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# Additional Pre-Specified Secondary Results on the Reduction of Ventricular Arrhythmias Presented at AHA from Vericel's Positive Phase 2b ixCELL-DCM Clinical Trial of Ixmyelocel-T

CAMBRIDGE, Mass., Nov. 14, 2016 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leading developer of autologous expanded cellular therapies for the treatment of severe diseases and conditions, today announced the presentation of additional pre-specified secondary endpoint results from the ixCELL-DCM trial at the American Heart Association (AHA) Annual Meeting Scientific Sessions. As previously 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 patients with advanced heart failure due to ischemic dilated cardiomyopathy (DCM). As previously reported, the composite endpoint was all-cause deaths, cardiovascular hospitalizations, or unplanned outpatient and emergency department visits to treat acute decompensated heart failure. The overall incidence of adverse events, including serious adverse events, was comparable or lower in the ixmyelocel-T than in the placebo group.

In a poster session today at the AHA Scientific Sessions (Abstract 19491), Dr. Tim Henry, director of cardiology at Cedars-Sinai Heart Institute, presented supportive secondary endpoint data for the ixCELL-DCM study, a Phase 2b, randomized, double-blind, placebo-controlled study in 114 treated patients with advanced heart failure. A pre-specified secondary endpoint included the measurement of ventricular arrhythmia episodes resulting in appropriate shocks or ATP (anti-tachycardia pacing). Ventricular arrhythmias, a form of abnormal heart rhythm that originates in the ventricles of the heart, are associated with sudden death and are common in patients with heart failure and cardiomyopathy (Koplan 2009) At 12 months follow-up, patients who received ixmyelocel-T had a 24% reduction in ventricular arrhythmia episodes compared with the placebo group [rate ratio = 0.76; *P*=0.0502)]. In addition, 8 patients in the placebo group had serious adverse events of ventricular fibrillation compared with 0 patients in the ixmyelocel-T group. These data suggest that reduction in ventricular arrhythmias may play a role in the clinical benefit observed with ixmyelocel-T multicellular therapy.

**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 Ventricular Arrhythmia and Fibrillation**
Ischemic heart disease is the most common cause of sustained ventricular arrhythmias, with ventricular fibrillation, a type of arrhythmia, the most common cause of out-of-hospital sudden death (Koplan 2009). Ventricular fibrillation occurs when the heart's electrical activity becomes disordered, resulting in the heart's lower chambers (ventricles) contracting in a rapid unsynchronized way. The lower chambers of the heart fibrillate or quiver, and the heart pumps little or no blood which leads to sudden cardiac arrest. The treatment for ventricular fibrillation in high risk patients is an implantable cardioverter defibrillator which continuously monitors the heart's electrical system and provides automatic correction when an arrhythmia starts. More information on ventricular arrhythmia can be found on the American Heart Association website (www.heart.org).

**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 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. 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. The composite endpoint was all-cause deaths, cardiovascular hospitalizations, or unplanned outpatient and emergency department visits to treat acute decompensated heart failure. 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.

**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 two cell therapy products in the United States. 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 two additional cell products. MACI® (autologous cultured chondrocytes on porcine collagen membrane) is a third generation autologous chondrocyte implant intended to treat cartilage defects in the knee. Ixmyelocel-T is 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 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, 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.*

**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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