



## **Osiris Therapeutics Receives Approval from Health Canada to Conduct Phase III Clinical Trial for Lead Stem Cell Drug**

### **Regulatory Action Allows Osiris to Expand Landmark Trial into Canada**

**BALTIMORE, Maryland – October 11, 2006** – Osiris Therapeutics, Inc. (NASDAQ:OSIR) has received regulatory approval to expand patient enrollment into Canada for its ongoing Phase III pivotal trial evaluating PROCHYMAL™ for the treatment of Graft vs. Host Disease.

Graft vs. Host Disease or GVHD is a life threatening immunological reaction that occurs in about 50% of patients who receive donated bone marrow or a similar transplant. GVHD is a form of rejection that occurs when the donated bone marrow attacks the recipient's organs. There is no approved treatment for GVHD. As a result, it is one of the leading causes of death in bone marrow transplant patients.

"We are excited to join this major international effort", said Dr. David Allan, Assistant Professor of Medicine at the Ottawa Hospital. "In Canada and around the world, there is a definite need for effective therapies to treat GVHD. The initial studies evaluating PROCHYMAL are promising and we look forward to participating in this confirmatory study."

To receive approval to conduct the trial in Canada, Osiris submitted a comprehensive application that included information about the safety and efficacy of the drug, manufacturing and quality specifications, and patient information. The application was reviewed and approved by Health Canada, the federal regulatory agency responsible for the approval of new drugs in Canada.

"This trial is a major undertaking with worldwide implications" said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "If successful, PROCHYMAL may not only be the first treatment approved for GVHD, but also the first stem cell drug approved for any indication. To accomplish this, we are coordinating an international effort among the world's leading physicians, hospitals, and regulatory agencies. Receiving approval to expand into Canada demonstrates the progress we are making and is a significant milestone for the team."

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 for the treatment of GVHD and Crohn's Disease. The Phase III trial for GVHD is anticipated to be the final trial before the drug is submitted to FDA, Canadian and European regulatory agencies for full approval. PROCHYMAL has been granted Fast Track status by FDA. The Fast Track program was established by FDA to accelerate the development of drugs that show promise for treating life threatening conditions. The drug has also been granted Orphan Drug status by FDA. Orphan Drug designation provides incentives to companies that develop drugs for small, underserved patient populations.

### ***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 3 clinical trials and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for regenerating cartilage in the knee, and Provacel™, for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed stem cell capabilities in research and development, manufacturing, marketing and distribution. 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 46 U.S. and 164 foreign patents owned or licensed. (OSIR-G)



### ***Forward Looking Statements***

This press release contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. 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; 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 Registration Statement on Form S-1, File No: 333-134037, as filed with the United States Securities and Exchange Commission and declared effective on August 3, 2006. 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 Lisa Rodemann at 410.522.5005, extension 610.**