



July 14, 2015

## **Vericel Announces Plan to Submit HDE Supplement to the FDA to Revise the Labeled Indications for Use and Add Pediatric Labeling for Epicel**

CAMBRIDGE, Mass., July 14, 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 following discussions with the U.S. Food and Drug Administration (FDA), the company plans to submit a Humanitarian Device Exemption (HDE) supplement to the FDA in the fourth quarter of 2015 to revise the labeled indications for use of Epicel<sup>®</sup> (cultured epidermal autografts) to specifically include pediatric patients and to add pediatric labeling for Epicel.

"While Epicel has been used to treat pediatric patients, it currently is not specifically indicated for use in this patient population," said David Recker, MD, chief medical officer of Vericel. "Revising the label to provide information describing the safety and clinical use of Epicel for pediatric patients will better inform surgeons regarding the safe use of Epicel in this potentially vulnerable patient population."

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% 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 a Humanitarian Use Device (HUD) under a Humanitarian Device Exemption (HDE).

### **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<sup>®</sup> (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel<sup>®</sup> (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<sup>™</sup>, 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](http://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, regulatory approval and timing of such approval, 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," "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 clinical trial and product development activities, regulatory submission and 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 perceived market 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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