ASX/News Release

Initial Pre-Emergency Use Authorization submission made to U.S. FDA for use of ReCell® in a Mass Casualty Scenario

Valencia, CA, USA, Perth, Australia and Cambridge, United Kingdom, 10 May 2017 — Avita Medical Limited (ASX:AVH; OTCQX:AVMXY), a regenerative medicine company focused on the treatment of wounds and skin defects, has received notification of the initial FDA review of the Pre-EUA (Emergency Use Authorization) submission to allow the emergency deployment of its ReCell® device for a mass casualty event involving burn injuries.

The Biomedical Advanced Research and Development Authority (BARDA) filed the Pre-EUA submission, and the review is conducted at this pre-approval stage because, during exigent circumstances, the time available for the submission and review of an EUA request may be severely limited. For the contract with BARDA, this brings the Company closer to establishing a national strategic stockpile of vendor-managed inventory of ReCell® autologous cell harvesting devices, which once approved, will allow physicians to rapidly deliver a suspension of skin cells to various wounds, including burns. Under Avita's USD 61.9m contract with BARDA, the initial order has a value of approximately USD 8m, and BARDA could opt to purchase in advance of FDA market approval, which the Company is also pursuing.

BARDA informed Avita that the pre-EUA submission has been reviewed by the FDA and that the agency has no 'additional comments or questions at this time.' BARDA said that a pre-EUA submission is not an indication of the FDA's views on the product's potential to be used under an EUA, nor that the sponsor has obtained or submitted all the information necessary for FDA to review a formal request for consideration of an EUA. BARDA explained that a pre-EUA submission is a mechanism to initiate early discussions with the FDA prior to an emergency only, and does not provide an independent legal basis for distributing or dispensing unapproved products or approved products for unapproved uses.

Avita will continue to update the required documentation to the FDA via communications with BARDA on an ongoing basis regarding any new information relevant to the ReCell® Device and its potential emergency use.

"Important boxes have been ticked, and it is very positive that the information supplied to date has satisfied FDA's initial review," said Avita CEO Adam Kelliher. "My team will keep supporting BARDA so that we can fulfill our contractual goal of delivering a significant number of ReCell® devices for use in the event of a U.S. emergency."

This represents another milestone for Avita Medical's support of BARDA under the terms of their contract. EUA is a provision whereby the FDA may authorize use of an investigational device when there are no adequate, approved, and available alternatives only after the Health and Human Services (HHS) Secretary has made a declaration of emergency or threat justifying authorization of emergency use. The

pre-EUA documentation submitted in advance of a mass casualty event allows FDA to be in position to rapidly authorize the use of the product in the event of a disaster. BARDA operates under the Department of Health and Human Services, and is charged with ensuring the US population is prepared should there be a mass casualty event caused by chemical, biological or nuclear action.

Avita says its program to get a U.S. Pre-Market Approval (PMA) from the FDA is on track, with all data collected from its pivotal clinical trial involving seven leading U.S. burns centers. The Company says it expects to submit its PMA application in mid-2017, with an anticipated FDA decision mid-2018. The FDA has approved ReCell® for cases of Compassionate Use, where it is needed for life-saving events, and has granted Continued Access to the device for those medical professionals who participated in the clinical trial.

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ABOUT RECELL® AND RES™

ReCell® is Avita Medical's unique proprietary technology that enables a clinician to rapidly create, at point of care in approximately 30 minutes, Regenerative Epithelial Suspension (RES™) using a small sample of the patient's skin. RES™ is an autologous suspension comprising the cells necessary to regenerate natural, healthy skin. RES™ has a broad range of applications and can be used to restart healing in unresponsive wounds, to repair burns using less donor skin, yet with improved functional and aesthetic outcomes, and to restore pigmentation and improve cosmesis of damaged skin.

ABOUT AVITA MEDICAL LIMITED

Avita Medical develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's lead product, ReCell®, is used in the treatment of a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell® is patented, CE-marked for Europe, 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, and a pivotal U.S. approval trial is underway. 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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