AVITA Medical Submits FDA PMA Application to Expand Indication to Vitiligo

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VALENCIA, Calif., and MELBOURNE, Australia, Dec. 19, 2022 (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, announced today the submission of a Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for its RECELL® System. The application, if approved, will expand the indication of RECELL to include the treatment of stable vitiligo.

“We are pleased to take the next step towards expanding the clinical application of RECELL into a treatment for vitiligo,” said Jim Corbett, AVITA Medical Chief Executive Officer. “RECELL offers first-in-class repigmentation of vitiligo lesions through the transplantation of melanocytes. Once approved, this indication will dramatically expand our reach in a huge market with limited treatment options. We anticipate a full launch of this treatment option in January 2025.”

This PMA application includes the recently released results of the pivotal trial for vitiligo. The study achieved its primary effectiveness endpoint of super-superiority ($p<0.025$). The study compared repigmentation success rates in treating patients with segmental and non-segmental stable vitiligo.

The RECELL System earned FDA Breakthrough Device designation for its proposed indication of vitiligo. Under the program, AVITA Medical will receive prioritized review and interactive communication with the FDA throughout the premarket review phase. The standard FDA review timeline for a PMA application is 180 days.

This PMA application follows the original PMA approval of the RECELL System in September 2018.

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

ABOUT VITILIGO

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 up to 6.5 million Americans,[ii] with an estimated 1.3 million suffering from stable vitiligo. Vitiligo has a comparable 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]

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 acute thermal burns in both adults and children, 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 and validated cost savings. 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, including soft tissue repair and repigmentation of stable vitiligo lesions.

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 approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

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 15,000 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 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.

FOR FURTHER INFORMATION:

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[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/f72257b8-ea0a-484e-8644-9bdcc9694fe5

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[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.

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