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World's First Approved Stem Cell Drug

April 24, 2012 | News | By BioSpectrum Bureau

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Singapore, May 22, 2012: Canadian company**,** Osiris Therapeutics 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.

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"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."

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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.

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"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, it 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."

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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.