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Vericel Announces FDA Approval of Epicel HDE Supplement

Revised Product Label Includes Indication for Use in Pediatric Patients and Now Specifies a Probable Benefit of Epicel Mainly Related to Patient Survival

CAMBRIDGE, Mass., Feb. 22, 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 approved the Company's Humanitarian Device Exemption (HDE) supplement for Epicel® (cultured epidermal autografts) to revise the labeled indications of use to specifically include pediatric patients and to add pediatric labeling. The revised product label also specifies that the probable benefit of Epicel, mainly related to survival, was demonstrated in two Epicel clinical experience databases and a randomized, controlled, independent physician-sponsored study comparing outcomes in patients with severe burns treated with Epicel and standard care compared to standard care alone.

"We are very pleased with the FDA's decision to expand the labeled indications for use of Epicel to reflect the experience of pediatric patients with severe burns who have been treated successfully with Epicel," said David Recker, M.D., chief medical officer of Vericel. "We believe that the revised label provides valuable information describing the safety and clinical use of Epicel in this vulnerable pediatric patient population, as well as the probable survival benefit for adult and pediatric patients with life-threatening injuries resulting from severe burns."

Data from a clinical database used to support the original Epicel HDE application, which included 552 patients treated with Epicel from 1989 to 1996 (mean TBSA burns of 68.6%), including 205 pediatric patients aged 21 years and younger, demonstrated a survival rate of 86.6% for all patients and 89.3% for pediatric patients at three months post-initial surgery. Data from the Epicel Medical Device Tracker, a post-approval registry of 402 patients treated with Epicel from October 2007 to June 2015 (mean TBSA burns of 66.0%), including 120 pediatric patients, demonstrated a survival rate of 81.3% for all patients and 88.3% for pediatric patients.

Data from the randomized, controlled, independent, physician-sponsored study of severe burn patients followed over a seven-year period demonstrated a survival rate of 90% for patients treated with Epicel (n=20, mean TBSA burns of 69.1%) and standard care, meaning excision plus allografting and/or split-thickness autografting, compared to a survival rate of 37.5% for patients in the control group (n=24, mean TBSA burns of 62.9%) who received standard care alone.

About Epicel

Epicel® (cultured epidermal autografts) is a permanent skin replacement indicated for use in adult and pediatric patients who have deep dermal or full thickness burns comprising a total body surface area greater than or equal to 30%. Epicel may be used in conjunction with split-thickness autografts or alone in patients for whom split-thickness autografts may not be an option due to the severity and extent of their burns. The probable benefit of Epicel, mainly related to survival, was demonstrated in two Epicel databases and one physician-sponsored study. Epicel has been used in the United States and internationally to treat severely burned patients since 1988, and was approved in the United States in 2007 as a Humanitarian Use Device (HUD) under a Humanitarian Device Exemption (HDE).

Important Safety Information

Epicel is contraindicated in patients with known hypersensitivity to vancomycin, amikacin, or amphotericin. Epicel should not be used in patients with sensitivities to materials of bovine or murine origin. Epicel is contraindicated for use on clinically infected wounds.

Because Epicel is manufactured with and contains residual amounts of murine cells, the FDA considers it a xenotransplantation product. Therefore, recipients should not donate whole blood, blood components, source plasma, source leukocytes, tissue, breast milk, ova, sperm or other body parts for use in humans because there is a potential risk of carrying an infection that is transmitted from mouse cells to humans. In addition, the risk of disease transmission from Epicel is unknown.

Squamous cell carcinoma (SCC) has been reported in patients with burn injury after being grafted with Epicel. The most common adverse reactions, occurring in ≥ 2% of patients were infection, graft shear, blister, drainage, sepsis, graft detachment and renal failure.

Patient information supplied by treating physicians and attending burn teams from 1989 to 1996 included 552 patients, 205

children (age 21 years and younger) and 347 adults reported death (13%) and the adverse reactions of highest incidence as: infection (13.8%), graft shear (7.8%), blister (4.2%) and drainage (3.3%).

From June 1998 through September, 2015, over 1,662 patients, including 589 children (age 21 and younger) and 1,073 adults were tracked through spontaneous reports via medical device reports, reports from burn sites and published literature. Adverse reactions were similar to the previously identified adverse reactions. Events that were reported in ≥ 2% of patients included death (8.8%), and adverse reactions of multi-organ failure, sepsis, infection and graft procedure complications. Because of the potential underreporting of adverse reactions from these sources, the percentages of adverse reactions should be interpreted with caution.

Epicel is intended solely for autologous use.

The effectiveness of Epicel has not been proven in clinical studies. The long-term safety of Epicel is unknown. The safety of Epicel has not been studied in pregnant and nursing women.

About Humanitarian Use Devices and the Humanitarian Device Exemption
Humanitarian Use Devices (HUD) 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 a Humanitarian Device Exemption (HDE) application based, among other criteria, on evidence of safety and probable benefit to health from use of the device. 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.

Based on the approval of this HDE supplement, Epicel is permitted to be sold for profit as long as the number of devices distributed in any calendar year does not exceed its annual distribution number (ADN), which is defined as the number of devices reasonably needed to treat a population of 4,000 individuals per year in the United States. The FDA has determined that the ADN for Epicel is 360,400.

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, 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, 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, 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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