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New Zealand approves stem cell drug Prochymal

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Singapore: Osiris Therapeutics 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 Dr C Randal Mills, 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 2011. Priority review provides expedited review for new drugs that 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 Dr Hans Klingemann, a professor of Medicine and the director of the Bone Marrow and 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 Md 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.