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Vericel Announces Positive Top-Line Results From Phase 2b ixCELL-DCM Clinical Trial of Ixmyelocel-T in Patients With Heart Failure Due to Ischemic Dilated Cardiomyopathy

Study Meets Primary Endpoint of Reduction in Clinical Cardiac Events

CAMBRIDGE, Mass., March 10, 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 top-line results from the company's Phase 2b ixCELL-DCM clinical trial of ixmyelocel-T in patients with advanced heart failure due to ischemic dilated cardiomyopathy (DCM). The 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. All clinical events in the primary and secondary endpoints were adjudicated in a blinded fashion by an independent adjudication committee. The incidence of adverse events, including serious adverse events, in patients treated with ixmyelocel-T was comparable to patients in the placebo group. Ixmyelocel-T has been granted orphan product designation by the U.S. Food and Drug Administration for use in the treatment of DCM.

"The results of the ixCELL-DCM study, which we believe is the largest randomized cell therapy trial to treat congestive heart failure completed to date, demonstrated a statistically significant and clinically meaningful reduction in cardiac events in patients who received treatment with ixmyelocel-T compared to placebo," said Dr. David Recker, Vericel's chief medical officer. "We are very excited about these study results given the lack of treatment options for end-stage heart failure patients."

The Phase 2b 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 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 trial was designed to provide approximately 80% power to show a 46% difference in cardiac events for ischemic DCM patients treated with ixmyelocel-T compared to placebo. A total of 114 patients were treated in the ixCELL-DCM clinical trial at 28 sites in the United States.

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, and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy. For more information, please visit the company's website at www.vcel.com.

This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of our products, intended product development, relative size of clinical trials, clinical activity timing and regulatory pathway and 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 clinical trial and product development activities and regulatory approval requirements. 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, 2014, filed with the Securities and Exchange Commission ("SEC") on March 25, 2015, 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.

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