



## Osiris Discontinues Enrollment in Crohn's Study Due to Concerns with Trial Design

### Drug safety not a factor in decision

**COLUMBIA, Maryland – March 27, 2009** – Osiris Therapeutics, Inc. (NASDAQ: OSIR) announced today that it has elected to end enrollment at 210 patients in its Phase III trial evaluating Prochymal for Crohn's disease. The Company believes there is a design flaw in the trial resulting in significantly higher than expected placebo response rates. The decision was made after the trial's final scheduled interim analysis showed that one of the two Prochymal dose arms had crossed a futility boundary. The dose arm was unlikely to achieve the primary endpoint of remission because of the high placebo response rate. This latest analysis continued to show no serious safety concerns with the therapy and safety was not a factor in the decision to stop enrollment.

C. Randal Mills, Ph.D. President and CEO of Osiris Therapeutics said, "We had a situation where we were experiencing much higher than expected placebo response rates. As we looked into possible causes, we discovered what we believe to be a systemic design flaw in the trial that would likely affect the utility of the data for purposes of registration. After careful discussion with the FDA, we elected to discontinue enrollment rather than attempt to re-power the trial. We will keep the trial blinded and expect a solid data package for use in designing future trials in Crohn's disease and to bolster Prochymal's safety database."

Mills continued, "I would like to personally thank the physicians, study professionals, and of course the patients who have dedicated their time to this trial, and appreciate their ongoing participation."

The Prochymal Crohn's program consists of two separate but related double blinded trials. The first trial evaluates patients' initial response to two dose levels of Prochymal as compared to placebo. The trial was originally designed to enroll 270 subjects. The potential trial design flaw may be related to the fact that patients responding to the initial therapy were eligible to participate in a second, longer-term trial evaluating Prochymal as a maintenance therapy. Because the current standard for determining response of Crohn's patients to therapy is largely subjective, there may have been response bias to meet the eligibility requirements for continuation of therapy in the longer-term maintenance trial.

David Meeker, M.D., Executive Vice President at Genzyme Corporation said, "We fully agree with the decision by Osiris to end enrollment in this trial due to what appears to be a problem with the trial design. We think this is prudent and will enable a more efficient path forward. The data from this trial will be extremely valuable in designing the subsequent trial and enabling the continued development of this first-in-class therapy."

### Webcast and Conference Call

The Company has scheduled a webcast and conference call to discuss the Crohn's clinical program on Friday, March 27, 2009, at 9:00 AM ET. To access the webcast, visit the Investor Relations section of the company's website at <http://investor.osiris.com/events.cfm>. Alternatively, callers may participate in the conference call by dialing (800) 289-0533 (U.S. participants) or (913) 981-5587 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through April 5, 2009. Callers can access the replay by dialing (888) 203-1112 (U.S. participants) or (719) 457-0820 (international participants). The audio replay passcode is 6072746. To access a replay of the webcast, visit the Investor Relations section of the company's website at <http://investor.osiris.com/events.cfm>.

### 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 a partnership with Genzyme Corp. for the development and commercialization of Prochymal and Chondrogen in countries outside the United States and Canada. 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](http://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 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 Collaboration Agreement with Genzyme include, among others: typical business transactional risks; risks related to product development and clinical trial design, performance and completion; uncertainty of the success of Prochymal and Chondrogen in clinical trials and their ability to treat disease; Genzyme's early termination and opt-out rights; the ability of Osiris and Genzyme to successfully navigate regulatory requirements and to manufacture and commercialize products; and the uncertainty as to the ability of the parties to successfully perform under the collaborative arrangement and for Osiris to earn milestone and royalty payments thereunder. 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:**

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