World's First Approved Stem Cell Drug; Osiris Receives Marketing Clearance from Health Canada for Prochymal

Historic decision offers hope to children suffering from life-threatening GvHD

COLUMBIA, Md. – May 17, 2012 – Osiris Therapeutics Inc. (NASDAQ: OSIR) announced today it has received market authorization from Health Canada to market its stem cell therapy Prochymal® (*remestemcel-L*), for the treatment of acute graft-vs-host disease (GvHD) in children. The historic decision marks the world's first regulatory approval of a manufactured stem cell product and the first therapy approved for GvHD — a devastating complication of bone marrow transplantation that kills up to 80 percent of children affected, many within just weeks of diagnosis.

"I am very proud of the leadership role Canada has taken in advancing stem cell therapy and particularly gratified that this historic decision benefits children who would otherwise have little hope," said Andrew Daly, M.D., Clinical Associate Professor, Department of Medicine and Oncology at the University of Calgary, Canada and Principal Investigator in the phase 3 clinical program for Prochymal. "As a result of Health Canada's comprehensive review, physicians now have an off-the-shelf stem cell therapy in their arsenal to fight GvHD. Much like the introduction of antibiotics in the late 1920's, with stem cells we have now officially taken the first step into this new paradigm of medicine."

Prochymal was authorized under Health Canada's Notice of Compliance with conditions (NOC/c) pathway, which provides access to therapeutic products that address unmet medical conditions and which have demonstrated a favorable risk/benefit profile in clinical trials. Under the NOC/c pathway, the sponsor must agree to carry out confirmatory clinical testing.

"Today is not only a great day for Osiris, but for everyone involved in the responsible development of stem cell therapies," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "Most importantly, today is a great day for children and their families who bravely face this horrific disease. While today marks the first approval of a stem cell drug, now that the door has been opened, it will surely not be the last."

Health Canada's authorization was made following the recommendation of an independent expert advisory panel, commissioned to evaluate Prochymal's safety and efficacy. In Canada, Prochymal is now authorized for the management of acute GvHD in children who fail to respond to steroids. The approval was based on the results from clinical studies evaluating Prochymal in patients with severe refractory acute GvHD. Prochymal demonstrated a clinically meaningful response at 28 days post initiation of therapy in 61-64 percent of patients treated. Furthermore, treatment with Prochymal resulted in a statistically significant improvement in survival when compared to a historical control population of pediatric patients with refractory GvHD ($p=0.028$). The survival benefit was most pronounced in patients with the most severe forms of GvHD. As a condition of approval, the clinical benefit of Prochymal will be further evaluated in a case matched confirmatory trial and all patients receiving Prochymal will be encouraged to participate in a registry that will monitor the long-term effects of the therapy.

"Refractory GvHD is not just deadly to the patients it afflicts, but is devastating for the family, friends, and caregivers who watch helplessly as the disease progresses," said Joanne Kurtzberg, MD, Head of the Pediatric Bone Marrow Transplant Program at Duke University and Lead Investigator for Prochymal. "I have personally seen Prochymal reverse the debilitating effects of severe GvHD in many of my patients and now, after nearly two decades of research, the data demonstrating consistently high response rates, a strong safety profile and improved survival clearly support the use of Prochymal in the management of refractory GvHD."

Prochymal is currently available in several countries, including the United States, under an Expanded Access Program (EAP). Prochymal will be commercially available in Canada later this year.

"Today Osiris turns the promise of stem cell research into reality, delivering on decades of medical and scientific research," said Peter Friedli, Chairman and Co-founder of Osiris. "It took 20 years of hard work and perseverance and I want to personally thank everyone involved for their dedication to this important mission."

In addition to the extensive intellectual property protection Osiris has around Prochymal, which includes 48 issued patents, Health Canada's decision will also provide Prochymal with regulatory exclusivity within the territory. Canada affords eight years of exclusivity to Innovative Drugs such as Prochymal, and an additional six-month extension is available since it addresses a pediatric population.

Webcast and Conference Call

A webcast and conference call is scheduled for tomorrow, May 18, 2012 at 9:00 a.m. 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 (877) 303-6133 (U.S. participants) or (970) 315-0493 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through May 24, 2012. Callers can access the replay by dialing (855) 859-2056 (U.S. participants) or (404) 537-3406 (international participants). The audio replay confirmation code is 82905846. 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 GvHD

GvHD represents a major unmet medical need with no approved treatment until Prochymal. GvHD is the leading cause of transplant related mortality, in which immune cells contained within the transplanted marrow recognize the recipient as foreign and mount an immunologic attack. Severe GvHD can cause blistering of the skin, intestinal hemorrhage and liver failure. Severe GvHD is extremely painful and fatal in up to 80 percent of cases. Currently, steroids are used as first-line therapy with a success rate of only 30-50 percent. When steroids fail, treatment options are limited to immunosuppressive agents used off-label with little benefit and significant toxicities.

About Prochymal (remestemcel-L)

Prochymal is the world's first approved drug which has a stem cell as its active ingredient. Developed by Osiris Therapeutics, Prochymal is an intravenous formulation of mesenchymal stem cells (MSCs), which are derived from the bone marrow of healthy adult donors between the ages of 18 and 30 years. The MSCs are selected from the bone marrow and grown in culture so that up to 10,000 doses of Prochymal can be produced from a

single donor. Prochymal is truly an off-the-shelf stem cell product that is stored frozen at the point-of-care and infused through a simple intravenous line without the need to type or immunosuppress the recipient. Prochymal is currently approved in Canada for the management of acute graft-versus-host disease (GvHD) in children and is available for adults and children in eight countries including the United States, under an Expanded Access Program. Prochymal is currently in Phase 3 trials for refractory Crohn's disease and also being evaluated in clinical trials for the treatment of myocardial infarction (heart attack) and type 1 diabetes.

About Notice of Compliance with Conditions

An NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. Such products have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to such products on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is the leading stem cell company, having developed the world's first approved stem cell drug, Prochymal. The company is focused on developing and marketing products to treat medical conditions in inflammatory, cardiovascular, orthopedic areas and wound healing areas. Osiris currently markets Prochymal for refractory GvHD, Grafix® for burns and chronic wounds, and Ovation® for orthopedic applications. 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 developed an extensive intellectual property portfolio to protect the company's technology, including 48 U.S. and 144 foreign patents.

Osiris, Prochymal, Grafix and Ovation are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, 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. 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 other Periodic 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.

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