AVITA Medical Announces Commencement of Manufacturing of RECELL® Device in Newly Acquired Facility in Preparation for Planned U.S. Launch

Valencia, Calif., USA, and Melbourne, Australia, 23 August 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMXY) today announced the successful completion of multiple production runs for the RECELL Device® within its newly acquired manufacturing facility in Ventura, California. Effective July 1, 2018 AVITA Medical acquired the facility from a Fortune 500 manufacturer that had previously assembled the RECELL Device on a contract basis. The manufacturing runs were performed after AVITA Medical's takeover of the facility and represent the first production activities undertaken by the Company's own manufacturing and quality control personnel. Components currently being manufactured in the facility will be used to supply clinical trial and international sales requirements and to support the Company's preparations for the expected U.S. launch of the RECELL Device in the U.S.

"I am proud of the results achieved by our manufacturing, quality control, regulatory and support teams who have successfully transitioned the RECELL Device to in-house production within our projected timelines," said Dr. Michael Perry, Chief Executive Officer. "The successful commencement of manufacturing of the RECELL Device within our own facility is a major milestone and ensures that we are prepared for the planned U.S. launch."

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.

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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 Epidermal 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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