AVITA Medical Submits FDA PMA Supplement for RECELL GO

VALENCIA, Calif., June 29, 2023 (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, today announced its submission of a premarket approval (PMA) supplement to the U.S. Food and Drug Administration (FDA) for RECELL GO™. The supplement follows the original PMA of its RECELL Autologous Cell Harvesting Device and subsequent PMA supplements.

With its innovative capabilities, RECELL GO revolutionizes the current, manually operated RECELL device by eliminating the need for manual management of skin samples. RECELL GO will utilize single-use processing cartridges integrated into a durable AC powered processing device. The automated workflow streamlines the critical steps of enzyme incubation, buffer rinse, mechanical disaggregation, and filtering, transforming the production process of Spray-On Skin™ Cells.

“This step is pivotal to advancing our platform and strategic growth plans,” said Jim Corbett, Chief Executive Officer of AVITA Medical. “The submission is a testament to our unwavering commitment to innovation and dedication to patient care. Upon approval, RECELL GO will serve as the catalyst that accelerates our growth trajectory. By significantly reducing the burden on medical professionals, we anticipate increased adoption of RECELL across our indications, amplifying our impact and transforming the lives of patients.”

As previously announced, RECELL GO maintains the FDA Breakthrough Device designation from predecessor devices. Under the Breakthrough Device program, the submission will receive prioritized, interactive review with an expected January 2024 approval.

Authorized for release by the Chief Executive 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 thermal burn wounds and full-thickness skin defects and for repigmentation of stable depigmented vitiligo lesions, 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. 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.

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.

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 statements. Applicable risks and uncertainties include, among others, the timing and realization 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.

FOR FURTHER INFORMATION:

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