United States Food and Drug Administration Grants an Investigational Device Exemption for Compassionate Use of ReCell

Highlights

- The IDE granted by the US FDA allows ReCell to be evaluated clinically as an investigational device in subjects with life-threatening conditions requiring extensive skin grafting
- ReCell will be used to augment skin grafting for patients who have insufficient healthy skin for conventional autografting
- Expands application of ReCell beyond burns and to larger, more serious defects than currently being studied in the US

Australia, 10 April 2014 — Regenerative medicine company Avita Medical Limited "Avita Medical" (ASX:AVH), (OTCQX:AVMXY) is pleased to advise that it has been granted Investigational Device Exemption (IDE) for the compassionate use of ReCell® 'Spray-on Skin®' by the United States Food and Drug Administration (FDA) to evaluate clinical performance in a number of specific cases.

The IDE allows Avita Medical to conduct clinical evaluation of ReCell on up to 12 subjects who have life-threatening wounds (due to burn, trauma or congenital anomaly, as examples) and insufficient healthy skin to harvest for necessary skin grafts. Investigational use of ReCell in these patients may be granted in cases where the treating physician believes that there is no suitable treatment alternative.

Avita Medical Interim Chief Executive Officer Tim Rooney explained that several requests by US physicians had been made for access to ReCell for patients with life-threatening injuries. On a case-by-case basis since October of 2013, the FDA granted compassionate use approvals at the Arizona Burn Center, Walter Reed National Military Medical Center and Wake Forest Baptist Medical Center. This new IDE approval puts Avita in position to manage, within FDA guidelines, the compassionate use of ReCell in the US in a limited number of patients meeting defined criteria.

For each of the compassionate use cases, ReCell cell suspension will be used in combination with widely meshed skin grafts to allow greater coverage by the grafts while using less donor skin area. This is critical for people with limited areas of appropriate, undamaged skin to be used for graft harvesting. Also within the compassionate cases, ReCell may be applied to the donor sites in preparation for potential re-harvesting as needed to complete the patients' wound care.

The new IDE does not impact the ongoing clinical trial of ReCell for second-degree burns in the United States.

As a result of the IDE, FDA review and approval of each treatment case presented will not be required and physicians who have a patient they believe will benefit from the use of ReCell will contact Avita Medical and seek approval from their Institutional (Ethics) Review Board.

ReCell is used to disaggregate cells from a patient's skin sample and to collect those cells into suspension for reintroduction to the patient. Avita Medical is focused on providing innovative and cost-effective solutions to customers while addressing key medical and commercial requirements of patients, clinicians and healthcare systems.

ABOUT AVITA MEDICAL LIMITED

Avita Medical (http://www.avitamedical.com/) develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary tissue-culture, collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's lead product, ReCell® Spray-On Skin®, is used in a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell is patented, CE-marked for Europe, TGA-registered in Australia, and SFDA-cleared in China. ReCell is not available for sale in the United States; in the United States, ReCell is an investigational device limited by federal law to investigational use. A Phase III FDA trial is in process.

# # #

FOR FURTHER INFORMATION:

Avita Medical Ltd.
Ian Macpherson
Chairman
Phone: +61 (0) 8 9474 7738
Email: imacpherson@avitamedical.com

Avita Medical Ltd.
Tim Rooney
Interim Chief Executive Officer/Chief Financial Officer
Phone: + 1 (818) 827-1695
Email: trooney@avitamedical.com