Vericel Reports Publication of Outcomes Data From 954 Burn Patients Treated With Epicel in the Journal of Burn Care and Research

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Results Demonstrate an Increased Survival Rate for Patients Treated with Epicel

CAMBRIDGE, Mass., Jan. 04, 2019 (GLOBE NEWSWIRE) -- Vericel Corporation (Nasdaq:VCEL), a leader in advanced cell therapies for the sports medicine and severe burn care markets, today announced the publication of outcomes data for 954 burn patients treated with Epicel® (cultured epidermal autografts) in the Journal of Burn Care and Research. The results demonstrated an increased survival rate for patients treated with Epicel when compared to results reported for patients in the National Burn Repository with comparable burns.

Epicel is a permanent skin replacement produced from patients' own cells and indicated for use in adult and pediatric patients who have deep dermal or full thickness burns comprising a total body surface area (TBSA) greater than or equal to 30%. The probable benefit of Epicel, mainly related to survival, has been previously demonstrated in two Epicel databases and one physician-sponsored study.

The publication summarized outcomes for the largest cohort of patients treated with Epicel published to date. The data set was compared to the National Burn Repository annual report which is the largest resource on epidemiology of thermal injury for patients admitted to burn centers and contains outcome data for 177,498 burn patients.

The overall mortality rate by burn size was lower for Epicel-treated patients than that reported in the National Burn Repository 2016 Report. The mean TBSA of burns in patients from the Epicel cohort was 67.5%, with an overall survival at discharge rate of 84.4% (804/953). According to the data set reported in the 2016 American Burn Association National Burn Repository, burns greater than 65 to 70% TBSA are associated with a 50% case mortality rate.[1] This comparative advantage in survival outcome was found to be consistent in both pediatric and adult patients treated with Epicel.

"This new dataset demonstrating increased survival rates for patients treated with Epicel over a period of 25 years supports the strong clinical benefit achieved with Epicel in large full thickness burns," said Jon Hopper, Vericel's chief medical officer. "These data are important to patients and physicians since Epicel is the only FDA-approved permanent skin replacement for adult and pediatric patients with full-thickness burns."

The publication is entitled "Twenty-five Years' Experience and Beyond with Cultured Epidermal Autografts (CEA) for Coverage of Large Burn Wounds in Adult and Pediatric Patients, 1989-2015" and the full abstract is available on pubmed:

https://academic.oup.com/jbcr/advance-article-abstract/doi/10.1093/jbcr/iry061/5220670

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 Vericel Corporation

Vericel is a leader in advanced cell therapies for the sports medicine and severe burn care markets. The company markets two cell therapy products in

the United States. MACI (autologous cultured chondrocytes on porcine collagen membrane) is 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. 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. For more information, please visit the company's website at www.vcel.com.

References

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

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