AVITA Medical Completes Enrollment in Pivotal Trial Evaluating the RECELL® System for Soft-Tissue Reconstruction

January 6, 2022

Topline data expected in second half of 2022

VALENCIA, Calif. and MELBOURNE, Australia, Jan. 06, 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 it has completed enrollment into its 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. Topline data will be shared later this year.

“Completing enrollment of the pivotal trial assessing use of the RECELL ® System for treatment of soft-tissue reconstruction is an important milestone for AVITA Medical and moreover, is synergistic with our current commercial focus in burns. Ultimately, with FDA approval of this indication, we expect to expand the use of RECELL to include all acute wounds,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “Early completion of enrollment in our soft tissue reconstruction trial underscores the need and physician desire for new treatment options.”

Skin grafting is the standard of care for soft tissue reconstruction, including post-trauma and post-surgical skin reconstruction. 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. 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.[i] The total addressable market (“TAM”) for soft tissue repair is approximately $1 billion and more than twice as large as the TAM for burns. Further, the existing reimbursement codes utilized for burn treatment with the RECELL System will apply to this indication.

“I’m very pleased to have participated in this clinical trial, which we expect will confirm that less donor skin is needed for soft-tissue injuries while not compromising healing outcomes relative to conventional autografting,” said Dr. Steven E. Mapula, Assistant Professor of Surgery TCU and Division Chief of Plastic Surgery at John Peter Smith Hospital. “We believe the RECELL System has the potential to become an important new treatment option for those in need of soft-tissue reconstruction.”

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

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.

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

FOR FURTHER INFORMATION:

U.S. Media Sam Brown, Inc. Christy Curran Phone +1-615-414-8668 christycurran@sambrown.com **O.U.S. Media** Rudi Michelson Phone +61 (0)3 9620 3333 Mobile +61 (0)411 402 737 rudim@monsoon.com.au	**Investors** ICR Westwicke Caroline Corner Phone +1-415-202-5678 caroline.corner@westwicke.com

[i] 2017 Procedural Data. © 2019 DR/Decision Resources, LLC