



AVITA Medical Announces Presentation of RECELL® Device Effectiveness and Safety in Treatment of Thermal Burns at Premier U.S. Military

August 22, 2018

Results from two U.S. pivotal trials featured in plenary session at U.S. Defense Department Military Health System Research Symposium

Valencia, Calif., USA, and Melbourne, Australia, 22 August 2018 — AVITA Medical (ASX [AVH](#), OTCQX: [AVMXY](#)) today announced that results from two U.S. pivotal clinical trials demonstrating the effectiveness and clinical benefits of the RECELL® Autologous Cell Harvesting Device were presented in the plenary session at the U.S. Defense Department Military Health System Research Symposium (MHSRS) in Kissimmee, Florida. The results were presented by James H. Holmes, IV, MD, FACS Wake Forest Baptist Medical Center, Winston-Salem North Carolina.

“The RECELL Device addresses an unmet need in the treatment of burn patients and provides the opportunity with a point-of-care technology to reduce the amount of skin required for epidermal regeneration and definitive closure of burns,” said Dr. Holmes. “The trial results demonstrate comparable burn wound healing between the RECELL Device and standard skin grafts while utilizing significantly less skin and resulting in improved healing of donor sites harvested for treatment with the RECELL Device.”

The MHSRS is the Department of Defense’s premier scientific meeting and provides a venue for presenting new scientific knowledge resulting from military-unique research and development. The MHSRS is the only military or civilian meeting that focuses specifically on the unique medical needs of the Warfighter. MHSRS provides a collaborative setting for the exchange of information between military providers with deployment experience, research and academic scientists, international partners, and industry on research and related health care initiatives falling under the topic areas of Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, Medical Simulation and Information Sciences, Military Infectious Diseases, and the Radiation Health Effects.

Key highlights of Dr. Holmes’ presentation included:

- The pivotal randomized, controlled clinical trial of the RECELL Device in the treatment of deep partial-thickness (second-degree) burns demonstrated statistically significant reduction in donor skin requirements (97.5 percent reduction) and pain, increased patient satisfaction and improved donor scar
- The pivotal randomized, controlled clinical trial in mixed and full-thickness (third-degree) burns met its co-primary endpoints and demonstrated statistically significant reduction in donor skin requirements (32.0 percent reduction).

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. Premarket Approval (PMA) application for the treatment of burn injuries is currently under review by the U.S. Food and Drug Administration (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 two U.S. pivotal clinical trials 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. In addition, funding for the trials was provided by the U.S. Department of the Army, AFIRM 1 Contract #W81XWH-08-2-0032.

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ABOUT AVITA MEDICAL LIMITED

AVITA Medical’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.

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