December 8, 2015

Vericel Submits HDE Supplement to the FDA to Revise the Labeled Indications for Use and Add Pediatric Labeling for Epicel

CAMBRIDGE, Mass., Dec. 8, 2015 (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 it has submitted a Humanitarian Device Exemption (HDE) supplement to the U.S. Food and Drug Administration to revise the labeled indications for use of Epicel® (cultured epidermal autografts) to specifically include use in pediatric patients and add pediatric labeling for Epicel.

Epicel is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns comprising greater than or equal to 30 percent of total body surface area. Epicel has been used in the United States and internationally to treat severely burned patients since 1988. Epicel was approved by the FDA in 2007 as Humanitarian Use Device (HUD) under the HDE regulations.

"We believe that the revised label will provide valuable information describing the safety and clinical use of Epicel for pediatric patients and will better inform physicians regarding the safety of Epicel in this patient population," said David Recker, MD, chief medical officer of Vericel.

About Humanitarian Use Devices and the Humanitarian Device Exemption

HUDs are medical devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States per year. Devices that receive HUD designation from the Office of Orphan Products Development of the FDA may be eligible for marketing approval under an HDE application. FDA approval of an HDE application authorizes the applicant to market the device, subject to certain profit and use restrictions.

Except in certain circumstances, HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). A HUD is eligible to be sold for profit after receiving HDE approval if the device meets certain eligibility criteria, including where the device is intended for the treatment of a disease or condition that occurs in pediatric patients and such device is labeled for use in pediatric patients in which the disease or condition occurs. If the FDA determines that a HUD meets the eligibility criteria, the HUD may be sold for profit as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). The ADN is defined as the number of devices reasonably needed to treat a population of 4,000 individuals per year in the United States.

About Vericel Corporation

Vericel Corporation (formerly Aastrom Biosciences, Inc.) 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, and revenue trends and gross margin improvements, intended product development, clinical activity timing and regulatory pathway and timing, integration of the acquired business, 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.

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