AVITA Medical Receives CE Mark for RECELL® GO, Enabling Commercialization Across Europe

September 14, 2025

VALENCIA, Calif., Sept. 14, 2025 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) ("AVITA Medical", or the "Company"), a leading therapeutic acute wound care company, today announced it has received the CE Mark under the European Union Medical Device Regulation (EU MDR) for RECELL GO. This allows the Company to commercialize RECELL GO in Europe and in other markets that recognize the CE Mark.

"CE Mark for RECELL ® GO is an important milestone for AVITA Medical and for patients," said Jim Corbett, Chief Executive Officer of AVITA Medical. "It enables us to bring this option to burn centers and clinicians in Europe to support their treatment of patients with acute wound injuries."

RECELL GO is a point-of-care device used by healthcare professionals to prepare a suspension of a patient's own skin cells (Spray-On Skin™ Cells) from a small sample of healthy skin. The cells are applied to promote healing in burns and traumatic or surgical wounds. RECELL GO builds on the RECELL System already in use across Europe.

Data recently presented at the 2025 European Burns Association Congress demonstrated that adults with deep partial-thickness (second-degree) burns treated with RECELL experienced a 36% reduction in hospital stays compared with traditional grafting, underscoring the clinical value of the RECELL technology.

With the CE Mark secured, AVITA Medical will begin commercialization of RECELL GO in select European countries, including Germany, Italy, and the United Kingdom, in collaboration with burn centers and clinical partners.

About AVITA Medical, Inc.

AVITA Medical® is a leading therapeutic acute wound care company delivering transformative solutions. Our technologies are designed to optimize wound healing, effectively accelerating the time to patient recovery. At the forefront of our platform is the RECELL® System, approved by the U.S. Food and Drug Administration for the treatment of thermal burn and trauma wounds. RECELL harnesses the healing properties of a patient's own skin to create Spray-On Skin™ Cells, offering an innovative solution for improved clinical outcomes at the point-of-care. In the U.S., AVITA Medical also holds the exclusive rights to manufacture, market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, and the exclusive rights to market, sell, and distribute Cohealyx™, an AVITA Medical-branded collagen-based dermal matrix.

In international markets, the RECELL System is approved to promote skin healing in a wide range of applications including thermal burn and trauma wounds, with regulatory clearances in Europe, and excluding RECELL GO, in Australia and Japan.

To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to significant risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements generally may be identified by the use of words such as "could," "expect," "may," "will," "would," and similar words or expressions, and the use of future dates. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation: industry market conditions; failure to obtain and/or maintain regulatory approvals and comply with applicable regulations; market reaction to growth or product initiatives; market penetration of our products; changes in the legal or regulatory environments; and other business effects, including the effects of industry, as well as other economic or political conditions outside of the Company's control. Any forward-looking statements made herein are made as of the date of this release, and the Company undertakes no obligation to publicly update or revise any of these statements, except as required by law. For additional information and other important factors that may cause actual results to differ materially from forward-looking statements, please see the "Risk Factors" section of the Company's latest Annual Report on Form 10-K and other publicly available filings for a discussion of these and other risks and uncertainties.

Investor & Media Contact:
Ben Atkins
Phone +1-805 341 1571
investor@avitamedical.com | media@avitamedical.com

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.