



AVITA Medical Announces FDA Approval of Expansion of RECELL Compassionate Use Program in Life Threatening Injuries

February 12, 2018

Expanded Protocol Allows Treatment of Up to 88 Patients

Valencia, CA, USA, and Melbourne, Australia, 12 February 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMYX) today announced that the U.S. Food and Drug Administration (FDA) has approved a significant increase in the number of patients who may be treated in the United States with the RECELL® Autologous Cell Harvesting Device under a FDA Compassionate Use Investigational Device Exemption (IDE) program. RECELL is a regenerative medical device designed to facilitate skin regeneration while reducing the amount of skin harvested at the time of surgery. This reduction in donor site skin requirements has important benefits from both clinical and health economic perspectives.

Under the expanded protocol, up to 88 patients with life-threatening injuries, including severe burns, may be treated with RECELL. This is the fifth expansion to the Compassionate Use protocol for RECELL approved by the FDA and expands by 20 the number of patients who may be treated. Eligible patients are those who have insufficient healthy skin available for standard skin grafting treatment of their injuries and whose treating physicians believe there to be no suitable alternative treatment.

To date, 64 Compassionate Use cases using RECELL have been conducted at leading institutions, including Arizona Burn Center at Maricopa Medical Center, Baton Rouge General Hospital, Massachusetts General Hospital, MedStar Washington Hospital Center, Regional Medical Center / University of Tennessee, Wake Forest Baptist Medical Center, Walter Reed National Military Medical Center, Riley Hospital for Children (Indianapolis), St. Christopher's Hospital for Children, Shriners Hospitals for Children – Boston, Sidney & Lois Eskenazi Hospital, U.S. Army Institute for Surgical Research (San Antonio), University of California San Diego Health System, and University of South Alabama.

Two abstracts related to cases from the Compassionate Use program have been accepted for presentation at the American Burn Association 50th Annual Meeting to be held from April 10 through 13, 2018 in Chicago, Illinois. The presentations will describe experience with RECELL in the treatment of patients with partial thickness facial burns, and in patients, including children, with extensive burn injuries.

"We appreciate the FDA approval of the expansion of our Compassionate Use program, which highlights the critical unmet need among patients with life-threatening injuries such as severe burns," said Dr. Michael Perry, AVITA Medical's Chief Executive Officer. "We thank the surgeons and other medical professional treating these patients for their support of this program and for their continued dedication to these patients."

Funding provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the US Department of Health and Human Services, to support the development of RECELL by AVITA has included support of the expanded

Compassionate Use program. In September 2017, AVITA submitted to the FDA a Pre-Market Approval (PMA) application for RECELL for the treatment of burn injuries, and the Company expects the PMA review to be completed during the 2nd or 3rd calendar quarter of 2018.

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ABOUT AVITA MEDICAL LIMITED: 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's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our medical devices work by preparing a REGENERATIVE EPITHELIAL SUSPENSION™, an autologous suspension comprised of the patient's own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This autologous suspension is then applied to the area to be treated.

In all countries outside of Europe in which our devices are registered for sale, our portfolio is marketed under the RECELL brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. RECELL is TGA-registered in Australia, and CFDA-cleared in China. In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. RECELL is designed for the treatment of burns and plastic reconstructive procedures; REGENERCELL™ has been formulated for chronic wounds including leg and foot ulcers; and RENOVACELL™ is tailored for aesthetic applications including the restoration of pigmentation. In the United States, RECELL is an investigational device limited by federal law to investigational use.

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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