AVITA Medical Announces Achievement of Co-Primary Endpoints in Updated Analysis of Pivotal Trial of RECELL® System for Soft Tissue Repair

November 9, 2022

VALENCIA, Calif. and MELBOURNE, Australia, Nov. 09, 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, today announced achievement of co-primary endpoints as a result of updated analysis of data from its clinical trial evaluating the safety and effectiveness of the RECELL® System for soft tissue repair.

The study design included two co-primary endpoints based on pairwise comparisons where each subject received both RECELL treatment and standard of care treatment (Control): one endpoint had a hypothesis of superiority for donor skin sparing and the other co-primary endpoint had a hypothesis of non-inferiority for healing.

Both co-primary endpoints have been met:

- RECELL achieved statistically significant donor sparing over Control ($p<0.001$).
- RECELL achieved statistical non-inferiority for healing versus Control ($p<0.025$).

“These results reinforce the potential for RECELL to become a new standard of care for soft tissue repair,” said Jim Corbett, AVITA Medical Chief Executive Officer. “We look forward to sharing the soft tissue repair outcomes with the FDA via our PMA submission expected in December 2022.”

Previously, the company announced that the donor sparing endpoint had achieved superiority and that the healing endpoint had just missed non-inferiority. Subsequently, further re-verification resulted in corrections to the healing data, ultimately leading to a conclusion of non-inferiority for healing.

AVITA Medical’s clinical trial in soft tissue repair has been funded in part with Federal funds from the Office of the Assistant Secretary for 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