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Vericel Receives FDA Fast Track Designation for Ixmyelocel-T, an Investigational Product for the Treatment of Patients with Advanced Heart Failure Due to Ischemic Dilated Cardiomyopathy

CAMBRIDGE, Mass., Feb. 21, 2017 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leading developer of autologous expanded cell therapies for the treatment of patients with serious diseases and conditions, today announced that the U.S. Food and Drug Administration (FDA) has designated the investigation of ixmyelocel-T for reduction in the risk of death and cardiovascular hospitalization in patients with chronic advanced heart failure due to ischemic dilated cardiomyopathy as a Fast Track Development Program.

"Receiving Fast Track designation highlights both the unmet medical need for improved therapies to treat advanced heart failure due to dilated cardiomyopathy and the significance of the results from the ixmyelocel-T Phase 2b ixCELL-DCM clinical study" said Nick Colangelo, president and CEO of Vericel. "We believe that achieving important regulatory milestones such as Fast Track designation enhances the value of ixmyelocel-T and our efforts to partner the further development of this program."

The Fast Track program is an expedited drug development and review program for new drugs or biologics intended to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need. The purpose of the program is to get important new drugs to the patient earlier. For more information on Fast Track, visit the FDA website (http://www.fda.gov/forpatients/approvals/fast/ucm405399.htm).

About Advanced Heart Failure
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. There is no cure for heart failure and there are limited treatment options in the advanced, refractory stage of the disease. Pharmacological interventions are typically introduced in earlier stages of heart failure and maximized as the condition progresses, with more invasive and aggressive interventions reserved for patients in later stages. By the time a patient progresses to the advanced stage of heart failure, they are being treated with multiple drugs with limited success for the treatment of persistent and severe symptoms, may have an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy, and have few remaining treatment options (Yancy 2013).

About Ixmyelocel-T
Ixmyelocel-T is an investigational autologous 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 Trial
The ixCELL-DCM clinical trial was 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 participants 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. All participants were on maximized pharmacological heart failure treatment and had an automatic implantable cardiac defibrillator or cardiac resynchronization therapy. The primary endpoint of the ixCELL-DCM clinical trial 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. Primary endpoint results were presented in a late-breaking clinical trial session at the American College of Cardiology's (ACC) 65th Annual Scientific Session. The ixCELL-DCM trial met its primary endpoint with a 37% reduction in the composite endpoint, primarily driven by a reduction in all cause deaths and cardiovascular hospitalizations. In addition, this study showed internal consistency (ie, repeatability) in observable or "hard" efficacy endpoints of survival and cardiovascular hospitalizations (total number and time to events), reduction in ventricular arrhythmias, and safety results including major cardiac adverse events (MACE), serious adverse events (SAEs), deaths, and intravenous pharmacological treatment for heart failure. Because the trial met the primary endpoint, patients who received placebo or were randomized to ixmyelocel-T in the double-blind portion of the trial but did not receive ixmyelocel-T, have been offered the option to receive

treatment with ixmyelocel-T.

About Vericel Corporation
Vericel develops, manufactures, and markets autologous expanded cell therapies for the treatment of patients with serious diseases and conditions. The company markets three cell therapy products in the United States. Vericel is marketing MACI® (autologous cultured chondrocytes on porcine collagen membrane), an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults, which has recently been approved by the FDA. Carticel® (autologous cultured chondrocytes) is an autologous chondrocyte implant for the treatment of cartilage defects in the knee in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. Epicel® (cultured epidermal autografts) is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns greater than or equal to 30% of total body surface area. Vericel is also developing ixmyelocel-T, an autologous multicellular therapy intended to treat advanced heart failure due to ischemic dilated cardiomyopathy (DCM). 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 ixmyelocel-T and our other products, 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, estimating the commercial potential of our products and product candidates, market demand for our products, product performance 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.

References

Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, et al. 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines. Circulation. 2013 Oct 15;128:e240-e327.

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