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Results from Vericel's Positive Phase 2b ixCELL-DCM Clinical Trial of Ixmyelocel-T Presented Today at ACC and Published in The Lancet

Patients Treated with Ixmyelocel-T had a 37 Percent Reduction in Clinical Events Compared to Placebo

CAMBRIDGE, Mass., April 04, 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 presentation and publication of results from the company's Phase 2b ixCELL-DCM clinical study of ixmyelocel-T in patients with advanced heart failure due to ischemic dilated cardiomyopathy (DCM). The data were presented today by Timothy Henry, M.D., at the Late-Breaking Clinical Trial Session and press conference at the American College of Cardiology's (ACC) 65th Annual Scientific Session and published in *The Lancet*. Dr. Henry is director of cardiology at Cedars-Sinai Heart Institute, principal investigator of the study and co-author of the Lancet publication.

"The ixCELL-DCM study met its primary endpoint of demonstrating a reduction in the total number of all-cause 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," said Dr. David Recker, Vericel's chief medical officer. "From a safety perspective, the incidence of adverse events, including serious adverse events, in patients treated with ixmyelocel-T was comparable to or lower than patients in the placebo group. We are very excited about the results of this clinical trial and greatly appreciate the contributions of the patients, investigators and dedicated personnel who participated in this study."

"We have a major unmet need in the treatment of class III and IV heart failure," said Amit N. Patel, M.D., director of clinical regenerative medicine and associate professor of surgery at the University of Utah and the Chair of the ixCELL-DCM Steering Committee. "Based on these positive results, we are encouraged that ixmyelocel-T has the potential, if approved, to represent an important new option for patients with class III and class IV heart failure due to ischemic cardiomyopathy."

The ixCELL-DCM clinical trial is a multicenter, randomized (1:1), double-blind, placebo-controlled Phase 2b study 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. A total of 126 patients with New York Heart Association (NYHA) Class III or IV heart failure were randomly assigned to receive either ixmyelocel-T or placebo, and 114 patients were treated at 28 sites in the United States. All clinical events in the primary and secondary endpoints were adjudicated in a blinded fashion by an independent adjudication committee.

The trial met its primary endpoint with patients in the ixmyelocel-T group having a 37 percent reduction in all-cause deaths, cardiovascular hospitalizations, or unplanned outpatient and emergency department visits to treat acute decompensated heart failure during the 12 months following treatment compared to the placebo group (p=0.0344). The primary endpoint was driven by a reduction in both all-cause deaths and cardiovascular hospitalizations. In the primary endpoint without procedure-related events, three percent of patients in the ixmyelocel-T group died and 38 percent had cardiovascular hospitalizations one or more times, compared to 14 percent and 47 percent, respectively, in the placebo group. All deaths were adjudicated to be due to cardiovascular causes.

With respect to the secondary endpoints of the trial, the components of the primary endpoint were also analyzed using the Win ratio in a hierarchical manner to incorporate both the incidence and timing of the endpoint components. The Win ratio result of 1.56 showed that more often ixmyelocel-T was the "winner" in that the time to death, left ventricular assist device placement, heart transplantation or time to cardiovascular hospitalization was shorter for placebo-treated patients, but this difference did not reach statistical significance. The time to first event was longer in the ixmyelocel-T group compared to placebo, but was not statistically significant. There were no significant structural changes in left ventricle cavity size or left ventricular ejection fraction as measured by echocardiogram in either the ixmyelocel-T or placebo groups. Both treatment groups had an improvement in the NYHA class and six minute walk test, with no statistical difference between the groups at month 12 using last observation carried forward.

Overall, there were fewer adverse events and serious adverse events in the ixmyelocel-T group compared to the placebo group. Adverse events included those typically related to catheterization or injection procedures.

The ixCELL-DCM trial showed a statistically significant reduction in clinical events driven by both cardiac mortality and cardiac hospitalizations at 12 months compared to placebo. These results are consistent with two previous Phase 2a studies which showed that ischemic DCM patients treated with ixmyelocel-T experienced fewer major adverse cardiovascular

events during follow up compared to control patients.

Vericel will host a webcast at 12:00pm ET on Tuesday, April 5, 2016 to review ixmyelocel-T and the Phase 2b ixCELL-DCM trial results. Dr. Gary L. Schaer, M.D., of Rush University Medical Center and a member of the ixCELL-DCM Steering Committee, will present an overview of the results from the ixCELL-DCM clinical trial and Dr. Ross Tubo, Vericel's chief scientific officer, will present additional background information on ixmyelocel-T and describe the potential benefits of expanded multicellular therapy in the repair and regeneration of ischemic tissue. The live webcast and a recording will be available at the events and presentations section of the Vericel website at investors.vcel.com/events.cfm. Both the Lancet publication and the ACC Scientific Sessions presentation, as well as additional data and analysis not presented at ACC, are currently available at investors.vcel.com/events.cfm.

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.

This document contains forward-looking statements, including, without limitation, statements concerning the clinical protocol and statistical plan for the Phase 2b ixCELL-DCM clinical study of ixmyelocel-T, objectives and expectations regarding ixmyelocel-T and potential for approval, 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.

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