Avita Medical Announces Positive Results from Randomized, Multicentre EU Study of ReGenerCell™ for Treatment of Chronic Venous Leg Ulcers

- Statistically significant improvements shown in wound size, pain and health-related quality of life
- Positive trends both in healing time and incidence of closure, particularly in large ulcers (over 10cm^2) which comprise the majority of VLUs
- Strong results support progression to a pivotal trial
- More than 12 million sufferers could benefit from this regenerative medicine approach

Northridge, CA, Perth, Australia and Cambridge, United Kingdom, 9 March 2016 — Avita Medical Ltd, (ASX: AVH), (OTCQX: AVMXY), a regenerative medicine company specialising in new treatments for wounds and skin defects today reported positive results from the Company's multicentre clinical trial of ReGenerCell™ in the treatment of chronic Venous Leg Ulcers (VLUs). In the seven-centre, 52-patient randomized study, ReGenerCell demonstrated statistically significant improvements in key measures of wound healing, pain and quality of life.

The study data show significant decreases in wound size from the time of treatment to the end of the 14-week study, with wounds in the ReGenerCell™ group closing an average of 9.1 cm^2, versus 1.2 cm^2 for the Control group (p=0.014). Treatment using ReGenerCell™ definitively places the wounds on a healing trajectory.

The study compared the addition of Regenerative Epithelial Suspension (RES™), produced using the Company's ReGenerCell™ medical device, to conventional medical therapy alone in 52 adult patients with VLUs evaluated at six centres in the UK and one in France. The Company said the positive results indicate that the cellular suspension delivered by ReGenerCell™ shows great promise as an effective treatment for healing chronic wounds that have resisted other approaches in this sizable area of unmet medical need, and that a statistically-powered pivotal trial is now justified.

In addition to significant decreases in wound size, patients in the ReGenerCell™ group reported significant drops of nearly 2 points on a 10-point pain rating scale two weeks after treatment (p=0.017), as compared to the control group, which showed no decrease in pain after two weeks. As a quality of life measure, the Charing Cross Venous Leg Ulcer Questionnaire showed consistent improvements in the evaluated areas of social interaction, domestic activity, emotional status and cosmesis, and again, despite the small sample size, statistical significance was shown on the emotional status portion of the questionnaire (p=0.044).

There was no difference in the adverse event rate observed in the ReGenerCell™ and Control groups, and all adverse events experienced were consistent with those seen in similar patient populations. This aligns well with the already-established low risk profile associated with the Company's autologous skin cell harvesting approach.

The positive results bolster the Company's strategy of extending its regenerative medicine device beyond its traditional market of burns, into much larger medical indications. In the UK, 1.65% of the population aged over 65 have VLUs, costing the NHS more than £1bn pa (A$1.92bn), chiefly in ongoing home visits for dressing changes of treatment-resistant ulcers. The condition is on the increase in the OECD nations as the population ages, and Avita sees a potential market size of more than 12m people in the current main markets in which it is operating, including some 3.2m sufferers in the US.

While not achieving statistical significance, other study measures showed positive trends. The incidence of complete wound closure was 26.9% in the ReGenerCell™ group, versus 15.4% in the Control group. Larger ulcers (>10 to ≤80 cm^2) showed a closure incidence of more than triple in the ReGenerCell™ group, which achieved complete closure in 23.1% of patients, versus 7.1% in the Control group. Larger ulcers appeared to heal in nearly half the time, with first closure of large ulcers happening in a mean time of 43 days with ReGenerCell™, versus 84 days in the Control group.

"VLUs tend to be a hidden epidemic, because patients are largely immobile and unseen in their homes," said Andrew Quick, Avita's Vice President of Research and Technology. "We believe this positive data demonstrates that our treatment approach could become a frontline therapy, if we find in a wider population that we can reduce patient pain, improve their life quality, and of course, heal them."

Mr. Paul Hayes, lead principal investigator and Consultant Vascular Surgeon at Addenbrookes Hospital in Cambridge, UK stated, "Chronic VLUs have a huge impact on patient's quality of life, as well as the economic burden to health services. I'm delighted that ReGenercell™ has shown a significant benefit for our patients in terms of quality of life and ulcer healing."

Mr. Hayes will present further analysis of the data at the upcoming Charing Cross International Symposium in London (26-29 April), where presentations will focus on vascular and endovascular challenges. Study results have also been accepted for presentation by Mr Hayes at the European Wound Management Association conference in Bremen, Germany, to be held in May.

The Company said the pilot trial had succeeded in delivering data on appropriate treatment directions, and it now plans to incorporate these results into discussions with regulatory authorities in the United States and Australia to determine next steps for ReGenerCell™ in pursuing an indication for treatment of venous leg ulcers. The benefits for health economics would be a key part of this dialogue, the Company said.

"Our favorable results in larger ulcers, notably halving the healing time, means our approach could really help those with the hardest wounds to heal, and reduce costs at a time of health budget challenges," said Avita CEO, Adam Kelliher. "The positive effects seen across the treated group are very encouraging, given the complexity and challenge presented by chronic venous leg ulcers."

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 regenerative product portfolio includes ReCell® for burns & plastic reconstructive procedures, ReGenerCell® for chronic wounds and ReNovaCell® of restoration of pigmentation and cosmesis. ReCell®, ReGenerCell® and ReNovaCell® are patented, CE-marked for Europe. 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, and a pivotal U.S. trial is well underway aimed at securing FDA approval.

To learn more, visit www.avitamedical.com.

AVITA'S REGENERATIVE TECHNOLOGY AND RES™

Avita Medical's unique proprietary technology enables a clinician to rapidly create, at the 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.

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mailto:

Avita Medical Ltd
Adam Kelliher
Chief Executive Officer
Phone: +44 (0) 1763 269770
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, Public Relations
Phone: +1 (646) 536-7012 / +1 (508) 280-6592
lroth@theruthgroup.com
/
kthomas@theruthgroup.com

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