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Osiris successfully defends patent challenge in Australia

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Singapore: Osiris Therapeutics, a Columbia-based company focused on developing and marketing stem cell products to treat serious medical conditions, has successfully defended a patent challenge in Australia by an opponent whose identity under Australian law was not disclosed. The patent at issue covers the administration of mesenchymal stem cells (MSCs), including Prochymal (remestemcel-L), for the treatment of inflammatory conditions involving the gastrointestinal tract, including Crohn's disease and ulcerative colitis.

As acknowledged in the Australian Official Journal of Patents Supplement, all claims to the patent will be maintained in full. The claims specifically include the use of allogeneic MSCs, an attribute central to making an off-the-shelf MSC product possible.

In 2012, Prochymal, an intravenous formulation of MSCs, became the world's first stem cell drug to gain approval by an internationally recognized regulatory authority. Prochymal is also the first drug approved for acute graft versus host disease

(GvHD) - a devastating complication of bone marrow transplantation that kills up to 80 percent of children affected, many within just weeks of diagnosis. Prochymal is now approved in Canada and New Zealand, and is currently available in seven other countries, including the US under an Expanded Access Program.

The European Medicines Agency has designated Prochymal as an orphan medicinal product. In Europe, the orphan drug designation provides a variety of incentives, including market exclusivity for up to 10 years following approval, to companies that develop drugs for under-served patient populations.