Avita Medical Completes Patient Recruitment for its FDA Approval Study Evaluating Use of ReCell® in Acute Burns

- *Represents a major Company milestone toward US approval and commercialisation*
- *Solidifies timeline for collection of pivotal clinical data required for FDA PreMarket Approval (PMA)*
- *Company on track for readout on primary effectiveness data by end of calendar Q1*

Northridge, CA, USA and Cambridge, United Kingdom, 11 January 2016 — Avita Medical Ltd. (ASX: AVH), (OTCQX: AVMXY), a regenerative medicine Company specializing in the treatment of wounds and skin defects, today announced that patient recruitment is complete for its U.S. Food and Drug Administration (FDA) approval study evaluating the use of ReCell® in combination with meshed autografting for the treatment of partial-thickness and full-thickness acute burns.

The recruitment of the last patient in this pivotal trial is a significant milestone and follows the announcement in December that the FDA granted the ReCell® Autologous Cell Harvesting Device an Expedited Access Pathway (EAP) designation. The Company anticipates that the priority review afforded by the EAP designation will have a positive effect on the approval timeline for ReCell®.

The primary objective of the trial is to demonstrate the safe and effective use of ReCell® to achieve definitive wound closure (healing) with a reduced requirement for donor skin harvesting. The trial's secondary objective is to show improved functional and aesthetic outcomes. Using less donor skin allows surgeons to achieve definitive closure in fewer surgical procedures, corresponding with a decreased length of hospital stay and less pain management, particularly for extensive burns. Better long-term functional and aesthetic outcomes result in a reduced need for follow-on procedures to address issues associated with scarring.

Recruitment completion means the Company is fully on track to collect the more challenging effectiveness data required for this 30-patient trial. Once treated, each patient follows a prescribed schedule of follow-up evaluations over the course of 52 weeks. Healing is evaluated during the first 10 weeks after treatment, so primary effectiveness data for healing are anticipated by the end of calendar Q1 2016. The secondary effectiveness endpoints are evaluated for each patient 24 weeks after treatment. Durability of wound healing will be monitored for the full 52 weeks after treatment.

Andrew Quick, Avita's Vice President of Research & Technology, said, "Our clinical development strategy is to drive mainstream adoption of ReCell® for burn surgery. We were able to find the right cohort for this study within the planned timeframe, which is particularly difficult for acute wounds such as burns. We have

recruited a complete cohort of subjects that meet the selection criteria and consented to participate for the duration of the trial. This means that our data collection completion and analysis are all on track."

Mr. Quick continued, "As with many clinical trials, successful recruitment of patients in a burn study is challenging and uncertain. Particularly with burn studies, care is regionalized and patients' homes may be a great distance from the burn center. Burn patients also often experience other challenges in their lives that can interfere with their ability to comply with the study's schedule of return visits to the burn center for follow-up evaluations. The research teams must be accordingly selective in determining whether a potential patient can meet the requirements for study participation. The timely completion of recruitment for this study is a reflection of the diligent efforts of the research teams at the burn centers involved and we thank them for their thoroughness."

Burn centers involved in the trial are Wake Forest Baptist University Medical Center Burn Center in Winston-Salem, North Carolina, the Burn Center at MedStar Washington Hospital Center in Washington, D.C., the Army Institute for Surgical Research in San Antonio, Texas, the Firefighter's Burn Center at Regional Medical Center in Memphis, Tennessee, the Arizona Burn Center at Maricopa Medical Center in Phoenix, Arizona, the North Carolina Jaycee Burn Center at University of North Carolina Health Care in Chapel Hill, and the Regional Burn Center at Tampa General Hospital and University of South Florida in Tampa, Florida.

In tandem, Avita Medical is in discussion with the FDA regarding the accelerated timelines under the EAP guidance, which is aimed at helping patients to get more timely access to life-saving medical devices while preserving the statutory standards of safety and effectiveness for Premarket Approval (PMA). The device has been granted an EAP designation, as "the device may offer significant, clinically meaningful advantages over existing legally marketed alternatives" said the FDA. The Company had originally estimated that regulatory approval would come in calendar Q3 17.

"We believe that ReCell® is a unique offering for healing burns victims, and we welcome the opportunity for submission and approval in the U.S. as soon as possible," said Adam Kelliher, CEO of Avita Medical.

Whilst in the U.S. ReCell® requires PMA and is thus an investigational device, it is already available for commercial use in a number of countries: ReCell® is CE-marked for Europe, TGA-registered in Australia, and CFDA-cleared in China.

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, pending the approval trial, ReCell® is an investigational device limited by federal law to investigational use. To learn more, visit www.avitamedical.com.

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