Vericel Reports Publication of Results from the Phase 3 SUMMIT Extension Study Demonstrating Sustained Clinical Benefit of MACI Out to Five Years

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CAMBRIDGE, Mass., March 23, 2018 (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 results from the MACI® (autologous cultured chondrocytes on porcine collagen membrane) Phase 3 SUMMIT Extension Study in the American Journal of Sports Medicine. The results demonstrated that the significantly greater improvements in Knee injury and Osteoarthritis Outcome Score (KOOS)[1] pain and function scores for MACI versus microfracture shown in the two-year Phase 3 SUMMIT (Superiority of MACI Implant Versus Microfracture Treatment) study were maintained over the additional three-year follow-up in the SUMMIT Extension Study.

MACI is an autologous cellular 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. MACI is the first FDA-approved product that applies the process of tissue engineering to grow cells on scaffolds using healthy cartilage tissue.

The FDA approval of MACI was based on the results of the SUMMIT study, a Phase 3, prospective, multicenter, randomized, controlled study that enrolled a total of 144 patients. The co-primary efficacy endpoint was the change from baseline to two years in the KOOS[2] pain and function scores. The SUMMIT study is the only Phase 3 clinical trial of a cartilage repair product to date to demonstrate statistically significant improvement over microfracture at both one and two years.[2]

The SUMMIT Extension Study was a three-year follow-up of the SUMMIT clinical trial, entailing up to five years of observation after surgery. Of the 144 patients randomized in the SUMMIT study, 128 (89%) continued observation out to five years in the SUMMIT Extension Study. Evaluation of these patients post treatment showed that there was sustained improvement in both KOOS pain and function for the study period. A post-hoc evaluation showed that the significantly greater improvement of MACI versus microfracture observed at the two-year endpoint was maintained at the five-year follow-up. The frequency of adverse events and subsequent surgical procedures were similar in both the MACI and microfracture treatment groups. The Extension Study is the first study in the field of cartilage repair to provide long-term, five-year follow-up results from a successful multicenter, superiority study in comparison to microfracture.

“MACI is the only FDA-approved cartilage repair product that has demonstrated significantly greater improvement versus microfracture in a Phase 3 controlled clinical trial,” said Nick Colangelo, Vericel’s president and chief executive officer. “It is important to both clinicians and patients that MACI, in addition to demonstrating significant improvements compared to microfracture as early as one year, maintains improvements over microfracture out to at least five years.”

The publication is entitled “Matrix-Applied Characterized Autologous Cultured Chondrocytes Versus Microfacture: Five-Year Follow-up of a Prospective Randomized Trial” and the full abstract is available on pubmed: http://journals.sagepub.com/doi/full/10.1177/0363546518756976

About MACI

MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellular scaffold product that is indicated for the repair of symptomatic single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. The MACI implant consists of autologous cultured chondrocytes seeded onto a resorbable Type I/III collagen membrane. Autologous cultured chondrocytes are human-derived cells which are obtained from the patient's own cartilage for the manufacture of MACI.

Limitations of Use

- Effectiveness of MACI in joints other than the knee has not been established.
- Safety and effectiveness of MACI in patients over the age of 55 years have not been established.

Important Safety Information

- MACI is contraindicated in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin. MACI is also contraindicated for patients with severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders. MACI is also not indicated for use in patients who have undergone prior knee surgery in the past six months, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant.
- MACI is contraindicated in patients who are unable to follow a physician-prescribed post-surgical rehabilitation program. The safety of MACI in patients with malignancy in the area of cartilage biopsy or implant is unknown. Expansion of present malignant or dysplastic cells during the culturing process or implantation is possible.
- Patients undergoing procedures associated with MACI are not routinely tested for transmissible infectious diseases. A cartilage biopsy and MACI implant may carry the risk of transmitting infectious diseases to healthcare providers handling the tissue. Universal precautions should be employed when handling the biopsy samples and the MACI product.

About Articular Cartilage Defects of the Knee
Articular cartilage is a highly organized avascular tissue composed of chondrocytes embedded within an extracellular matrix of collagens, proteoglycans and noncollagenous proteins. Its primary function is to enable the smooth articulation of joint surfaces, and to cushion compressive, tensile and shearing forces. Articular cartilage damage is caused by both acute and repetitive trauma resulting in knee pain, effusion or mechanical symptoms such as catching and locking, and swelling. Since articular cartilage is avascular it has little capacity to repair itself or regenerate. Articular cartilage lesions that are left untreated may progress to debilitating joint pain, dysfunction, and osteoarthritis.[3] The prevalence rate for cartilage lesions in the knee has been reported to be 63% in patients undergoing investigational arthroscopies.[4]

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.

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 including maintenance of clinical benefit, 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, 2017, filed with the Securities and Exchange Commission ("SEC") on March 5, 2018, 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]Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes. 2003;1:64.

[2]Saris D, Price A, Widuchowski W, Bertrand-Marchand M, Caron J, Drogset JO, et al. Matrix-applied characterized autologous cultured chondrocytes versus microfracture: two-year follow-up of a prospective randomized trial. Am J Sports Med. 2014 Jun;42(6):1384-94.

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