AVITA Medical Announces Update to Automation Device

April 13, 2023

VALENCIA, Calif. and MELBOURNE, Australia, April 13, 2023 (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 that its automated device, RECELL GO, maintains the Food and Drug Administration (FDA) Breakthrough Device designation for the treatment of acute wounds. RECELL GO represents an evolution of the existing RECELL technology and is designed to automate the process of cell disaggregation.

“RECELL GO is a critical component of our platform, and we believe it will greatly accelerate our growth,” said Jim Corbett, Chief Executive Officer of AVITA Medical. “Automating the disaggregation process will substantially reduce training requirements, allowing us to leverage selling time more effectively. Additionally, it will ease the burden on physicians and operating room staff, leading to increased adoption. Our dedication to our automation program reflects our continued commitment to innovation and patient care.”

As previously announced, AVITA Medical plans to submit a Premarket Approval (PMA) supplement to the FDA for RECELL GO by June 30, 2023. Under the Breakthrough Device program, the submission will receive prioritized, interactive review with an expected January 2024 approval.

Authorized for release by the Chief Executive 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:

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