AVITA Medical Submits FDA PMA Supplement to Further Expand Indication to Soft Tissue Repair

December 12, 2022

VALENCIA, Calif., and MELBOURNE, Australia, Dec. 12, 2022 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration, announced today the submission of a Premarket Approval (PMA) supplement application to the U.S. Food and Drug Administration (FDA) for the company's RECELL ® System. The supplement, if approved, will expand the indication of RECELL to include soft tissue repair.

"The submission is a significant milestone in our effort to expand the label of RECELL into the soft tissue repair market opportunity," said Jim Corbett, AVITA Medical Chief Executive Officer. "Soft tissue repair encompasses a broad label of RECELL applications and allows us to target all level 1 and level 2 trauma centers in the U.S. Once approved, this indication expands our current market opportunity by at least three times and is expected to create a significant growth opportunity for us beginning July 2023."

This PMA supplement includes the recently released results of the pivotal trial for soft tissue repair. The study met both co-primary endpoints, demonstrating that RECELL is statistically significant in donor sparing and statistically non-inferior in healing outcomes. For purposes of the clinical study, soft tissue injuries included any full-thickness acute skin defect, such as degloving or peeled back skin injuries, road rash, surgical wounds, and flesh-eating disease.

The RECELL System earned FDA Breakthrough Device designation for its proposed soft tissue repair indication. Under the program, AVITA Medical will receive prioritized review and interactive communication with the FDA throughout the premarket review phase. The standard FDA review timeline for label expansion through a PMA supplement is 180 days.

This PMA supplement application follows the original PMA approval of the RECELL System in September 2018.

AVITA Medical's clinical trial in soft tissue repair has been funded in whole or in part with Federal funds from the Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under contract no. HHSO100201500028C.

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

ABOUT AVITA MEDICAL, INC.

AVITA Medical® is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The RECELL® System technology platform, approved by the FDA for the treatment of acute thermal burns in both adults and children, harnesses the regenerative properties of a patient's own skin to create Spray-On Skin™ cells. Delivered at the point-of-care, RECELL enables improved clinical outcomes and validated cost savings. RECELL is the catalyst of a new treatment paradigm and AVITA Medical is leveraging its proven and differentiated capabilities to develop first-in-class cellular therapies for multiple indications, including soft tissue repair and repigmentation of stable vitiligo lesions.

AVITA Medical's first U.S. product, the RECELL System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL System is approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 15,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL Autologous Cell Harvesting Device (https://recellsystem.com) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

In international markets, our products are approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, soft tissue repair, vitiligo, and aesthetics. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

FOR FURTHER INFORMATION:

Investors & Media
AVITA Medical, Inc.
Jessica Ekeberg
Phone +1-661-904-9269
investor@avitamedical.com
media@avitamedical.com