AVITA Medical Announces Expanded Compassionate Use of RECELL® Device in Life-Threatening Burns

FDA approves expansion of program to include up to 108 patients and 26 U.S. burn centers

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Valencia, Calif., USA, and Melbourne, Australia, 9 August 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMXY) 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 U.S. using the RECELL® Autologous Cell Harvesting Device under a Compassionate Use Investigational Device Exemption (IDE) program. Under the expanded program, up to 108 patients with severe burns may be treated using the RECELL Device, and up to 26 U.S. burn centers may participate in the program.

The Compassionate Use program allows the treatment of eligible patients with the RECELL Device in advance of FDA approval. Eligible patients are those who have insufficient healthy skin available for conventional skin grafting treatment of their injuries and whose treating physicians believe there to be no suitable alternative treatment. Currently, 82 patients have already been treated under the Compassionate Use program.

Major U.S. burn centers that have treated patients with the RECELL Device under the Compassionate Use program include Arizona Burn Center at Maricopa Medical Center, Baton Rouge General Hospital, Grady Burn Center – Grady Health System, Maine Medical Center - MaineHealth, 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.

"The participation of these major U.S. burn centers in the Compassionate Use program highlights the critical unmet need amongst patients with life-threatening burns, and we are pleased to make the RECELL Device available under this program," said Dr. Michael Perry, AVITA Medical's Chief Executive Officer. "We are also encouraged by the fact that 24 U.S. burn centers have treated patients with the RECELL Device through a combination of our clinical trials, Continued Access program, and Compassionate Use program, giving the product candidate broad exposure within the U.S. burn community. Combined with the over 7,000 patients who have been treated with the RECELL Device globally, these programs provide us a large body of experience regarding the potential clinical benefits as well as the costs savings associated with use of the RECELL Device."

Currently the RECELL Device is not approved for sale in the U.S. and is limited by Federal Law to investigational use.

The RECELL Device is designed to enable medical professionals to produce, at the point-of-care, a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™) using a small sample of the patient's own skin. The autologous suspension contains cells necessary to regenerate epidermis and provides a new way to achieve permanent closure in burns and other wounds while reducing the amount of skin harvested at the time of surgery. Reduction in donor-site skin requirements has important benefits from both clinical and health economic perspectives. A U.S. PMA application for the treatment of burn injuries is currently under review by the FDA. AVITA Medical expects completion of the FDA review of the PMA during the third quarter of calendar 2018, followed by U.S. approval and market launch.

Funding for the Compassionate Use program was provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

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ABOUT AVITA MEDICAL LIMITED

ABOUT AVITA MEDICAL LIMITED 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 (RES), an autologous suspension comprised of the patient's own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated.

In all countries outside of Europe, 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 the United States, RECELL is not approved for sale and is limited by federal law to investigational use.

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.

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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