



AVITA Medical Completes Enrollment in Pivotal Trial Evaluating the RECELL® System for Repigmentation of Stable Vitiligo

December 15, 2021

Topline data expected in second half of 2022

VALENCIA, Calif. and MELBOURNE, Australia, Dec. 15, 2021 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, announced today that it has completed enrollment into its pivotal trial for the use of the RECELL® System for repigmentation of stable vitiligo. Currently, the RECELL System is indicated in the U.S. for use in the treatment of acute thermal burns.

"Recruitment of the last patient in this blinded, randomized pivotal trial is a significant milestone and lays the groundwork for the regulatory approval and commercialization of the RECELL System in 2023 for use in patients with stable vitiligo," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "We look forward to sharing the topline data from this trial next year."

Vitiligo is a disease that attacks pigment-producing cells, called melanocytes, resulting in their destruction or malfunction. The result is a loss of pigmentation in patches of skin. Vitiligo affects up to 2% of the population worldwide,ⁱ including an estimated 3-6.5 million Americans.ⁱⁱ Vitiligo has a comparable market size and psychosocial impact to other major dermatology diseases including psoriasis (thick, scaly skin) and atopic dermatitis (red, cracked skin).^{iii iv v} Like these diseases, those living with vitiligo may suffer from poor body image along with low self-esteem, leading to an impaired quality of life.^{vi}

"There is currently no cure for vitiligo and no FDA-approved treatment options, so this is a very exciting clinical trial," said Dr. Anand Ganesan, professor of dermatology and biological chemistry in the University of California Irvine School of Medicine. "We believe the RECELL System has the potential to become an important new treatment option for the millions of people with stable vitiligo."

For more information about the RECELL System, please visit www.RECELLSystem.com.

ABOUT AVITA MEDICAL, INC.

AVITA Medical is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing a RES® REGENERATIVE EPIDERMAL SUSPENSION, an autologous suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

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 indicated for use in the treatment of acute thermal burns. 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 10,000 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 marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds, and aesthetics. The RECELL System is TGA-registered in Australia and received CE-mark approval in Europe. To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING 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 statement. Applicable risks and uncertainties include, among others, the timing 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.

This press release was authorized by the review committee of AVITA Medical, Inc.

FOR FURTHER INFORMATION:

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ⁱ Picardo et al. Vitiligo. Nature Reviews Disease Primers. 2015.

ⁱⁱ John Harris, MD, PhD – Presentation as part of Incyte Corporate presentation. (Harris, UMass, is a global leader in Vitiligo; AVITA collaborator).
<https://investor.incyte.com/static-files/01f77a1c-6351-4348-adc2-597e2bc1f42eSERT>

ⁱⁱⁱ National Psoriasis Foundation – Statistics, <https://www.psoriasis.org/psoriasis-statistics/> Accessed 10/5/2020

^{iv} The burden of vitiligo: Patient characteristics associated with quality of life. Homan, et al. JAAD. 2009

^v Comparison of the Psychological Impacts of Asymptomatic and Symptomatic Cutaneous Diseases: Vitiligo and Atopic Dermatitis. Noh, et al. Annals of Derm. 2013

^{vi} Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009