



## Osiris Receives Orphan Drug Status from FDA for Lead Stem Cell Drug

**BALTIMORE, Maryland – December 20, 2005** - Osiris Therapeutics, Inc. announced today that it has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for PROCHYMAL™, an adult stem cell product under investigation for the treatment of acute Graft vs. Host Disease (GVHD). Orphan drug status provides market exclusivity to the company for up to 7 years.

PROCHYMAL is a formulation of a specific type of adult stem cell that has the ability to modulate the immune system in a way that may benefit patients suffering from a variety of immunological disorders. Osiris has two ongoing clinical trials of PROCHYMAL for the treatment of GVHD, a complication of bone marrow transplantation. In January of this year, PROCHYMAL became the first stem cell drug to be granted Fast Track status from FDA. FDA established the Fast Track program to expedite the development of promising treatments for life-threatening conditions.

“Having both orphan drug designation and Fast Track status clearly adds support to the development of PROCHYMAL for patients suffering from life-threatening GVHD. Our team is working with an excellent network of physicians to advance the program as safely and quickly as possible,” said C. Randal Mills, PhD, President and CEO of Osiris Therapeutics. “We also appreciate the significant financial incentives that orphan drug status provides to Osiris.”

The orphan drug program promotes the development of products for diseases in underserved markets. To qualify for orphan drug status, the target disease must affect relatively small numbers of patients, fewer than 200,000 per year in the United States. In addition to providing market exclusivity, another significant benefit of orphan drug status is that the fees associated with FDA filing and registration are waived. Tax incentives for as much as 50% of the clinical development costs are also available to the company.

GVHD is a life threatening immune disorder that affects approximately 50% of patients who receive donated bone marrow transplants for the treatment of cancers such as leukemia. GVHD is a form of immune rejection between the newly transplanted bone marrow cells and the patient's own cells, leading to a cascade of syndromes often resulting in death. This new approach may potentially offer treatment options not only for patients with GVHD, but also other immune diseases such as rheumatoid arthritis. Osiris is currently enrolling patients in two Phase II clinical trials for the treatment of severe GVHD. For more information on these clinical programs, visit [www.cureGVHD.com](http://www.cureGVHD.com). Most recently, Osiris began a Phase II study with PROCHYMAL for the treatment of Crohn's disease.

*Osiris® Therapeutics, Inc. is the leader in adult stem cell therapy. The stem cells produced by Osiris are obtained from adult volunteer donors, avoiding the technical problems and controversy surrounding other stem cell technologies. Using proprietary methods, these cells are grown in culture to very high numbers, allowing a single donor's cells to treat thousands of patients. These cells can be used in patients unrelated to the donor, without rejection, eliminating the need for donor matching and recipient immune suppression. Once transplanted, the cells promote healing of damaged or diseased tissues. The Company's current focus includes the use of adult stem cells to improve outcomes in bone marrow recipients being treated for leukemia, to treat Crohn's disease, to repair damage following a heart attack or congestive heart failure, and to prevent and treat arthritis.*

**For additional information, please contact Lisa Rodemann at 410.522.5005, extension 610.**

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