



## **AVITA Medical Announces Modification of BARDA Contract to Advance Development of RECELL® System in Soft Tissue Reconstruction**

March 21, 2022

### **Funds will support completion of the ongoing pivotal clinical trial**

VALENCIA, Calif. and MELBOURNE, Australia, March 21, 2022 (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 Biomedical Advanced Research and Development Authority (BARDA) has modified its existing contract with the Company to support AVITA Medical's clinical trial in soft tissue reconstruction. BARDA is a part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS).

"We are extremely pleased that BARDA is supporting advanced treatment options for soft tissue reconstruction," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "The RECELL System has already proven itself as a safe and effective tool for those with burns, and we are committed to expanding its use to include all acute wounds. We are pleased BARDA recognizes the potential it holds for a broader group of patients experiencing trauma. BARDA has been an outstanding partner, and we are excited to continue our work to expand the indication for the RECELL System with their support."

Soft tissue reconstruction is of particular concern to BARDA and AVITA Medical, as skin grafting, the current standard of care for soft tissue reconstruction, requires the harvesting of donor skin which can result 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. While skin grafting is commonly associated with burn treatment, in 2017, approximately 80% of acute wounds that required skin grafting were non-burn related injuries accounting for more than 200,000 procedures in the U.S.<sup>1</sup>

AVITA Medical is currently completing a pivotal trial for the use of the RECELL System for soft tissue reconstruction. Currently, the RECELL System is indicated in the U.S. for treatment of acute thermal burns. The clinical trial will compare the clinical performance of conventional autografting to that of widely meshed autografting with the RECELL System on acute non-burn full-thickness skin defects, with the goal of demonstrating that less donor skin is needed without compromising healing outcomes. Topline data from the trial will be shared later this year.

AVITA Medical has had a long-term positive relationship with BARDA since September 2015 and was of fundamental importance to the Company being able to achieve premarket approval for the RECELL System in late 2018.

This project has been funded in whole or 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

### **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<sup>®</sup> 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<sup>®</sup> System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018 and a new ease-of-use design was approved in 2022. The RECELL System is indicated for use in the treatment of acute thermal burns. The RECELL System is used to prepare Spray-On Skin<sup>™</sup> 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<sup>®</sup> 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](http://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.

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

**FOR FURTHER INFORMATION:**

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