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Outcomes Data From Over 950 Severe Burn Patients Treated With Epicel Presented at the 49th Annual Meeting of the American Burn Association

CAMBRIDGE, Mass., March 23, 2017 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leading developer of expanded autologous cell therapies for the treatment of patients with serious diseases and conditions, today announced the presentation of Epicel® (cultured epidermal autografts [CEA]) data at the 49th Annual Meeting of the American Burn Association (ABA) on Thursday, March 23, 2017 during Scientific Sessions on Reconstruction.

The presentation, entitled "Cultured Epidermal Autografts (CEA) for Coverage of Large Burn Wounds in Pediatric and Adult Patients, 1989-2015", was based on the clinical database used to support the original Epicel Humanitarian Device Exemption application in 2007 and the Epicel Medical Device Tracker, a post-approval patient registry. Combined, the outcomes data included 953 patients between 1989 and 2015. The mean total body surface area (TBSA) burned of patients in the databases was 67.3% (SD 17.48), with median graft take at discharge of 75%, and an overall survival to discharge rate of 84% (804/953). The databases included 325 pediatric patients with survival rates being similar for pediatric and adult patients (88.8% vs 81.7%, respectively). These results are consistent with earlier analyses of the Epicel clinical experience databases and a controlled, physician-sponsored study comparing outcomes in patients with severe burns treated with Epicel and standard care compared to standard care alone.

"According to a data set reported in the 2016 ABA National Burn Repository, burns greater than 65 to 70% TBSA are associated with a 50% case mortality rate[1]" said Dr. Dave Recker, chief medical officer of Vericel. "The reported 84% survival rate from the Epicel clinical experience databases in over 950 patients with a mean TBSA of 67% continues to support a probable survival benefit of Epicel in severe burn patients."

The full abstract is available on the ABA website at: http://www.abstractsonline.com/pp8/#!/4303/presentation/88

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 to treat severely burned patients in the U.S. and internationally 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.

Vericel develops, manufactures, and markets expanded autologous cell therapies for the treatment of patients with serious diseases and conditions. The company markets three cell therapy products in the United States. Vericel is marketing MACI® (autologous cultured chondrocytes on porcine collagen membrane), an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. 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 ixmyelocel-T, 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 anticipated progress, objectives and expectations regarding the commercial potential of our products and growth in revenues, intended product development, clinical activity timing, regulatory progress, 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 competitive developments, clinical trial and product development activities, regulatory approval requirements, estimating the commercial growth 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, 2016, filed with the Securities and Exchange Commission ("SEC") on March 13, 2017, 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

[1] American Burn Association National Burn Repository 2016 Report. Version 12.0:10.

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