AVITA Medical Announces FDA Approval of RECELL GO mini, Optimizing Treatment for Smaller Wounds

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VALENCIA, Calif., Dec. 23, 2024 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a commercial-stage regenerative medicine company focused on first-in-class devices for wound care management and skin restoration, today announced that the U.S. Food and Drug Administration (FDA) has approved its premarket approval (PMA) supplement for RECELL GO® mini. As a line extension of the RECELL GO system, the RECELL GO mini disposable cartridge is designed specifically to treat smaller wounds up to 480 square centimeters, compared to the standard RECELL GO disposable cartridge, which treats an area of 1,920 square centimeters.

RECELL GO mini

AVITA Medical receives FDA approval of RECELL GO mini, a new addition to the RECELL Spray-On Skin™ technology platform.

RECELL GO mini addresses a critical need in the full-thickness skin defect market, which includes a high volume of smaller wounds. As part of the RECELL GO platform, RECELL GO mini uses the same multi-use processing device as the standard disposable cartridge but features a modified cartridge optimized for smaller skin samples that reduces resource use and minimizes waste. This design provides an entry point for clinicians who may not have previously used the RECELL GO platform for smaller wounds, enabling broader accessibility and use in trauma and burn centers.

“The FDA approval of RECELL GO mini strengthens our ability to provide clinicians with fit-for-purpose solutions that meet the diverse needs of patients with full-thickness wounds,” said Jim Corbett, Chief Executive Officer of AVITA Medical. “By introducing a treatment option specifically for smaller wounds, we are expanding the accessibility of RECELL to a wider range of patients. We believe this addition will drive greater adoption across trauma centers, where smaller wounds are common, and support our broader growth strategy.”

The company expects RECELL GO mini to serve as a growth driver within the broader RECELL GO platform, further advancing AVITA Medical’s strategy to expand its impact on patient care. Rollout will begin with trauma and burn centers that currently treat smaller wounds during the first quarter of 2025.

The PMA supplement follows the original PMA of RECELL Autologous Cell Harvesting Device and subsequent PMA supplements.

About AVITA Medical, Inc.
AVITA Medical is a commercial-stage regenerative medicine company transforming the standard of care in wound care management and skin restoration with innovative devices. At the forefront of our platform is the RECELL System, approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient’s own skin to create Spray-On Skin ™ Cells, delivering a transformative solution at the point-of-care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes. In the United States, AVITA Medical also holds the exclusive rights to market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, and 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 burns, full-thickness skin defects, and vitiligo. The RECELL System, excluding RECELL GO ™, is TGA-registered in Australia, has received CE mark approval in Europe, and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

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 “anticipate,” “expect,” “intend,” “could,” “would,” “may,” “will,” “believe,” “continue,” “estimate,” “look forward,” “forecast,” “goal,” “target,” “project,” “outlook,” “guidance,” “future,” and similar words or expressions, and the use of future dates. Forward-looking statements include, but are not limited to, statements relating to the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; anticipated market share growth and revenue generation from certain 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, as well as other economic or political conditions outside of the Company’s control. These statements 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.

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

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/b6b7df71-e67c-4a6e-847c-bdcca54fad27

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