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Osiris Receives Second Approval for Life-Saving Stem Cell Drug; Prochymal Granted Marketing Consent by New Zealand

COLUMBIA, Md.--(BUSINESS WIRE)-- [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), announced today it has received consent from New Zealand to market its first-in-class stem cell therapy Prochymal® (*remestemcel-L*), for the treatment of acute graft-vs-host disease (GvHD) in children. With this decision New Zealand joins [Canada](#), which last month became the world's first internationally recognized regulatory authority to grant approval to a stem cell drug. Prochymal is also 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.

"With each of our approvals it becomes clearer that the time for life-saving stem cell therapies in the practice of medicine has arrived, and we are humbled to have a leading role," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "I would like to thank the professionals at Medsafe for their thoughtful and expeditious review of this complex application. I would also like to thank the team at Osiris that continues to do an outstanding job of making Prochymal available to children around the world suffering from the devastating effects of GvHD."

Osiris submitted a New Medicine Application (NMA) to Medsafe (New Zealand's medical regulatory agency) in May of 2011, and was granted Priority Review in June of 2011. Priority review provides expedited review for new drugs which offer a significant clinical advantage over current treatment options. Prochymal was granted provisional consent under Section 23 of the Medicines Act 1981.

"The incidence of GvHD is likely to rise as the demographic profile of our transplant population evolves," said Hans Klingemann, M.D., Ph.D., a Professor of Medicine and the Director of the Bone Marrow & Hematopoietic Stem Cell Transplant Program at Tufts University School of Medicine. "Effective strategies to manage the often lethal consequences of GvHD reduce the overall risk to transplantation and provide the transplant physician with better options when approaching their most difficult cases."

Clinical trials have shown that Prochymal is able to induce an objective, clinically meaningful response in 61-64 percent of children with GvHD that is otherwise refractory to treatment. Furthermore, treatment response with Prochymal resulted in a statistically significant improvement in survival.

"As a mother who watched my son Christian suffer and die from the horrifying effects of GvHD, while waiting for the regulatory approvals necessary to allow him access to Prochymal, words cannot express how happy I am that significant progress is finally being made," said Sandy Barker, President and Co-founder of the Gold Rush Cure Foundation. "We are proud to stand side-by-side with Osiris in this historic battle for our children around the world. Our motto is '*not one more child, not one more family*' and when it comes to GvHD mortality, zero is the only acceptable number."

Prochymal is now approved in Canada and New Zealand, and is currently available in seven other countries including the United States under an Expanded Access Program (EAP). It is expected that Prochymal will be commercially available in New Zealand later this year.

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 with 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 approved in Canada and New Zealand 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 is also being evaluated in clinical trials for the treatment of myocardial infarction (heart attack) and type 1 diabetes.

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 and wound healing markets. In Biosurgery, Osiris currently markets Grafix® for burns and chronic wounds and Ovation® for orthopedic applications. 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 issued 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)

About Christian Barker & Gold Rush Cure Foundation

At only 13-years-old, Christian was diagnosed with a rare form of leukemia. The treatment for this cancer required a bone marrow transplant. However, due to the aggressive nature of the cancer, Christian relapsed and a second transplant was conducted. The treatment regimen consisted of extreme chemotherapy, radiation, and multiple surgeries. Despite the negative side effects from those treatments, nothing compared to the brutal suffering which occurred after he contracted graft-vs.-host disease, which painfully destroyed every part of Christian's body. The disease caused Christian's skin to peel off, and he vomited several liters of blood daily due to the destruction of his gastro intestinal tract. To make matters even worse, Christian experienced liver failure and suffered daily with extreme pain from head to toe. This condition was prevalent for the four months, and eventually lead to his death. No child should have to suffer like this, and watching Christian's body being destroyed by the disease was as horrifying for him as it was for our family and his caregivers.

After Christian died in December 2007, his mother and father, Sandy and Gary, established the Gold Rush Cure Foundation (GRCF), which is dedicated to raising public awareness and funding to help eradicate childhood cancer. GRCF is also committed to being advocates for children fighting cancer. In June, GRCF made its 11th trip to Washington, D.C., since Christian's passing to meet with lawmakers about the vital need for more funding and awareness for childhood cancer, which is the leading cause of death by disease for children. For more information, please visit, www.goldrushcure.org.

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.

Source: Osiris Therapeutics, Inc.

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