ASX | News Release

U.S. FDA Approves Increased Compassionate Use Patient Cases and Sites for ReCell® in Life-Threatening Injuries

Now allows up to 68 patients to be treated at 18 US burns centers

Valencia, CA, Perth, Australia and London, United Kingdom, 7 April 2017 — The U.S. Food and Drug Administration has approved a further increase in the number of patients who can be treated in the United States with the ReCell® regenerative medical device under a compassionate use protocol, Avita Medical Ltd. (ASX: AVH), (OTCQX: AVMXY) said today.

The regenerative medicine company, which specializes in the treatment of wounds and skin defects, said the FDA had approved its fourth and largest expansion of its Compassionate Use Investigational Device Exemption (IDE) program for ReCell®, now allowing treatment of up to 68 patients who have insufficient healthy skin available for standard skin grafting treatment of their injury. The FDA also approved an increase to the total number of hospitals that could deploy the protocol from 15 to 18, enabling other hospitals not already involved in the ongoing Continued Access protocol to be introduced to Avita's autologous cell harvesting approach in cases where the patients' treating physicians believe there to be no suitable alternative treatment.

"We are pleased to receive this compassionate use expansion, which we think underscores both the necessity of our product for treating life-threatening burns, and the growing interest within the U.S. burns community," said Avita CEO Adam Kelliher. "We look forward to submitting for premarket approval (PMA) of ReCell in coming weeks with the goal of launching the product, if approved, into the broader burns market in 2018."

The FDA first approved the IDE for up to 12 subjects in life-threatening circumstances in April 2014. Since then, requests have increased from surgeons to access the exemption and treat their patients. In September 2015, the FDA allowed a doubling of the number of patients permitted under the IDE, from 12 to 24 patients. In February of 2016 the FDA approved an increase to the number of patients to 36 and another increase approval was granted again in October 2016 to 48 patients.

To date, 49 compassionate use cases using ReCell® have been conducted at several leading institutions, including Wake Forest Baptist Medical Center, the Arizona Burn Center at Maricopa Medical Center, Walter Reed National Military Medical Center, MedStar Washington Hospital Center, University of California San Diego Health System, Regional Medical Center / University of Tennessee, the U.S. Army Institute for Surgical Research (San Antonio), University of South Alabama, Baton Rouge General Hospital, Riley Hospital for Children (Indianapolis), and Massachusetts General Hospital.

"We are thrilled that the FDA is allowing us to continue to serve severely burned patients through the Compassionate Use program," said Andrew Quick, Avita's Senior VP Clinical Development. "This also

allows us to further build our collaborations with U.S. surgeons as we develop best practices for treatment of burn injuries in front of our planned launch of ReCell next year."

Avita is seeking a Pre-Market Approval (PMA) for its ReCell® device, and its fully enrolled clinical trial has involved seven leading US burns centers. The Company expects to submit its clinical and non-clinical data package in mid-2017, with an anticipated FDA approval in the second calendar quarter of 2018.

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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 and compassionate 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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