Avita Medical secures US FDA approval to modify ReCell® clinical burns trial

Highlights

- The US FDA has approved Avita's request for expanded use of ReCell® and broadened eligibility criteria for study participants
- The broadened eligibility criteria are anticipated to resolve ongoing delays with recruitment, and simultaneously position ReCell for a wider commercial opportunity
- The revised eligibility criteria allow for treatment of more extensive and severe (deeper) burn injuries, and include participation of children as young as five years of age
- Approved changes to the study put ReCell onto a predictable timeline to regulatory approval for broad use of ReCell in the US burns market

Australia, 16 September 2014 — Regenerative medicine company Avita Medical Limited "Avita" (ASX:AVH) (OTCQX:AVMXY) is excited to announce that it has secured US Food and Drug Administration (FDA) approval for extensive changes to the US clinical trial of ReCell®, making the trial more accessible to study participants and broadening the scope of use of ReCell to improve market penetration post regulatory approval.

After a period of positive dialogue initiated by Avita Medical, the US FDA informed Avita that it has approved, without conditions, the Company's application to broaden the intended clinical indication of ReCell, and to expand patient eligibility. The revised clinical program takes advantage of US clinical experience to date within both the burns trial and FDA-approved compassionate use cases, allowing for evaluation of ReCell as a complementary treatment to expanded meshed skin grafting in a small confirmatory cohort of 25 patients.

The major changes to the trial reflect the Company's renewed focus on commercialisation efforts.

Avita Medical Chairman Lou Panaccio said: "The changes to the US burns trial initiated by Avita are a significant leap forward for the Company and will provide better trial outcomes to enhance future commercial opportunities for ReCell."

The unique role of ReCell in burn care is to improve clinical outcomes for burn patients primarily by substantially reducing the amount of healthy donor skin that is harvested during surgical grafting procedures to treat burn injuries.

The trial to date had been designed to demonstrate the superior expansion of donor skin achieved with ReCell by comparing the use of the autologous cell suspension created with ReCell to conventional mesh graft treatment. The trial protocol specified an age range limited to 18-65 years, total body surface area (TBSA) injured under 20%, and treatment of only specific ("deep" partial-thickness) second-degree burns.

The newly-approved changes allow an age range of five years and older with up to 50% TBSA burns. Further, the complementary use of ReCell in combination with expanded mesh grafts allows the product to be part of the treatment of injuries for which skin grafting is required, regardless of depth. This technique has become the clinical standard in Western Australia, and is also how US surgeons have used ReCell for individual FDA-approved compassionate use cases.

The prior study design was motivated to ensure limited confounding factors by enforcing narrow, homogeneous selection of study participants. The unintended effect was great difficulty in recruitment, and burn patients who had the most to benefit from a reduction in requirement for graft donor skin were precluded from participation. Harvesting donor skin is painful and the availability of healthy skin to harvest is limited, most especially for paediatric cases and for patients of any age suffering from extensive burns.

Avita VP of Research and Technology Andrew Quick said the US FDA approval of the trial modifications would improve patient enrolment rates, which frequently had been less than one subject per month and had stalled Avita's regulatory progress in the US burns market.

"The limitation caused by the previous restrictive trial criteria was a frustrating impediment to gaining ultimate approval to use ReCell in the burns segment of the US market," Mr Quick said.

"The revised trial criteria remove that impediment, resulting in a clearer and timelier path to market, and the opportunity to highlight the clinical benefits of using ReCell for a greater range of patients.

"We have every confidence that ReCell, when used to complement expanded mesh grafting, will demonstrate statistically superior patient outcomes versus mesh grafts alone. This aligns directly with the revised positioning Avita has initiated in burns for the primary benefit of the reduction in the size of donor sites required by skin grafting procedures. Donor sites expose patients to substantial pain and risk of infection. This advancement in burn care benefits both patients and the healthcare systems supporting them.

"The increase to the allowed TBSA broadens the population who can participate, but more importantly will serve to highlight the benefit of reduced donor area in the larger burns."

Avita expects to begin enrolling a new cohort of 25 patients into the modified trial in early 2015, with enrolment completed by the end of 2015. The study design requires each participant to be followed for 12 months, however Avita may initiate a PMA application prior to all patients completing the 12 month follow-up. The change to include children five years and older in the modified IDE allows the Company to avert the time and cost associated with a separate paediatric trial for product approval in that population.

"After years of frustratingly slow progress, there is now a clear timeframe and path forward to achieve regulatory approval for the use of ReCell in a larger segment of the US burns market than was previously being sought," Mr Quick said.

Avita Interim CEO Tim Rooney said he was pleased with the final outcome and with the collaborative nature of the dialogue that the Company has successfully pursued with the US FDA.

"ReCell can satisfy the unmet need in burn care for the reduction of donor skin harvesting, and the improvements to the patient selection criteria and the type of use in the revised protocol will help Avita demonstrate ReCell's effectiveness and safety," he said. "In addition to supporting a US pre-market approval (PMA) application, this study will support our marketing and reimbursement efforts outside the US."

Avita Chairman Lou Panaccio congratulated the new Avita management on initiating the changes to revive the stalled trial.

"This is an important milestone in Avita's long held desire to gain regulatory clearance to access the US burns market," he said.

"Our clinical team can now direct renewed attention to progressing the revised trial. However, Avita remains focused on the continued commercial development of ReCell in target markets in the aesthetics and chronic wounds segments which represent considerably larger market opportunities."

The trial modification agreement was formalised through FDA approval of a supplemental Investigational Device Exemption (IDE) application, which will ultimately be used to support the Company's PMA application for the ReCell® Autologous Cell Harvesting Device.

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

Avita Medical Ltd.
Lou Panaccio
Chairman
Phone: +61 (0) 8 9474 7738
Email: lpanaccio@avitamedical.com