

World's First Stem-Cell Drug Approval Achieved in Canada

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On May 17, 2012, **Osiris Therapeutics** announced that Canadian health regulators approved **Prochymal**, its drug for acute graft-versus host disease in children who have failed to respond to steroid treatment. Prochymal is the first **stem cell drug** to be approved anywhere in the world for a systemic disease.

Graft-versus-host disease, a potentially fatal complication from bone marrow transplant, involves the newly implanted cells attacking the patient's body. Until now, there have been no approved treatments for the disease. Prochymal is designed to control inflammation and promote tissue regeneration. Since the drug is made up of bone marrow stem cells derived from an adult donor, it circumvents ethical concerns that are raised by the use of stem cells derived from embryos.

The Canadian approval is contingent on Osiris conducting further post-market testing—and it's anticipated that if the **FDA** approves the drug when marketing authorization is sought later this year, similar conditions would be imposed.

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