BARDA to Initiate Procurement of the RECELL® System for Emergency Response Preparedness

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VALENCIA, Calif. & MELBOURNE, Australia--(BUSINESS WIRE)--Jul. 13, 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 that the Biomedical Advanced Research and Development Authority (BARDA), a part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), will procure the RECELL® System as part of the HHS mission to build preparedness for public health emergencies.

BARDA has agreed to the purchase, storage and delivery of RECELL Systems utilizing a vendor-managed inventory (VMI) plan valued at U.S. $7.6 million. Further, BARDA has expanded its awarded contract to provide supplemental funding of $1.6 million to support emergency deployment of RECELL Systems for use in mass casualty or other emergency situations. Delivery of RECELL Systems under the VMI plan is expected to commence later this calendar year.

“We are very pleased to continue collaborating with BARDA to ensure healthcare providers have access to the RECELL System to help patients in large-scale emergencies,” said Dr. Mike Perry, AVITA Therapeutics Chief Executive Officer. “The ongoing preparation from BARDA underscores the importance of public-private partnerships in advancing biomedical innovation to address unmet medical needs.”

“BARDA’s mission is to secure medical countermeasures needed to save lives in public health emergencies, which means we continually work to prepare for any potential threats, whether natural or intentional, that could result in mass injuries. Our nation has to be prepared to treat as many people as possible quickly and effectively,” said BARDA Acting Director Gary Disbrow, Ph.D. “We look forward to continuing to work with AVITA Therapeutics to ensure this technology will be available to medical professionals in an emergency or mass casualty incident."

AVITA Therapeutics, through its subsidiary AVITA Medical Limited, has had a long-term positive relationship with BARDA. BARDA and AVITA signed a contract in September 2015 through which BARDA is providing technical and financial support for pre-market and post-market clinical and healthcare provider educational programs. BARDA’s partnership for the RECELL System was of fundamental importance to the Company being able to achieve premarket approval for the RECELL System in late 2018. These initiatives support BARDA's overarching goal of building burn care preparedness, by securing effective medical countermeasures for burn injuries for use in case of a mass casualty.

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

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

ABOUT BARDA

The Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 55 BARDA-supported products have achieved FDA approval, licensure or clearance. To learn more, visit medicalcountermeasures.gov and PHE.gov/BARDA.

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.

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