



Osiris Completes Enrollment in Second Prochymal Phase III Trial for Graft vs. Host Disease

Company submits first portion of Biological License Application to FDA for review

Columbia, Maryland – April 17, 2009 – [Osiris Therapeutics, Inc.](http://www.osiris-therapeutics.com) (NASDAQ: OSIR) today announced that it has successfully completed patient enrollment in its pivotal, Phase III trial evaluating Prochymal as a first-line treatment for acute graft vs. host disease (GvHD), a life-threatening complication of bone-marrow transplantation. The double-blind, placebo-controlled trial enrolled 190 patients from 52 leading transplant centers across the United States, Canada and Australia. Osiris has now completed enrollment in two pivotal stem cell trials in GvHD and expects top-line data from both studies in the second half of 2009.

Additionally, the company announced that it has confirmed with the U.S. Food and Drug Administration, receipt of the first portions of its Biological License Application or BLA for Prochymal as part of a rolling submission. A BLA is a comprehensive regulatory submission prepared by a biologic drug's sponsor to obtain full marketing approval from the FDA. Rolling submission is an FDA provision available to drug candidates that have received Fast Track designation, which allows for completed sections of a BLA to be submitted on an ongoing basis. It can facilitate the process by allowing FDA to initiate review of sections as soon as they are available.

"Completing patient enrollment in this second trial and initiating the application process with FDA are two important milestones for Osiris," said Lode Debrabandere, Ph.D., Senior Vice President of Therapeutics at Osiris. "GvHD has a very high mortality rate and today there are no approved treatments. With over 400 patients participating between the two studies, we are compiling the largest data set ever assembled for this devastating disease. We appreciate all of the efforts of the Food & Drug Administration in the development of this first-in-class stem cell therapy."

"We sincerely appreciate the participation of clinicians and patients in this trial, who share Osiris' commitment to address the needs of this underserved population," said Rod Monroy, Ph.D., Senior Director of the acute GvHD program at Osiris Therapeutics. "We are now focused, along with our partners at Genzyme, on preparing for world-wide registration activities."

About the Phase III Acute GvHD Trial

The Phase III double-blind, placebo controlled trial will evaluate the safety and efficacy of Prochymal in conjunction with steroid therapy in patients with newly diagnosed acute GvHD, grades B-D. The target enrollment for the trial was 184 patients. The primary endpoint of the trial is 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 are 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 90 days following initial treatment.

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 Phase III trials for 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. Prochymal is being studied in Phase II trials for the treatment of COPD, type 1 diabetes, and acute myocardial infarction. Additionally, the Department of Defense has awarded Osiris a contract to develop Prochymal as a treatment for acute radiation syndrome.

About Osiris Therapeutics

Osiris Therapeutics, Inc. 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 48 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 commercialization of Prochymal and Chondrogen. Under the terms of the agreement, Osiris will commercialize Prochymal and Chondrogen in the United States and Canada, with Genzyme responsible for 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 the sale of our Osteocel assets and related transactions include typical business transactional risks, the risk of changing relationships with customers, suppliers or employees; and the risk that we may not be able to fully perform or generate or receive milestone payments. 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 Quarterly 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.

For additional information, please contact:

Erica Elchin
Osiris Therapeutics, Inc.
(443) 545-1834
OsirisPR@Osiris.com

Media Contacts:
Stacey Holifield/Andrew Law
Schwartz Communications
(781) 684-0770
Osiris@schwartz-pr.com