March 7, 2016

Vericel Announces FDA Acceptance for Filing of BLA for MACI for the Treatment of Symptomatic Cartilage Defects in the Knee

CAMBRIDGE, Mass., March 07, 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 that the U.S. Food and Drug Administration has accepted for filing its recently submitted Biologics License Application (BLA) for MACI™ (matrix applied characterized autologous cultured chondrocytes), the company's investigational autologous cellular product intended for the treatment of symptomatic cartilage defects of the knee in adult patients. The FDA provided a PDUFA (Prescription Drug User Fee Act) goal date of January 3, 2017. In addition, the FDA communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.

"The FDA's acceptance of the MACI BLA for review represents another important milestone toward our goal of providing a new treatment option for the repair of symptomatic cartilage defects of the knee in adult patients," said David Recker, MD, chief medical officer of Vericel. "We look forward to continuing to work closely with the FDA during the BLA review process for MACI in the United States."

About MACI
MACI (matrix applied characterized autologous cultured chondrocytes) is a third-generation autologous chondrocyte implant (ACI) product intended for the treatment of symptomatic cartilage defects of the knee in adult patients. MACI is an autologous implant consisting of autologous cultured chondrocytes seeded onto a resorbable Type I/III collagen membrane. Autologous cultured chondrocytes are human-derived cells which are obtained from the patient's own cartilage for the manufacture of MACI.

MACI is an investigational product that was studied in the pivotal Phase 3 clinical trial SUMMIT ("Superiority of MACI Implant to Microfracture Treatment") and the three-year SUMMIT Extension trial. SUMMIT was a two year, prospective, multicenter, randomized, open-label, parallel-group clinical trial designed to evaluate the safety and efficacy of MACI to reduce pain and improve function compared with arthroscopic microfracture in the treatment of patients (n = 144) with symptomatic Outerbridge Grade III or IV focal cartilage defects. The SUMMIT Extension trial evaluated the safety of both treatments for an additional three years.

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, 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 competitive developments, integration of the acquired business, 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 products and 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, 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.

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