Vericel Announces FDA Approval and Commercial Availability of MACI Arthro

August 26, 2024 at 7:46 AM EDT

First Restorative Biologic Cartilage Repair Product Approved for Arthroscopic Administration

Targets the Largest Segment of MACI's $3 Billion Addressable Market

CAMBRIDGE, Mass., Aug. 26, 2024 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) expanding the MACI® (autologous cultured chondrocytes on porcine collagen membrane) label to include arthroscopic delivery of MACI to repair symptomatic single or multiple full-thickness cartilage defects of the knee up to 4 cm^2 in size. MACI Arthro™ provides a less invasive technique compared to the current approach, allowing surgeons to evaluate and prepare the defect site as well as deliver the MACI implant through small incisions using custom-designed MACI Arthro instruments.

"The approval of MACI Arthro represents another significant milestone in our strategy to provide innovative solutions for patients suffering from pain and dysfunction caused by cartilage defects in the knee," said Nick Colangelo, President and CEO of Vericel. "MACI Arthro provides orthopedic surgeons and their patients with a less invasive option for MACI administration, which we believe has the potential to significantly increase penetration into the largest segment of the MACI addressable market and will support sustained top-tier revenue growth for the Company in the years ahead."

MACI is the first FDA-approved cellularized scaffold product that applies tissue engineering processes to grow cells on scaffolds using healthy cartilage tissue from the patient's own knee. MACI is the only restorative biologic cartilage repair product approved for arthroscopic administration. MACI Arthro incorporates the advantages of an arthroscopic approach with the long-term durability and established clinical results of MACI. The custom MACI Arthro instruments are designed to treat the most common defects in the MACI addressable market, which are 2-4cm^2 defects on the femoral condyles, representing approximately 20,000 patients per year or one-third of the $3 billion addressable market for MACI. In conjunction with the launch of MACI Arthro, Vericel is expanding its target surgeon base from 5,000 to 7,000 to include surgeons that perform high volumes of cartilage repair surgeries, predominantly through arthroscopic procedures.

"Arthroscopic delivery of MACI represents a significant advancement in cartilage repair," said Grant H. Garcia, MD, Orthopedic Specialists of Seattle. "The technique and specially-designed MACI Arthro instrumentation provides surgeons with a less invasive option to administer a clinically-proven treatment to patients, and may be preferable for patients given the many post-operative benefits of arthroscopic versus open surgery."

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. For more information, please visit www.maci.com.

Indication: MACI is an autologous cellularized scaffold product indicated for the repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults.

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

- **Contraindications:** MACI is contraindicated in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides, products of porcine or bovine origin, in patients with severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders, in patients who have undergone prior knee surgery in the past 6 months, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant, or in patients unable to cooperate with a physician-prescribed post-surgical rehabilitation program.
- **Warnings and Precautions:**
  - Malignancy: The risk of MACI in patients with malignancy in the area of cartilage biopsy or implant is unknown. Expansion of malignant or dysplastic cells present in biopsy tissue during manufacture and subsequent implantation may be possible.
  - Transmissible infectious diseases: Because patients undergoing procedures associated with MACI are not routinely tested for transmissible infectious diseases, cartilage biopsy and MACI implant may carry risk of transmitting infectious diseases.
  - Presurgical Comorbidities: Local inflammation or active infection in the bone, joint, and surrounding soft tissue, meniscal pathology, cruciate ligament instability, and misalignment should be assessed and treated prior to or concurrent with MACI implantation.

    - Product Sterility: Final sterility test results are not available at the time of shipping.
- **Adverse Reactions:** The most frequently occurring adverse reactions reported for MACI (≥5%) were arthralgia, back pain, joint swelling, and joint effusion. Serious adverse reactions reported for MACI were arthralgia, cartilage injury, meniscus injury, treatment failure, and osteoarthritis.
- **Specific Populations:**
    - Use of MACI in pediatric patients (younger than 18 years of age) or patients over 65 years of age has not been established.
    - The MACI implant is not recommended during pregnancy. For implantations post-pregnancy, the safety of breastfeeding to an infant has not been determined.
- To report negative side effects, contact Vericel Corporation at 1-800-453-6948 or FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.
- **Please see Full Prescribing Information.**

About Vericel Corporation
Vericel is a leading provider of advanced therapies for the sports medicine and severe burn care markets. The Company combines innovations in biology with medical technologies, resulting in a highly differentiated portfolio of innovative cell therapies and specialty biologics that repair injuries and restore lives. Vericel markets three products in the United States. MACI 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. Vericel also holds an exclusive license for North American rights to NexoBrid® (anacaulase-bcdb), a biological orphan product containing proteolytic enzymes, which is indicated for eschar removal in adults and pediatric patients with deep partial-thickness and/or full-thickness burns. For more information, please visit www.vcel.com.

Forward Looking Statements
Vericel cautions you that all statements other than statements of historical fact included in this press release that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Our actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions.

Among the factors that could cause actual results to differ materially from those set forth in the forward-looking statements include, but are not limited to, uncertainties associated with our expectations regarding future revenue, growth in revenue, market penetration for MACI, MACI Arthro, Epicel, and NexoBrid, growth in profit, gross margins and operating margins, the ability to continue to scale our manufacturing operations to meet the demand for our cell therapy products, including the timely completion of a new headquarters and manufacturing facility in Burlington, Massachusetts, the ability to achieve or sustain profitability, contributions to adjusted EBITDA, the expected target surgeon audience, potential fluctuations in sales and volumes and our results of operations over the course of the year, timing and conduct of clinical trial and product development activities, timing and likelihood of the FDA's potential approval of the use of MACI to treat cartilage defects in the ankle, the estimate of the commercial growth potential of our products and product candidates, competitive developments, changes in third-party coverage and reimbursement, surgeon adoption of MACI Arthro, physician and burn center adoption of NexoBrid, supply chain disruptions or other events or factors affecting MediWound's ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, including but not limited to the ongoing Israel-Hamas war, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine and the Israel-Hamas war, adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, global geopolitical tensions or record inflation and potential future impacts on our business or the economy generally stemming from a resurgence of COVID-19 or another similar public health emergency.

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, 2023, filed with the Securities and Exchange Commission (SEC) on February 29, 2024, Vericel's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 1, 2024, and in other filings with the SEC. These forward-looking statements reflect our views as of the date hereof and Vericel does not assume and specifically disclaims any obligation 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.

Investor Contact:
Eric Burns
ir@vcel.com
+1 (734) 418-4411

Media Contact:
Julie Downs
media@vcel.com