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## **Prochymal Significantly Reduces Hypertrophy, Arrhythmia and Progression to Heart Failure in Patients Suffering a Heart Attack**

COLUMBIA, Md.--(BUSINESS WIRE)-- [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), announced today interim one-year results from its groundbreaking clinical trial evaluating Prochymal® (*remestemcel-L*) for the treatment of patients experiencing first-time acute myocardial infarction. The trial is the largest study of allogeneic or "off-the-shelf" stem cells ever conducted in heart attack patients. A total of 220 patients were given a single infusion of either Prochymal or placebo through a standard intravenous line within seven days of an acute heart attack.

Cardiac MRI assessments were conducted for six months following infarct to evaluate cardiac remodeling. Patients receiving Prochymal had significantly less cardiac hypertrophy, as measured by cardiac MRI, compared to patients receiving placebo ( $p < 0.05$ ). Patients treated with Prochymal also experienced significantly less stress-induced ventricular arrhythmia ( $p < 0.05$ ). Cardiac hypertrophy and ventricular arrhythmia are indicators of pathological remodeling following heart injury and provide insight into the mechanism by which mesenchymal stem cells attenuate heart injury following a myocardial infarction.

The mechanistic data is complemented by clinical data showing treatment with Prochymal resulted in a statistically significant reduction in heart failure. In the study, seven patients who were treated with placebo have progressed to heart failure requiring treatment with intravenous diuretics, compared to none of the Prochymal patients ( $p=0.01$ ). Furthermore, patients receiving placebo tended to require re-hospitalization for cardiac issues sooner than the patients receiving Prochymal (median 27.5 days vs. 85.5 days).

"This study is the largest of its kind and provides key insights into the mechanism of action of mesenchymal stem cells in the setting of acute myocardial infarction," said Lode Debrabandere, Ph.D., Senior Vice President of Therapeutics at Osiris. "These important mechanistic observations are consistent with data obtained from our preclinical models and from the first placebo-controlled human trial with Prochymal published in the *Journal of the American College of Cardiology*. Given the quality of the data and highly encouraging results observed thus far, we are extending the trial's duration to capture a better understanding of the long-term clinical benefits of MSCs."

The trial also demonstrated that treatment with Prochymal was safe. There were no infusional toxicities observed in patients receiving Prochymal. Serious adverse events occurred with equal frequency in both treatment groups (31.8%). To date, there have been 5 deaths in the trial, 2 in the Prochymal group and 3 in the placebo group.

"For interventional cardiologists, keeping our myocardial infarction patients from progressing to heart failure is central to our mission," said Mark Vesely, M.D., Principal Investigator on the Study and Assistant Professor of Medicine (Interventional Cardiology) at the University of Maryland School of Medicine. "It is remarkable and very encouraging to see significant changes in clinically meaningful parameters this early in the study. We look forward to the additional data that will be gathered as the study progresses, which will help us to better understand both the magnitude and durability of the benefit to treatment."

Prochymal, the world's first and only stem cell drug approved by an internationally recognized regulatory authority, is used for the treatment of graft vs. host disease (GvHD). GvHD is a devastating complication of bone marrow transplantation that kills up to 80 percent of children affected. 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 (EAP).

### **About the Trial**

This Phase 2, multi-center, randomized, double-blind, placebo-controlled study is evaluating the safety and efficacy of Prochymal (*ex-vivo* cultured adult human mesenchymal stem cells) intravenous infusion following acute myocardial infarction. A total of 220 patients were randomized (1:1) at 33 centers in the United States and Canada and received a single intravenous infusion of Prochymal or placebo within 7 days following first acute myocardial infarction. In addition to screening and baseline visits prior to the infusion, initially follow-up evaluations were scheduled to be conducted through 2 years. Given the encouraging results observed at the one year time-point, the trial is being extended to include 5 years of follow-up. Both male and female subjects between 21 and 85 years of age were enrolled. Patients had to have a left ventricular ejection fraction (LVEF) between 20% and 45% as determined by quantitative echocardiography or cardiac MRI at least 24 hours after successful reperfusion of the culprit vessel. In addition, troponin levels must have been greater than 4 times the upper limit of normal during the first 72 hours of hospitalization for the MI.

## **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 Grafix® 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, Grafix and Ovation are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, [www.Osiris.com](http://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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