

Avita Medical Announces Submission of U.S. FDA Premarket Approval (PMA) Application for the ReCell® Device for Treatment of Burn Injuries

Valencia, CA, USA, Perth, Australia and London, United Kingdom, 28 September 2017 — Avita Medical (ASX: [AVH](#), OTCQX: [AVMXY](#)), a regenerative medicine company specializing in the treatment of wounds and skin defects, announced today that it has submitted to the Food & Drug Administration (FDA) a Pre-Market Approval (PMA) application for its ReCell® Autologous Cell Harvesting Device for treatment of burn injuries.

Use of the ReCell® Autologous Cell Harvesting Device is intended to reduce the amount of skin harvesting required relative to conventional treatment of burn injuries, which has important benefits from both clinical and health economic perspectives.

The PMA submission includes clinical data from the two U.S. randomized, controlled trials with combined enrolment of 131 patients at twelve leading burn centers across the United States. The later trial demonstrated over 30% reduction in donor skin harvesting while achieving comparable near-term healing and long-term scar outcomes for treatment of third-degree burn injuries. Results from the earlier trial demonstrate a 97.5% reduction in donor skin harvested for treatment of second-degree burn injuries. The submission also includes a review of 55 cases of compassionate use of ReCell for extensive burn injuries.

“This PMA submission represents the culmination of years of effort by our Avita team and we are thrilled to have moved a step closer to making ReCell available to patients in the United States. Our clinical data are compelling and we look forward to potentially providing a novel and innovative therapeutic for the treatment of burns,” said Dr. Michael Perry, Avita Medical’s Chief Executive Officer. “We continue to strengthen our organization in preparation for a successful U.S. commercial launch in 2018.”

Development of the PMA for the ReCell® device has been supported through Avita’s Contract with the Office of Biomedical Advanced Research and Development Authority (BARDA), within the Assistant Secretary for Preparedness and Response (ASPR), a division of the U.S. Department of Health and Human Services. Funding support from BARDA has been instrumental in various aspects of ReCell development including execution of Avita’s clinical trials and PMA preparation activities. Market approval of ReCell aligns with BARDA’s overarching goal of building national burn care preparedness, by securing effective medical countermeasures for burn injuries critical in a mass casualty scenario.

###

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

patients' 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 an investigational device 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:

<p>Australia Monsoon Communications Sarah Kemter Phone: +61 (0)3 9620 3333 Mobile: +61 (0)407 162 530 sarahk@monsoon.com.au</p>	<p>USA Westwicke Partners Jamar Ismail Phone +1 (415) 513-1282 jamar.ismail@westwicke.com</p>
--	---