

Press Release

Osiris First to Announce FDA Fast Track Designation for a Stem Cell Product

Decision seen as a positive sign for both Osiris and the emerging stem cell industry

BALTIMORE, Maryland – January 27, 2005 – Osiris Therapeutics, Inc. announced today that it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for Prochymal™, an adult stem cell product formulated for the treatment of acute Graft vs. Host Disease or GVHD. Osiris believes FDA's decision makes the company the first to receive Fast Track designation for a preformulated stem cell drug.

Prochymal™, now entering Phase II clinical trials, 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 problems. This new approach may potentially offer treatment options not only for patients with GVHD, but also other immune diseases such as rheumatoid arthritis and Crohn's disease. Osiris has already successfully completed a two year Phase I clinical study.

"Clearly this is a major milestone not only for Osiris but the entire field of stem cell therapy", said C. Randal Mills, PhD, President and CEO of Osiris Therapeutics. "We have made great progress with this program and look forward to working closely with FDA to expedite the review of this important drug. We are deeply committed to the development of Prochymal™ and believe that it has the potential to help a great number of patients suffering from certain types of cancer and serious immune disorders."

FDA established Fast Track to facilitate the development and accelerate the premarket review of treatments for life-threatening conditions, so that these products can reach the market and thereby impact patients more rapidly. To receive Fast Track designation, FDA must determine that the drug has the potential to address an unmet need for a serious medical condition, and that it has demonstrated the potential to address such needs through preclinical and/or clinical testing. FDA based their decision on a review of preclinical and human testing results submitted by Osiris, as well as the product development plan. A valuable feature of Fast Track is that the company is provided the opportunity to work closely with FDA to improve the efficiency of the product development program.

GVHD is a life threatening immune disorder that affects approximately 50% patients who receive donated bone marrow transplants for the treatment of cancers such as leukemia and lymphoma. 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.

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 hundreds of patients. These remarkable 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 promote cardiac repair resulting from a heart attack or congestive heart failure, and prevention of arthritis. Osiris is partnered with Boston Scientific for the commercialization of the cardiac products and with JCR Pharmaceuticals for the commercialization of the bone marrow transplantation products in Japan.

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