First Patient Enrolled in AVITA Therapeutic's Pivotal Study Evaluating the RECELL System for Repigmentation of Stable Vitiligo

Valencia, Calif, USA, and Melbourne, Australia, September 14, 2020 — AVITA Therapeutics, 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 the initiation of the pivotal study assessing the use of the RECELL® System to treat stable vitiligo with the enrollment of the first patient at Miami Dermatology and Laser Institute in Miami, FL. The study will evaluate the safety and effectiveness of AVITA Therapeutic's RECELL System to repigment skin in patients who have vitiligo that has been stable for at least one year.

"The initiation of the vitiligo clinical study is a milestone in advancing AVITA Therapeutic's pipeline to leverage the utility and full potential of our innovative RECELL technology platform to address unmet medical needs in dermatological applications," said Dr. Mike Perry, AVITA Therapeutic Chief Executive Officer. "Globally, there have been several published case series and pilot randomized clinical trials reporting positive results with the use of RECELL for treating patients with stable vitiligo and repigmenting depigmented skin lesions. We are pleased to initiate this pivotal study as a next step toward offering a treatment option for the millions of Americans who live with vitiligo."

Vitiligo is an autoimmune disease that attacks the epidermis layer of skin resulting in loss of color or pigmentation. This serious skin condition affects up to 2% of the population worldwide, including an estimated 6.5 million Americans.[i] Vitiligo has a comparable market size & psychosocial impact to other major dermatology diseases including psoriasis (thick, scaly skin) and atopic dermatitis (red, cracked skin).[iv-vi] Like these diseases, patients with vitiligo may suffer from poor body image along with low self-esteem, leading to an impaired quality of life.[ii] There is currently no cure for vitiligo, nor a universally accepted method for limiting the spread of the disease. Although many treatments are being used for the management of vitiligo, they are often temporary with a high rate of recurrence.[iii]

"While often considered a cosmetic issue, vitiligo can greatly impact the quality of life of those living with the disease, and treatment options are limited," said Jill Waibel, MD, owner and Medical Director of Miami Dermatology and Laser Institute. "We look forward to assessing the safety and efficacy of the RECELL System in restoring skin color in stable vitiligo lesions and potentially offering those who live with vitiligo hope with a new, easy in-office treatment."

The multi-center pivotal study will assess the safety and effectiveness of the RECELL System in treatment of depigmented vitiligo lesions at 24 weeks in patients whose vitiligo is stable, meaning they have not had new vitiligo lesions or lesions that have expanded for at least one year. Clinicians will obtain a small amount of the study participant's own healthy skin at the point-of-care to prepare a suspension of Spray-On Skin™ Cells using the RECELL System that will then be applied to the vitiligo lesion. Additional

long-term safety and effectiveness data, including sustained repigmentation of the vitiligo lesion, will be collected over the course of the study.

In parallel with the clinical study, AVITA Therapeutics is partnering with the University of Massachusetts Medical School on a complementary and more scientifically-oriented vitiligo feasibility study.

Of note: Use of the RECELL System in patients undergoing reconstruction of skin defects not associated with a burn injury is limited by the Federal law to investigational use.

Authorized for release by the Chief Executive Officer of AVITA Therapeutics, Inc.

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ABOUT AVITA THERAPEUTICS, INC.

AVITA Therapeutics is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Therapeutics' 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 Therapeutics' 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 in patients 18 years and older. 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 8,000 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 letter 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 letter 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 letter 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 letter. 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 letter 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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[ii] Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009

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[v] The burden of vitiligo: Patient characteristics associated with quality of life. Homan, et al. JAAD. 2009

[VI] Comparison of the Psychological Impacts of Asymptomatic and Symptomatic Cutaneous Diseases: Vitiligo and Atopic Dermtitis. Noh, et al. Annals of Derm. 2013