



Prochymal New Drug Submission Granted Priority Review by Health Canada

Health Canada to add first-in-class stem cell therapy to Register of Innovative Drugs providing eight years of market exclusivity

COLUMBIA, Md. – July 21, 2010 - [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR) announced today that the Biologics and Genetic Therapies Directorate of Health Canada has completed its initial evaluation and accepted for full review the company's New Drug Submission (NDS) of Prochymal (remestemcel-L), an adult stem cell therapy for the treatment of graft vs. host disease (GvHD). Based on a separate review of summary clinical data, Health Canada has notified Osiris that the application has been granted Priority Review, shortening the examination period from 300 to 180 days. If successful, Prochymal would become the world's first approved stem cell therapy.

[Priority Review](#) is granted when Health Canada determines that the summary clinical data provided demonstrates substantial evidence of the drug's effectiveness in treating a life-threatening condition. Priority Review candidates are subject to the same quality, safety and efficacy requirements as non-priority submissions, but are processed more quickly.

The application is the first in Osiris' global registration strategy for Prochymal. The NDS was filed in the electronic Common Technical Document (eCTD) format to facilitate review and allow for efficient submission in other territories. The submission marks the first application for full approval of a stem cell therapy anywhere in the world. Prochymal is currently available to patients with refractory acute GvHD in the United States under an expanded access program.

As part of the review, Health Canada has also informed Osiris of its plans to add Prochymal to its Register of Innovative Drugs subject to a final review upon approval. Registration confers eight years of market exclusivity beginning on the date of Prochymal's approval, during which no submission for a generic version of Prochymal will be approved.

About Prochymal

Prochymal (remestemcel-L) is a preparation of mesenchymal stem cells (MSCs) formulated for intravenous infusion. The MSCs utilized in Prochymal are isolated from the bone marrow of healthy young adult donors, avoiding the controversy surrounding embryonic and fetal cell sources. They are grown in culture, permitting large-scale production. Because the cells can be expanded, thousands of doses can be produced from a single donation. Studies indicate that MSCs are able to down-regulate severe inflammation and work at the cellular level to rebuild damaged tissue through the coordinated release of tissue-specific growth factors.

Prochymal is being evaluated in clinical programs for the treatment of Crohn's disease, acute myocardial infarction, type 1 diabetes and pulmonary disease. Prochymal has been granted Fast Track status by the FDA for GvHD and Crohn's disease, and is the first stem cell product to receive FDA expanded access approval, making the product available now to patients with life-threatening GvHD. Prochymal also obtained Orphan Drug status for GvHD and type 1 diabetes from the FDA as well as Orphan Drug status for GvHD from the European Medicines Agency.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is the leading stem cell therapeutic company focused on developing products to treat serious medical conditions in the inflammatory, autoimmune, orthopedic and cardiovascular areas. The



Company's pipeline of internally developed biologic drug candidates under evaluation includes Prochymal for inflammatory, autoimmune and cardiovascular indications, as well as Chondrogen for arthritis in the knee. 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 49 U.S. patents each having one or more foreign counterparts. Osiris, Prochymal and Chondrogen are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

Osiris and Genzyme formed a strategic alliance for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, Osiris retains commercialization rights to Prochymal and Chondrogen in the United States and Canada. Genzyme holds these rights in all other countries except Japan, where JCR Pharmaceuticals holds rights to Prochymal for the treatment of patients with hematological malignancies.

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. Risks and uncertainties related to our Collaboration Agreement with Genzyme for the development and commercialization of Prochymal and Chondrogen include, among others: typical business transactional risks; risks related to product development and clinical trial design, performance and completion; uncertainty of the success of Prochymal and Chondrogen in clinical trials and their ability to treat disease; Genzyme's early termination and opt-out rights; the ability of Osiris and Genzyme to successfully navigate regulatory requirements and to manufacture and commercialize products; and the uncertainty as to our ability to successfully perform under the collaborative arrangement and earn milestone and royalty payments thereunder. 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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