



## AVITA Medical Announces FDA Breakthrough Device Designations for the RECELL® System

November 3, 2022

VALENCIA, Calif. and MELBOURNE, Australia, Nov. 03, 2022 (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, announced today that the Food and Drug Administration (FDA) granted the RECELL System designations as a Breakthrough Device for its proposed soft tissue repair indication as well as its vitiligo indication.

The goal of the FDA Breakthrough Devices Program is to provide patients and health care providers with timely access to new medical devices and technologies by expediting the development, assessment, and review of devices that provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. Under the program, AVITA Medical will receive prioritized review and interactive communication with the FDA throughout the premarket review phase.

“We are pleased that the FDA has recognized the therapeutic potential of our RECELL System for our proposed soft tissue repair and vitiligo indications with the Breakthrough Device designations,” said Jim Corbett, AVITA Medical Chief Executive Officer. “We are hopeful that the designations will help ensure timely patient access to RECELL as therapeutic treatments for both soft tissue repair and vitiligo, and we look forward to interacting with the agency in its review of RECELL for these proposed indications.”

AVITA Medical’s clinical trial in soft tissue repair has been funded 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.

Authorized for release by the Chief Financial 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 acute thermal burns in both adults and children, 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 soft tissue repair and 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. 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 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 15,000 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 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](http://www.avitamedical.com).

### FOR FURTHER INFORMATION:

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