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Vericel Announces Publication of Clinical Trial Rationale and Study Design for the Phase 2b ixCELL-DCM Trial of Ixmyelocel-T in Patients with Heart Failure Due to Ischemic Dilated Cardiomyopathy

CAMBRIDGE, Mass., March 28, 2016 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leading developer of patient-specific expanded cellular therapies for the treatment of severe diseases and conditions, today announced the publication of the clinical trial rationale and study design for the company's Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T in patients with advanced heart failure due to ischemic dilated cardiomyopathy (DCM) in the journal *Cell Transplantation*.

On March 10, 2016, Vericel announced that the ixCELL-DCM trial met its primary endpoint of demonstrating a reduction in the total number of deaths, cardiovascular hospitalizations or unplanned outpatient and emergency department visits to treat acute decompensated heart failure during the 12 months following treatment with ixmyelocel-T compared to placebo. The ixCELL-DCM trial is believed to be the largest randomized, double-blind, placebo-controlled cell therapy clinical trial to treat heart failure due to ischemic DCM completed to date.

The publication by Dr. Timothy Henry and colleagues (Henry T.D., Schaer G., Demaria A., et al., The ixCell-DCM Trial: Rationale and Design, *Cell Transplantation*, 2016) describes the study design, study population, treatment preparation and protocol, clinical endpoints, and statistical analysis plan for the ixCELL-DCM clinical trial.

The full data results from the ixCELL-DCM trial are scheduled to be presented at the upcoming Late-Breaking Clinical Trial Sessions of the American College of Cardiology 65th Annual Scientific Session & Expo on April 4, 2016, and also will be submitted for publication.

About Dilated Cardiomyopathy

Dilated cardiomyopathy (DCM), a progressive disease of the heart, is a leading cause of heart failure and heart transplantation. DCM is characterized by weakening of the heart muscle and enlargement of the heart chambers, leading to systolic abnormalities (difficulty of the left ventricle to pump blood). Heart enlargement and poor function generally lead to progressive heart failure with further decline in the ability of the heart to pump blood efficiently throughout the body.

About Ixmyelocel-T

Ixmyelocel-T is a patient-specific, expanded multicellular therapy manufactured from the patient's own bone marrow using Vericel's proprietary, highly automated, fully closed [cell-processing system](#). This process selectively expands the population of mesenchymal stromal cells and alternatively activated macrophages, which are responsible for production of anti-inflammatory and pro-angiogenic factors known to be important for repair of damaged tissue. Ixmyelocel-T has been designated as an orphan drug by the U.S Food and Drug Administration for use in the treatment of DCM.

About the ixCELL-DCM Clinical Trial

The ixCELL-DCM clinical trial is a multicenter, randomized, double-blind, placebo-controlled Phase 2b study designed to assess the efficacy, safety and tolerability of ixmyelocel-T compared to placebo (vehicle control) when administered via transendocardial catheter-based injections to subjects with end-stage heart failure due to ischemic DCM, who have no reasonable revascularization options (either surgical or percutaneous interventional) likely to provide clinical benefit. The primary endpoint of the ixCELL-DCM clinical trial study is the number of all-cause deaths, cardiovascular hospital admissions, and unplanned outpatient and emergency department visits to treat acute decompensated heart failure over the 12 months following administration of ixmyelocel-T compared to placebo.

About Vericel Corporation

Vericel Corporation is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. The company markets two autologous cell therapy products in the U.S.: Carticel[®] (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel[®] (cultured epidermal autografts), a permanent skin replacement for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30% of total body surface area. Vericel is also developing MACI[™], a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee. For more information, please visit the company's website at www.vcel.com.

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This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, the clinical protocol and statistical plan for the Phase 2b ixCELL-DCM clinical study of ixmylocel-T, objectives and expectations regarding ixmylocel-T, intended product development, clinical activity timing and objectives and expectations regarding our company described herein, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "can continue," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with competitive developments, clinical trial and product development activities, regulatory approval requirements, the availability and allocation of resources among different potential uses, estimating the commercial potential of our product candidates and growth in revenues and improvement in costs, market demand for our products, and our ability to supply or meet customer demand for our products. These and other significant factors are discussed in greater detail in Vericel's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission ("SEC") on March 14, 2016, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect management's current views and Vericel does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

CONTACT:

Chad Rubin
The Trout Group
crubin@troutgroup.com
(646) 378-2947
or
Lee Stern
The Trout Group
lstern@troutgroup.com
(646) 378-2922