ASX | News Release

Avita Medical Announces U.S. FDA Approval for Increase in Compassionate Use of ReCell® Patient Cases

Now allows total of 36 patients for skin regeneration treatment with ReCell®

Northridge, CA and Cambridge, United Kingdom, 7 March 2016 – Avita Medical Ltd. (ASX: AVH), (OTCQX: AVMXY), a regenerative medicine company specializing in the treatment of wounds and skin defects, today announced approval from the U.S. Food and Drug Administration (FDA) for a second expansion of its Compassionate Use Investigational Device Exemption (IDE) program for ReCell®.

This IDE supplement allows Avita Medical to increase the total number of patients allowed for clinical evaluation of ReCell® by 50 percent, bringing the total number of patients from 24 to 36 patients who have insufficient healthy skin available for standard skin grafting of their injury. The IDE allows the application of ReCell® beyond burns and to larger, more serious defects than those studied in the U.S. pivotal trial. Under the compassionate use protocol, investigational use of ReCell® may be granted in cases where the patient's treating physician believes that there is no suitable alternative treatment.

"A second approval from the FDA to expand the number of compassionate use cases in our ReCell® IDE program is another mark of validation for the technology, particularly as we continue our pivotal U.S. trial for ReCell® in burns, for which we recently completed enrollment, " commented Adam Kelliher, CEO of Avita Medical. "This expansion allows for the opportunity to treat even more patients who have no other alternative treatment options with ReCell® for a catalyzed, effective regenerative healing effect that may lead to potentially life-saving outcomes."

The FDA approved the initial IDE for up to 12 subjects with life-threatening wounds in April 2014. Under the original IDE, 12 compassionate use cases using ReCell® have been conducted with success at several leading institutions, including Wake Forest Baptist Medical Center, Maricopa Medical Center, Walter Reed National Military Medical Center and MedStar Washington Hospital Center. In October 2015, the FDA doubled the number of patients permitted to be treated under the IDE, from 12 to 24 patients. To date, 23 patients have been enrolled in the IDE program and treated successfully with ReCell® at additional leading institutions, including University of California San Diego Health System and Regional Medical Center / University of Tennessee.

Individual and case series results have been presented to the international medical community at various professional meetings over the past two years, such as the Southern Region Burn Conference, the 17th Biennial Congress of the International Society for Burn Injuries, the 47th Annual Meeting of the American Burn Association, Avita's Skin Regeneration Symposium, the Military Health System Research Symposium, and the Tissue Engineering and Regenerative Medicine International Society World Congress.

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 and wound healing factors 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. A pivotal U.S. trial is underway, with patient enrollment completion anticipated by the end of 2015. To learn more, visit www.avitamedical.com.

###

FOR FURTHER INFORMATION

Avita Medical Ltd
Adam Kelliher
Chief Executive Officer
Phone: +44 (0) 1763 269 770
akelliher@avitamedical.com

Avita Medical Ltd
Tim Rooney
Chief Financial Officer
Phone: + 1 (818) 356-9400
trooney@avitamedical.com

Avita Medical Ltd
Gabriel Chiappini
Company Secretary
Phone +61(0) 8 9474 7738
gabriel@laurus.net.au

UK/EU
Instinctif Partners
Gemma Howe/Sue Charles
Phone +44 (0)20 7866 7860
avitamedical@instinctif.com

USA
The Ruth Group
Lee Roth, Investor Relations
Kirsten Thomas
Phone: +1 (646) 536-7012 /
+1 (508) 280-6592
lroth@theruthgroup.com
/ kthomas@theruthgroup.com

Australia
Monsoon Communications
Dean Felton
Investor Relations / PR
Phone: +61 3 9620 3333
rudim@monsoon.com.au