



RECELL® System Vitiligo Clinical Trial Protocol to be Presented at the Global Vitiligo Foundation Annual Scientific Symposium

March 23, 2022

VALENCIA, Calif. and MELBOURNE, Australia, March 23, 2022 (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 an abstract highlighting the clinical trial protocol utilizing the RECELL® Autologous Cell Harvesting Device (RECELL® System) to treat vitiligo will be presented at the Global Vitiligo Foundation Annual Scientific Symposium. The conference is being held in Boston and will highlight research and knowledge of both up and coming vitiligo researchers and those who have and continue to build the foundational knowledge about vitiligo.

"We are pleased to share our clinical study protocol, which aims to establish safety and effectiveness for repigmentation of stable vitiligo lesions utilizing the RECELL System, with leaders of the vitiligo community," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "With enrollment of our vitiligo pivotal trial complete, we look forward to sharing results of our blinded, randomized study in the near future and working with the FDA to bring our novel treatment option to patients."

RECELL System Abstract

- March 24 at 9:38am, Abstract #4: RECELL Autologous Cell Harvesting Device: A Review of the Science of Autologous Skin Cell Suspension and Clinical Protocol Aimed in Establishing Safety and Effectiveness for Repigmentation of Stable Vitiligo Lesions. Authors: K. Bush, A. Hopkin, E. Kirshner, A. Quick

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.

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 and a new ease-of-use design was approved in 2022. 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.avitammedical.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