AVITA Medical Submits Response to FDA, Resuming Review Clock for RECELL GO PMA Supplement

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VALENCIA, Calif., Feb. 29, 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 it has submitted its response to the U.S. Food and Drug Administration (FDA) for additional information requested in connection to its premarket approval (PMA) supplement for RECELL GO ™. This submission resumes the substantive interactive review process under the Breakthrough Devices Program.

The response addresses various questions and incorporates data from in-house testing to support the PMA supplement and fulfil the additional information request, which we received in October of 2023. Upon receipt by the FDA, the application of the PMA supplement resumes its 180-day real time review, with 90 days remaining in the review period. Therefore, we expect FDA approval on May 30, 2024, positioning us for a product launch on May 31, 2024.

“RECELL GO will enhance our capabilities and reach to continue our already impressive growth,” said Jim Corbett, Chief Executive Officer of AVITA Medical. “RECELL GO reduces the training burden on medical professionals and our field sales organization. In doing so, we anticipate broader adoption of RECELL across various applications, ultimately amplifying our impact and transforming patient care."

The supplement follows the original PMA of its 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 Food and Drug Administration 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. AVITA Medical also holds the exclusive rights to market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, in the United States.

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 is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

Forward-Looking Statements
Statements in 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,” “may,” “will,” “believe,” “estimate,” “look forward,” “forecast,” “goal,” “target,” “project,” “continue,” “outlook,” “guidance,” “future,” and similar words or expressions, and the use of future dates. Forward-looking statements in this press release include but are not limited to statements concerning our product development activities and regulatory approval of our products. 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.

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