AVITA Medical Announces FDA Approval of RECELL for Skin Repigmentation in Vitiligo Patients

June 16, 2023

VALENCIA, Calif. and MELBOURNE, Australia, June 16, 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 that the U.S. Food and Drug Administration (FDA) has approved its application for premarket approval (PMA) of its RECELL® System for the treatment of vitiligo.

RECELL for repigmentation of stable depigmented vitiligo lesions is the first FDA-approved therapeutic device offering a one-time treatment at the point-of-care. Using the device, a clinician prepares and delivers autologous skin cells from pigmented skin to stable depigmented areas, offering a safe and effective treatment for vitiligo.

“RECELL represents first-in-class treatment for repigmentation through the delivery of normal, healthy skin cells,” said Jim Corbett, Chief Executive Officer of AVITA Medical. “This is a breakthrough approval for AVITA Medical, significantly expanding the clinical applications for RECELL, and demonstrates our continued commitment to patient care. We look forward to offering a meaningful one-time treatment option for patients with stable vitiligo across the U.S.”

PMA approval was based upon results from the company’s pivotal trial evaluating the safety and effectiveness of the RECELL System for repigmentation of stable vitiligo lesions. The study compared repigmentation success rates with RECELL treatment in areas of skin resurfaced using ablative laser, versus standard of care (control) treatment in another area. Repigmentation was evaluated by an expert central review committee (CRC) at 6 and 12 months after treatment. The CRC reported 36% of RECELL treatments (versus 0% of control treatments) resulted in repigmentation of at least 80% of the treated area at 6 months, establishing super-superiority for the primary endpoint ($p<0.025$), with 100% durability of repigmentation at 12 months. At the same 6-month point, treating physicians reported RECELL treatment as a success for 68% of patients, and 80% of patients self-reported RECELL treatment as a success.

The RECELL System is an autologous cell harvesting device that is used to prepare and deliver a regenerative cell suspension, Spray-On Skin™ Cells, using a small amount of a patient’s own skin. The Spray-On Skin Cells contain a combination of single living cells that stimulate healing and repigmentation throughout the wound bed. The preservation of melanocytes is important for restoring natural pigmentation to the recipient area. The suspension of Spray-On Skin Cells is suitable for application to skin resurfaced by an ablative laser. A portion of the suspension of Spray-On Skin Cells may also be applied to the donor site.

The PMA received prioritized review through the FDA’s Breakthrough Device program. The FDA grants the Breakthrough Device designation to medical devices that provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions.

Authorized for release by the Chief Executive 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 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, AVITA Medical 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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[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/f72257b8-ea0a-484e-8644-9bdcc9694fe5

[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.