

AVITA Medical Announces Acquisition of Manufacturing Facility to Support Planned U.S. Launch of RECELL® Device

Valencia, Calif., USA, and Melbourne, Australia, 28 June 2018 — AVITA Medical (ASX: AVH, OTCQX: AVVMXY) today announced that it has entered into an agreement to acquire a manufacturing facility to support the planned U.S. launch of the RECELL® Autologous Cell Harvesting Device in the treatment of burns. The facility is currently operated by a Fortune 500 contract manufacturer that assembles the RECELL Device for AVITA Medical. AVITA Medical will take over operations of the 2,200 square meter (23,000 square foot) manufacturing plant, located in Ventura, California, effective July 1, 2018 and will retain key employees.

“Having direct control over the manufacturing of RECELL will ensure that we have the capacity to meet commercial demand, including the planned U.S. launch and the BARDA procurement, and provide us further control over our production processes and timelines,” said Dr. Michael Perry, Chief Executive Officer. “Acquiring this facility that has a track record of producing RECELL allows us to realize the benefits of in-house production while maintaining the continuity of proven manufacturing and quality processes and systems.”

Housed within the Ventura facility is the segregated, vendor managed inventory warehouse that AVITA Medical constructed to meet the requirements of the RECELL Device procurement component of the contract with 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. BARDA has provided funding under ongoing USG Contract No. HHSO100201500028C.

The RECELL Device is an investigational medical device in the U.S. that 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). The Company expects completion of the FDA review of the PMA during the third quarter of calendar 2018, followed by U.S. approval and market launch. In April 2018 researchers from major burn centers throughout the U.S. made six presentations at the 50th Annual Meeting of the American Burn Association (ABA), in Chicago, describing the clinical and cost-savings advantages of the RECELL Device in the treatment of severe burns.

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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 EPITHELIAL SUSPENSION™, an autologous suspension comprised of the patient's skin cells and wound healing factors necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

In the United States, the RECELL Device is an investigational device limited by federal law to investigational use. In September 2017, AVITA Medical submitted to the U.S. Food and Drug Administration (FDA) a Premarket Approval (PMA) application for the RECELL Device for the treatment of burn injuries.

In all countries outside of Europe, our portfolio is marketed under the RECELL Device brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL Device 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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