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Osiris Bolsters its Stem Cell Intellectual Property Estate

COLUMBIA, Md.--(BUSINESS WIRE)-- [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), announced today the expansion of its intellectual property protection around Prochymal® (*remestemcel-L*). The United States Patent and Trademark Office recently granted Osiris two patents that cover multiple mechanisms of action related to cardiac tissue repair. Additionally, Osiris has enhanced its mesenchymal stem cell (MSC) patent estate with the issuance of patents across Europe and Australia covering stem cells expressing all therapeutically useful levels of cell surface receptors for TNF-alpha, a receptor essential to the cell's ability to counteract inflammation. These patents further support Osiris' considerable intellectual property position, which includes 48 issued U.S. patents around the production, composition, testing and use of the mesenchymal stem cell from both allogeneic and autologous sources.

"These recent additions to Osiris' patent estate, combined with the existing broad coverage of our pioneering MSC platform technology, reinforce our industry leading IP portfolio and bolster our dominant position regarding the manufacture and use of mesenchymal stem cells for the treatment of a broad range of diseases," said Chris Alder, Chief Intellectual Property Counsel of Osiris. "We have invested significant time and resources building our intellectual property estate, and with the commercialization of Prochymal, we are preparing to take the necessary action to enforce our considerable rights."

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. With Prochymal (*remestemcel-L*) entering commerce, Osiris has initiated the process of identifying entities that may be infringing upon its intellectual property rights and will take appropriate action as necessary.

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 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 a Phase 3 trial 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 Graftix® 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 patents.

Osiris, Prochymal, Graftix and Ovation are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, www.Osiris.com. (OSIR - G)

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.

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