Brownback, who strongly supports broader access for patients who have exhausted all traditional medical options. "Providing sick children, who otherwise have little hope of treatment, access to this promising investigational therapy is a great step forward. And once again, ethical adult stem cells are leaving controversial embryonic stem cells in the dust when it comes to actual human treatments and applications."

Under the expanded access program, children 2 months to 17 years in age inclusive with Grades B-D GvHD not responsive to steroids are eligible for treatment. For consideration and further eligibility criteria e-mail prochymal@osiris.com.

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 three, double-blind, placebo controlled Phase III studies, including steroid refractory GvHD, acute GvHD, and Crohn's disease. Prochymal has been granted Fast Track status by FDA for all three of these indications. Prochymal also obtained Orphan Drug status by FDA and the European Medicines Agency 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 a Phase II trial for the treatment of type 1 diabetes. Additionally, the Department of Defense recently awarded Osiris a \$224.7 million contract to develop Prochymal for acute radiation syndrome.

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 being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also 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. Prochymal is also being developed for the repair of heart tissue following a heart attack and for the protection of pancreatic islet cells in patients with type 1 diabetes. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for arthritis in the knee. 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 253 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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