



## **Osiris Therapeutics Awarded Department of Defense Contract for Prochymal(TM) Fully Valued at \$224.7 Million**

### **First award granted under Osiris - Genzyme partnership is aimed at protecting U.S. military from the lethal effects of acute radiation syndrome**

COLUMBIA, Md., Jan 03, 2008 (BUSINESS WIRE) -- Osiris Therapeutics (Nasdaq:OSIR) announced today that it has been awarded a \$224.7 million contract, including purchase options, from the United States Department of Defense (DoD) to develop and stockpile Prochymal, an adult stem cell therapy, for the repair of gastrointestinal injury resulting from radiation exposure.

Under the terms of the contract, the DoD will provide funding to Osiris for the development of Prochymal for acute radiation syndrome (ARS) in two stages, with an initial amount of \$4.2 million in 2008. Upon Food and Drug Administration approval for ARS, the contract provides for the purchase of up to 20,000 doses, at \$10,000 per dose, of Prochymal in four 5,000 dose increments. Prochymal was selected by the DoD as part of an open and competitive solicitation with pre-specified criteria that included safety and efficacy data, manufacturing capacity, soundness of the development plan, and time to final product delivery.

"We are honored that the Department of Defense has selected Prochymal in this critical effort to better safeguard our armed forces against the potentially horrendous effects of battlefield exposure to a radiological weapon," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "The contract also brings into focus a substantial new market opportunity for Prochymal. We are working diligently towards licensure of Prochymal for ARS and stand ready to assist other sectors of the United States government and allied nations in their emergency preparedness efforts."

"Prochymal's unique mechanism of action and strong clinical profile make it very well suited to address the complicated injuries associated with ARS," said Major General John Parker, MD, (Ret.), former Commanding General responsible for countermeasure development and acquisition, and member of Osiris' Medical Countermeasure Advisory Board. "Currently, every scenario contemplating a radiological emergency, both civilian and military, involves people suffering from the life-threatening effects of ARS without effective treatments. Today's decision by DoD sets in motion a sound plan to change that, by expeditiously completing development of the first effective therapy for ARS."

Osiris and Genzyme Corporation (Nasdaq:GENZ) recently announced an agreement to jointly develop Prochymal for use by U.S. and allied nations for emergency preparedness. The Department of Defense decision to fund Prochymal marks the first award under this new partnership.

"We are pleased to partner with Osiris in developing this innovative cell therapy to treat the potentially lethal complications of ARS for the U.S. military," said Henri A. Termeer, Chairman and Chief Executive Officer of Genzyme Corporation. "With our combined first-in-class technology and development expertise, Osiris and Genzyme have the necessary resources to complete this assignment for the Department of Defense and to work with other governmental organizations committed to safeguarding our nation and its allies."

Prochymal is currently in Phase III clinical trials for the treatment of Graft vs. Host Disease and Crohn's Disease and a Phase II trial for type 1 diabetes. Prochymal has also demonstrated preliminary efficacy in the treatment of patients experiencing heart attacks. Prochymal has demonstrated a strong safety profile in 7 previous Phase I and II trials and has shown the potential to reverse cellular damage and improve survival in disease states similar to ARS.

"Prochymal represents a breakthrough in countermeasure development for ARS," said Thomas J. MacVittie, Ph.D., Professor of Radiation Oncology and Pathology at the University of Maryland and member of the NIAID Medical Countermeasures and CDC Strategic National Stockpile Radiation Working Groups. "Prochymal has demonstrated therapeutic utility in humans repairing many of the major organ systems affected by radiation injury. Where most approaches only target a single component of ARS, Prochymal has the potential to address the entire syndrome including both acute and delayed effects in multiple organ systems." Dr. MacVittie also serves as a member of Osiris' Medical Countermeasure Advisory Board.

#### About Acute Radiation Syndrome

Acute Radiation Syndrome (ARS) involves damage to DNA predominately affecting the rapidly dividing cells of the gastrointestinal (GI) tract, skin and the bone marrow. The clinical manifestation of ARS can be divided into four distinct stages:

prodrome, latency, manifest illness, and recovery or death. Typically, the prodromal phase consists of GI symptoms that include abdominal pain, nausea, vomiting and diarrhea lasting 2 to 6 days. Depending on exposure, during the latent phase there is a brief abatement of symptoms as the patient appears to recover from the initial illness. However, within days to weeks, a hematopoietic (blood-forming) crisis ensues as a consequence of the depletion of both white blood cell and red blood cell progenitors within the bone marrow. The manifest illness is characterized by immunosuppression, fever and diarrhea. Victims can die within days to several months following initial exposure.

#### About Prochymal

Prochymal is a highly purified formulation of mesenchymal stem cells (MSCs) that are grown in culture, permitting large-scale production. The MSCs utilized in Prochymal are isolated from the bone marrow of healthy adult donors. Because the cells can be expanded, thousands of doses can be produced from a single donation. Numerous studies have demonstrated that the stem cells in Prochymal are able to facilitate tissue repair through a number of mechanisms. Specifically, MSCs are able to down-regulate severe inflammation, which is responsible for much of the tissue destruction that occurs as a result of radiation exposure. MSCs also work at the cellular level to rebuild damaged tissue through the coordinated release of tissue specific growth factors. Preliminary studies suggest that these characteristics are able to abate many of the complications of ARS.

Prochymal offers several unique advantages as a countermeasure for the treatment of ARS both for civilian and military populations. These include:

-- Flexible Treatment Paradigm - Prochymal is intended for the treatment of patients post-exposure, even in those who are already exhibiting symptoms, eliminating the need for immediate administration in a predefined treatment window. This approach has the added benefit of not requiring biodosimetry.

-- Advanced Development Stage - Prochymal has demonstrated safety and efficacy in 7 clinical trials, and has advanced into Phase III for three indications, each of which has been granted FDA Fast Track status. The product also has an established stability profile that permits long-term storage.

-- Large scale manufacturing - Osiris has existing capacity at multiple manufacturing sites to mass produce large quantities of Prochymal under GMP conditions.

-- Multiple Applications - Exposure to a radiological weapon can affect multiple organ systems, referred to as combined injury. Because MSCs are normally responsible for the repair of tissue injury in adults, Prochymal has the potential to address multiple aspects of ARS, including combined injury.

#### About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 9,500 employees in locations spanning the globe and 2006 revenues of \$3.2 billion. In 2007, Genzyme was chosen to receive the National Medal of Technology, the highest honor awarded by the President of the United States for technological innovation. In 2006 and 2007, Genzyme was selected by FORTUNE as one of the "100 Best Companies to Work for" in the United States.

With many established products and services helping patients in nearly 90 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopedics, cancer, transplant, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as immune disease, infectious disease, and other areas of unmet medical need.

#### 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(R) for regenerating bone in orthopedic indications. Prochymal(TM) is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also Crohn's disease, and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris has also partnered with Genzyme Corporation to develop Prochymal(TM) as a medical countermeasure to nuclear terrorism and other radiological emergencies. Prochymal is also being developed for the repair of heart tissue following a heart attack and for the protection of pancreatic islet cells in patients with type 1 diabetes. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen(TM) for arthritis in the knee. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. 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 47 U.S. and 215 foreign patents owned or licensed. 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; 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 mesenchymal stem cells 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 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission. Risk factors relative to the matters discussed in this press release also include risks of adverse changes in U.S. government spending priorities; failure to retain existing U.S. government contracts or to obtain option awards, task orders, or funding under contracts; risks of contract performance; risks of contract termination, either for default or for the convenience of the U.S. government; adverse results of U.S. government audits of our U.S. government contracts; and risks associated with complex U.S. government procurement laws and regulations. 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.

SOURCE: Osiris Therapeutics

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