Avita Medical Announces Last Patient Visit in U.S. Pivotal Trial

March 7, 2018
Highlights

- Clinical data collected from final patient, completing trial
- Company plans PMA submission upon receipt of shelf-life stability data
- PMA decision anticipated during the 2nd calendar quarter of 2018

Valencia, CA, USA, Perth, Australia and Cambridge, United Kingdom, 7 March 2017 —Avita Medical Limited (ASX:AVH; OTCQX:AVMXY), a regenerative medicine company focused on the treatment of wounds and skin defects, has collected long-term follow-up data from the final patient enrolled in its pivotal FDA trial of the ReCell® Autologous Cell Harvesting Device for the treatment of burns, and achieved a key milestone in its U.S. regulatory pathway, the Company said today.

Collection of the last data set at the end of a 52-week follow-up period formally marks the completion of the trial, which commenced in January 2015. The Company now has the necessary clinical data to conduct the analyses needed for a Premarket Approval (PMA) application. PMA approval would give access to the world's largest healthcare market for the Company's ReCell® device, which gives medical professionals the means to rapidly create a suspension of skin cells to facilitate wound healing. Work toward collection of other nonclinical data, including shelf-life stability, continues.

In an update to the market now that PMA timings are more defined, the Company explained that dialog with the FDA via the Expedited Access Pathway (EAP) resulted in communication of updated guidance concerning preparation of materials for shelf-life stability testing, which has impacted the PMA submission timeline by one calendar quarter. Shelf-life (stability) data for ReCell, in compliance with the additional FDA requirements, are scheduled to become available in June 2017, and the Company will file the PMA application soon after. The FDA makes a decision on 90% of submissions requiring Advisory Committee input within 320 days of receipt of an accepted submission, meaning that an FDA decision can be anticipated during the second calendar quarter of 2018. Avita is engaged with the agency on the PMA submission via the EAP, and also has ongoing dialogue surrounding its open Investigational Device Exemptions (IDEs) for Compassionate Use and Continued Access, under which the device can continue to be used during the pre-approval period.

"We would like to thank the patients, the investigators and their staff, for getting us to this point, and now that we have all the clinical data, we can conduct our analyses and confirm what the data tells us about the safety and effectiveness of ReCell®," said Andy Quick, Avita's Senior VP of Clinical Development. "We will now complete this evaluation of the clinical outcomes, so that when we receive the requisite nonclinical information, we will be able to swiftly file the PMA."

A key concern in burn care is the requirement for harvesting healthy donor skin from burn patients to allow for conventional autografting treatment for closure of their burn injuries. Avita's study looks at use of Regenerative Epithelial Suspension™ (RES™) prepared with the ReCell® device when applied to autografts meshed more widely than conventional practices. The randomized trial seeks to establish that use of Avita's regenerative medicine approach can result in better care for burns patients by

minimizing donor skin required while achieving similar healing at the graft site and superior healing at the donor site compared with standard autografting. Use of less donor skin can mean that patients' burn-related injuries are closed earlier. Patients participating in the study were followed for 52 weeks to look at the durability of the healed burn-injury areas and aesthetic outcomes.

A total of 30 patients participated in the trial, conducted at six leading US burn centers. While 15% attrition was planned for, twenty-seven subjects (90%) completed 52-weeks of follow-up. Patients five years of age and older whose burn injuries were sufficiently deep to require autografting and ranged in size from 5% to 50% of their body surface area were included in the study.

"Completion of follow-up visits in our clinical trial represents a significant milestone in our timeline for FDA approval, as obviously there is a lot of potential variability when one is running the treatment period of a trial," said Avita CEO Adam Kelliher. "So it is fair to say that the most challenging part of the process is now behind us."

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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, and a pivotal U.S. approval trial is underway. To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward- looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

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