U.S. Food and Drug Administration Approves Expanded Use of the RECELL® System for the Treatment of Extensive Burns and Pediatric Patients

Expanded indication for use includes RECELL System for treatment of full-thickness acute burn wounds of all sizes in pediatric and adult patients

VALENCIA, Calif., USA, and MELBOURNE, Australia, June 10, 2021 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today announced that the U.S. Food and Drug Administration (FDA) has approved expanded use of the RECELL® System in combination with meshed autografting for the treatment of all sizes of acute full-thickness thermal burn wounds for both pediatric and adult patients. Specifically, RECELL is now indicated to treat full-thickness thermal burns in patients 1-month of age and older (removing the prior limitation of use in patients younger than 18 years of age). In addition, the indication now includes treatment for full-thickness thermal burns that extend beyond 50% total body surface area (TBSA).

"We are pleased that the RECELL System, with both its clinical and health economic benefits, can now more broadly support surgeons in treating full-thickness burns of all sizes, including treatment of patients over 1-month of age," said Dr. Mike Perry, AVITA Medical's Chief Executive Officer. "Supported by a substantive body of clinical evidence and peer-review publications, the RECELL System is rapidly becoming the standard of care in burn treatment, and we are committed to pursuing and realizing the full potential of this innovative regenerative technology platform to address other clinical indications where significant unmet need exists."

The revised indication for the RECELL System is based on clinical data from the RECELL Compassionate Use (IDE 15945) and Continued Access (IDE 13053) studies, which were supported by the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), under USG Contract HHSO100201500028C. As BARDA's mandate includes building preparedness by expanding the indications of medical countermeasures (MCMs) for vulnerable populations, such as pediatrics, an independent contract option dedicated to this goal was exercised between BARDA and AVITA Medical in support of a pediatric burn clinical trial (NCT03626701).

"BARDA and AVITA Medical have decided to stop recruitment for the ongoing pediatric burn study and follow currently enrolled patients for 12 months in alignment with the study protocol. We look forward to continuing work under the contract, with the ongoing maintenance of the established vendor-managed inventory of RECELL System devices and collaboration toward enhancing the sustainability of the RECELL System as a mass casualty MCM and an improvement to everyday burn care in the United States," said Dr. Perry.

Unfortunately, nearly a quarter of the burn cases in the United States occur in children under the age of 16 years old.[i] One of the main goals within the burn community is to avoid multiple surgical grafting

procedures. RECELL significantly reduced the mean number of pediatric grafting procedures compared to the National Burn Repository (1.6 treatments vs 3.6 treatments, respectively).

“Skin grafting, which is currently the standard of care used to treat many pediatric burns, is painful, results in an additional wound, can be disfiguring, and may result in additional complications as a child grows,” said Anjay Khandelwal, MD, FACS, FICS, Akron Children’s Hospital Burn Center, Akron, Ohio. “There has been a high unmet need for alternative treatments for pediatric burns, so I am pleased that the RECELL System, with its proven efficacy to accelerate the burn healing process with less donor skin requirements, is now available as an FDA-approved treatment option for my younger burn patients.”

For full-thickness burns, the initial PMA study of RECELL treatment was limited to patients with burn wounds up to 50% TBSA injuries, which was also reflected in the initial FDA-approved RECELL indication. The updated indication no longer constrains treatment of full-thickness injuries based on an upper limit of 50% TBSA. The median number of autograft procedures for patients with extensive burns treated with RECELL under Compassionate Use was two, versus a matching cohort of patients in the National Burn Registry (NBR) for which the median number of autograft treatments was five.

“For patients with large injuries, the availability of viable skin for conventional skin grafting to treat the burn injury is often challenging to the point of becoming critical,” said Nicole Kopari, MD, University Medical Center, New Orleans. “Reducing the amount of donor skin needed for treatment with the RECELL System is beneficial for efficient healing, which can result in less pain and scarring, as well as a decrease in the overall cost of care since with fewer operations, and patients can typically go home earlier when treated with the RECELL System.”

Initially approved by the FDA in September 2018 to treat severe thermal burn wounds in patients 18 years and older, the RECELL System enables medical professionals to collect cells from a small sample of a patient’s own skin to create a suspension of Spray-On Skin™ Cells that are necessary to regenerate the outer layer of natural, healthy skin. The RECELL System can be used to prepare enough Spray-On Skin Cells to treat a wound up to 80 times the size of the donor skin sample, so a skin sample about the size of a credit card can be used to treat a wound that covers an adult patient’s entire back. Prepared at the point of care in as little as 30 minutes, the Spray-On Skin Cells are applied directly on a second-degree (partial-thickness) burn or with an expanded skin graft on a full-thickness (third-degree) burn, allowing for broad and even distribution of live cells across the entire wound bed to facilitate healing across the whole wound rather than from the outside edges inward.

For more information about the RECELL System, please visit https://recellsystem.com/.

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ABOUT AVITA MEDICAL, INC.

AVITA Medical is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical’s patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient’s own skin. The medical devices work by preparing a RES® REGENERATIVE EPIDERMAL SUSPENSION, an autologous suspension comprised of the patient’s skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

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 indicated for use in the treatment of acute thermal burns. 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 10,000 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 marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds, and aesthetics. The RECELL System is TGA-registered in Australia and received CE-mark approval in Europe. To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This letter 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 letter 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 letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing 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 letter. 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 letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

This press release was authorized by the review committee of AVITA Medical, Inc.

FOR FURTHER INFORMATION:

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[i] National Burn Repository 2019 Update – Report of data from 2009-2018