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

September 28, 2017

Approval facilitates enrolment and allows participation of additional burn center

Valencia, CA, USA, Perth, Australia and London, United Kingdom, 4 October 2017 —Avita Medical (ASX: AVH, OTCQX: AVMXY), a regenerative medicine company specializing in the treatment of wounds and skin defects, announced today that the Food & Drug Administration (FDA) has approved a supplement to the Company's Investigational Device Exemption for its ReCell® Autologous Cell Harvesting Device. The approved protocol for treatment of burn injuries has been simplified from the previously-approved Continued Access protocol and the number of approved investigational sites has increased from 8 to 15.

To date, treatment of patients with the ReCell® device under Continued Access was done according to a complex protocol requiring a randomized comparison between two distinct areas of burn injury, with one area treated using conventional skin grafts and one area treated with more expanded autografts applied in combination with Regenerative Epithelial Suspension (RES) from the ReCell® device. The newly approved protocol allows for the use of RES with expanded (meshed) autografts without requiring the randomized comparison to a conventional graft. This change makes the protocol more straightforward for burn teams and patients. Furthermore, the Continued Access protocol is complementary to the Compassionate Use protocol in that participants' burn injuries can range from 5-50% of their total body surface area, whereas the Compassionate Use is limited to the most extensive of burn injuries.

"Based on what we have seen this product do, confirmed by the recent positive analysis of the study results, consenting a patient to have an area of their burn injury treated *without* ReCell purely for purposes of comparison causes concern from a medical perspective. The new Continued Access protocol, without a comparison, allows us to continue use of ReCell with more focus on what's best for the patient," said Dr James H Holmes IV, Medical Director of the Burn Center at Wake Forest Baptist Medical Center.

The Continued Access provision of the FDA's Investigational Device Exemption (IDE) guidance allows doctors to access a medical device while the premarket approval (PMA) application is under review, if "there is a public need for the device," and "there is preliminary evidence that the device is likely to be effective and no significant safety concern have been identified for the proposed indication." The FDA's principles on granting the Continued Access further state that "it could be contrary to public health to prevent access to potentially safe and effective new devices during an evaluation period."

The PMA application for the ReCell® device was submitted September 27, 2017, and is currently under review by the FDA.

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. Continued Access to ReCell

aligns with BARDA's overarching goal of building national burn care preparedness through increasing familiarity and acceptance of effective medical countermeasures for burn injuries in a mass casualty scenario.

"Continued Access allows Avita to further develop our understanding of the integration of ReCell® into the U.S. burn surgeons' armamentarium, while helping patients and providing a platform for learning for burn care teams," said Andy Quick, Avita's Senior VP Clinical Development.

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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.

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FOR FURTHER INFORMATION:

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