ASX/News Release

AVITA Medical Announces FDA Approval of the RECELL® System for the Treatment of Severe Burns in the U.S.

Point-of-care regenerative medicine technology approved to treat second- and third-degree burns using Spray-On Skin™ Cells product

U.S. market launch planned for 4th calendar quarter 2018.
Target market for burns approximates USD $200 million

Valencia, Calif., USA, and Melbourne, Australia, 21 September 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, today announced that the U.S. Food and Drug Administration (FDA) approved the Company's Premarket Approval (PMA) application to market the RECELL® Autologous Cell Harvesting Device (RECELL® System) to treat severe thermal burns in patients 18 years and older. The RECELL System uses a small amount of a patient's own skin to prepare Spray-On Skin™ Cells at the point of care in as little as 30 minutes, providing a new way to treat thermal burns. The two randomized, controlled clinical trials supporting the FDA approval demonstrated that treatment of acute burn wounds with the RECELL System required substantially less donor skin than required with conventional split-thickness autografts to achieve closure of burn wounds. Reduction in donor skin requirements provides key clinical benefits to patients and significant reductions in the cost of treatment.

"Patients are at the center of everything we do at AVITA Medical and we are pleased to be able to provide an innovative solution for the treatment of severe burn injuries," said Dr. Michael Perry, Chief Executive Officer. "Today's approval of the RECELL System marks an important milestone for us and provides a new way to treat burns for the thousands of patients with significant unmet medical needs. We are grateful to those patients who participated in clinical trials of the RECELL System and to the clinical trial investigator teams whose dedication and scientific rigor made this approval possible. We also greatly appreciate our collaboration with BARDA and the support that they have provided to us throughout the development of the RECELL System."

The RECELL System is approved to be used at the point of care by trained healthcare professionals to treat adult patients with severe thermal burns. The RECELL System can be used alone in the treatment of partial-thickness burns, or in combination with autografting for the treatment of full-thickness burns. A small skin sample is collected and immersed in the Company's proprietary Enzyme solution in the RECELL System to separate the skin cells to produce Spray-On Skin Cells. The resultant Regenerative Epidermal Suspension™ (RES™) includes keratinocytes, fibroblasts, and melanocytes, which play a critical role in wound healing. The suspension is then sprayed directly onto the prepared burn wound, providing a broad and even distribution of live cells across the entire wound bed. The RECELL System can be used to prepare enough RES™ to treat a wound up to 80 times the size of the donor skin sample, so a skin sample approximately the size of a credit card can be used to treat a wound that covers a patient's entire back.

"Today's approval of the RECELL System is a significant advancement in how we treat patients with burns," said James H Holmes IV, MD, FACS, Wake Forest Baptist Medical Center, Winston-Salem, North Carolina. "Dramatically reducing the amount of donor skin needed to treat second- and third-degree burns has important implications for pain, scarring and costs of care, while still providing comparable healing to the current standard of care. Additionally, the potential reduction in mortality is extremely promising."

FDA Approval Supported by the Results from Two Randomized, Controlled Clinical Trials

FDA approval was based on the results of two randomized, controlled clinical trials comparing the treatment of burn patients with the RECELL System against the standard of care. The first controlled trial compared treatment with the RECELL System versus treatment with conventional split-thickness autografts in patients with deep partial-thickness (second-degree) burn injuries. During the pivotal trial, the patient donor skin required to be harvested to treat burn sites with the RECELL System was 97.5% less than the amount harvested to treat burn sites using standard of care resulting in a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved donor scar outcomes. Despite the statistically significant reduction in donor skin required to treat with the RECELL System, burn sites treated with RECELL achieved definitive closure comparable to the burn sites treated with standard of care. Results from the second-degree burn pivotal trial were published online on May 24, 2018 in the *Journal of Burn Care & Research* (JBCR), followed by publication in the September/October 2018 issue (Volume 39, Issue 5) of JBCR. The results have also been presented at multiple scientific conferences, including the Top Five Abstract plenary session of the American Burn Association (ABA) 50th Annual Meeting held in April 2018.

The second randomized, controlled pivotal clinical trial evaluated treatment of deep full-thickness (third-degree) burns with the RECELL System combined with split-thickness autografts, versus treatment with standard of care. During the pivotal trial, the patient donor skin required to be harvested to treat burn sites with the RECELL System was 32 percent less than the amount harvested to treat burn sites with the standard of care ($p<0.001$). Despite the statistically significant reduction in donor skin required to treat with the RECELL System, burn sites treated with the RECELL System achieved definitive closure comparable to the burn sites treated with standard of care. At eight weeks post treatment, 92 percent of the burn sites treated with the RECELL System achieved complete healing versus 85 percent for the sites treated with the standard of care, demonstrating non-inferiority. Results from the pivotal trial in third-degree burns have been presented at multiple scientific conferences, including the ABA Meeting in April 2018.

In addition to the two pivotal trials, the RECELL System has been used in the treatment of over 90 burn patients under a Compassionate Use program, and over 65 patients under a Continued Access program. Both programs were approved by the FDA and allowed the treatment of patients with severe burns while the PMA was under review. In addition, more than 7,000 patients worldwide have been treated to date with the RECELL System.

"I have participated as an investigator in the two pivotal clinical trials of the RECELL System as well as the Compassionate Use and Continued Access programs," said William Hickerson, MD, FACS, Firefighter Burn Center, Memphis, Tennessee, and University of Tennessee Health Science Center, Memphis, Tennessee. "Based on my personal experience treating patients with the RECELL System, and the strength of the entire body of clinical evidence supporting this innovative technology, today's approval will improve the treatment of burn patients."

Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device for a full description of important safety information including contraindications, warnings and precautions.

Economic Model Demonstrates Significantly Reduced Treatment Costs for RECELL System

The frequency of burn-related injuries and the cost of treatment are high. The Centers for Disease Control and Prevention (CDC) reported that 486,000 patients receive emergency medical treatment for burns annually. Burn injuries result in approximately 3,400 deaths each year, the third-leading cause of accidental home injury deaths. Burns covering up to 90 percent of a person's body surface area, once considered fatal injuries, have become survivable with appropriate treatment. Although split-thickness autografts are the current standard treatment, grafting is associated with significant donor site pain, delayed healing and scarring.

IQVIA, with support from AVITA Medical and the Biomedical Advanced Research and Development Authority (BARDA), developed a Burn Care Pathway Health Economic Model to determine cost savings to burn centers as a result of using the RECELL System compared to the current standard of care to treat second- and third-degree burns of varying sizes. The validated model demonstrates that using the RECELL System alone in second-degree burns or in combination with autografts in third-degree burns reduces hospital costs and length of stay, regardless of comorbidities, lowering the cost of treatment by 44 percent or more for patients with large burns. In addition, the model concluded that in a 200-bed burn center, the use of the RECELL System would reduce annual total treatment costs by USD $13 million.

BARDA Funding Supports Development of RECELL System

Funding for the development of the RECELL System 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. Since 2015, BARDA has committed USD $50 million towards specific development initiatives including the two randomized, controlled clinical trials, the Compassionate Use and Continued Access programs, the PMA and related activities, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials which will evaluate the RECELL System in the pediatric population. Procurement of the RECELL System by BARDA under a vendor-managed inventory system would be triggered in the future to bolster preparedness by providing availability for use in a national disaster. In addition, part of the funding for the pivotal clinical trials was provided by the U.S. Department of the Army, AFIRM 1 Contract #W81XWH-08-2-0032.

"While severe thermal burns happen every day, in a national security emergency an overwhelming number of people may need burn care quickly," said BARDA Director Rick Bright, PhD. "Medical providers need easy-to-use treatments on hand to save more lives. Our goal is not only to support product development but also to integrate those products into routine care to build preparedness."

U.S. Market Launch

In anticipation of approval, AVITA Medical has undertaken substantial efforts to prepare for the U.S. market launch. These initiatives include the recruitment of sales and marketing leadership highly experienced in regenerative medicine and the treatment of burns, completion and assimilation of extensive direct market research, and establishment of pricing and reimbursement strategies and support infrastructure. With the receipt of FDA approval, the Company will finalize its product packaging and promotional materials to reflect the final approval details and will complete the recruitment and hiring of its field sales team. The Company expects to formally launch the RECELL System in the U.S. in the fourth calendar quarter of 2018. The Company estimates that inpatient treatment of burns in the U.S., the initial target for the RECELL System, is an approximately USD $200 million market.

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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 Medical's 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 REGENERATIVE EPIDERMAL SUSPENSION™ (RES™), 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 Medical's first FDA approved product, the RECELL® System, produces 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 7,000 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.

In international markets outside of Europe, our portfolio is 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 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. The RECELL Autologous Cell Harvesting Device is designed for the treatment of burns and plastic reconstructive procedures; REGENERCELL™ Autologous Cell Harvesting Device has been formulated for chronic wounds including leg and foot ulcers; and RENOVACELL™ Autologous Cell Harvesting Device 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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