AVITA Medical Announces FDA Approval of RECELL for Treatment of Full-Thickness Skin Defects

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VALENCIA, Calif. and MELBOURNE, Australia, June 07, 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, today announced that the U.S. Food and Drug Administration (FDA) has approved its premarket approval (PMA) supplement for the use of its RECELL® System to treat full-thickness skin defects.

“This is a landmark approval representing an inflection point for AVITA Medical,” said Jim Corbett, AVITA Medical Chief Executive Officer. “The FDA approval now offers surgeons a best-in-class treatment option for a multitude of severe wounds within inpatient and outpatient settings.”

The expanded indication represents a broad label of full-thickness skin defects, such as wound injuries after traumatic avulsion (e.g., degloving), surgical excision (e.g., necrotizing soft tissue infection), or resection (e.g., skin cancer), thereby dramatically expanding the company’s market opportunity at least five times.

“We had a high level of confidence in the FDA’s approval timeline of RECELL for the treatment of skin defects,” continued Mr. Corbett. “In anticipation of the expanded indication, we more than doubled our field sales organization in the first few months of the year. Our sales team is now ready, trained, and fully prepared for the commercial launch, which will commence July 1, 2023. On behalf of AVITA Medical, I’d like to express my utmost appreciation to the many patients and healthcare providers who partnered with us to help bring our innovative technology to more patients across the U.S.”

The RECELL System was first approved in the U.S. for the treatment of severe burns in 2018. The system is an autologous cell harvesting device that prepares, produces, and delivers a regenerative cell suspension, Spray-On Skin™ Cells, using a small amount of a patient’s own skin. The Spray-On Skin Cells contain a combination of single living cells that stimulate healing and repigmentation throughout the wound bed.

Currently, skin grafting is the standard of care for full-thickness skin defects, including post-trauma and post-surgical skin reconstruction. However, skin grafting requires the harvesting of donor skin, resulting in an additional wound to the patient. Significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration, and scarring are associated with donor site wounds. Based on results from the company’s pivotal trial for soft tissue repair and reconstruction, RECELL demonstrated statistically non-inferior healing rates with statistically significant donor sparing, meaning less skin from the patient is required to repair and close the wound without compromising the healing outcomes relative to convention autografting.

The PMA supplement received prioritized review through the FDA’s Breakthrough Device program. The FDA grants the Breakthrough Device designation to medical devices that provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. The PMA supplement approval follows the original PMA approval of the RECELL System for the treatment of severe burns in September 2018.

AVITA Medical’s clinical trial in soft tissue repair has been funded in part with Federal funds from the U.S. Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract number HHSO100201500028C.

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 thermal burn wounds and full-thickness skin defects, 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 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 and full-thickness skin defects after traumatic avulsion (e.g. degloving) or surgical excision (excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer), in patients 15 years of age and older. 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 wounds, 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 or in combination with meshed autographs for full-thickness skin defects. 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.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational, and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Applicable risks and uncertainties include, among others, the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

FOR FURTHER INFORMATION:

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