AVITA Medical Announces Expanded Medicare Reimbursement to Outpatient Hospital and Ambulatory Surgical Centers

November 3, 2021

Effective January 1, 2022, a new code describes the RECELL® System

VALENCIA, Calif. and MELBOURNE, Australia, Nov. 03, 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, announced today that the Centers for Medicare & Medicaid Services (CMS) has approved AVITA Medical's application for a Transitional Pass-Through Payment device category code that will provide separate payment for RECELL® Autologous Cell Harvesting Devices (RECELL® System) used in procedures that are performed in hospital outpatient facilities and ambulatory surgical centers (ASC).

The new Healthcare Common Procedure Coding System (HCPCS) device category C code will be effective January 1, 2022 and will be used by facilities to bill for RECELL Systems used in the hospital outpatient and ASC settings. The pass-through payment is intended to facilitate the adoption of new technology for Medicare beneficiaries by offsetting the cost of the device to facilities.

"We are pleased with yesterday's CMS approval, which will expand access to the RECELL System as a critical treatment option for Medicare burn patients treated in the hospital outpatient and ambulatory surgical settings. The new code will enable health care providers to treat burn patients with RECELL in various care settings especially during the pandemic, and over the long run, help foster adoption of RECELL in small burns as well as in future indications," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "In addition to expanding burn treatment to a new care setting with existing customers, this device code lays the reimbursement foundation for the soft tissue repair indication we are working towards which has a serviceable addressable market valuation of $450M."

"The autologous skin cell suspension procedure is a long-awaited, major technological improvement in the treatment of burns that significantly reduces the patient's donor site pain due to the substantial reduction in donor skin requirements," said Dr. William Hickerson, current Coding Committee Chair and former President of the American Burn Association. "CMS is to be commended for taking these steps that will directly improve Medicare patient access to innovative treatments for burns."

The pivotal studies leading to the RECELL System's FDA premarket approval for the treatment of acute thermal burns demonstrated that the RECELL System treated burns using 97.5[i] percent less donor skin when used alone in second-degree burns, and 32 percent less donor skin when used with autograft for third-degree burns.[ii] This statistically significant reduction in donor skin required to treat burn patients with the RECELL System produced healing comparable to the standard of care while providing a significant reduction in donor site pain and improved donor site healing.[i] In the three years since FDA approval, more than 85% of burn surgeons throughout the United States have been certified to use the RECELL System, which is used in 77% of major burn centers.

For more information about the RECELL System, please visit www.RECELLSystem.com.

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

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 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 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 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.

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[i] Holmes JH, Molnar JA, Carter JE, et al. A comparative study of the RECELL® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. J Burn Care Res. 2018

[ii] Holmes JH, Molnar JA, Shupp JW, et al. Demonstration of the safety and effectiveness of the RECELL System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. Burns. 2019;45:772-782