Avita Medical Announces Positive Results from Pivotal Trial

May 18, 2017

Highlights

- Co-primary endpoints achieved in pivotal trial deploying ReCell® in patients with severe burns
- Positive results also seen in another supportive trial
- Company on-track to file a PMA with the U.S. Food & Drug Administration in mid-2017
- Avita primed to execute on U.S. commercialization strategy as early as Q2 2018

Valencia, CA, USA, Perth, Australia and Cambridge, United Kingdom, 18 May 2017 —Avita Medical Limited (ASX:AVH; OTCQX:AVMXY), a regenerative medicine company focused on the treatment of wounds and skin defects, today said it achieved both co-primary endpoints in its pivotal clinical trial which will soon be submitted for U.S. market approval of its ReCell® device to treat severe burns. The company also released supportive results from a previous burns trial in a dual data release.

These data will be submitted to the US Food and Drug Administration as part of an application to support Premarket Approval (PMA) for the ReCell® Autologous Cell Harvesting device. The Company is now focused on fulfilling requirements for remaining non-clinical data needed for the PMA submission, which is on track for mid-2017. Based on expected timelines, approval could occur by Q2 2018, the Company said.

"The positive results from both clinical trials clearly demonstrate the efficacy of ReCell® for treating burn injuries," said Dr James Holmes, from Wake Forest Medical Center, North Carolina, who led the pivotal trial. "Submission of the PMA, and FDA approval, will be the final steps on a long road to improve burn care. The addition of ReCell® to the U.S. burn surgeon's armamentarium is eagerly awaited and will undoubtedly advance burn care in the U.S."

The 30-patient trial was conducted at seven leading U.S. burn centers between 2015 and early 2017. Co- primary endpoints were designed to demonstrate the effectiveness of ReCell® when combined with widely meshed (expanded) skin grafting in the closure of deep-partial and full-thickness burn injuries.

Within the trial design, treatment was randomly allocated to two separate parts of each patient's burn wound such that a controlled comparison of outcomes could be made for conventional skin grafting versus the combination of ReCell® with a more expanded skin graft. Independent analyses of the study data showed that the co-primary endpoints have both been met.

The first co-primary effectiveness endpoint gauged superiority of donor skin expansion, to resolve whether using ReCell® could lead to less donor skin being needed. This difference in donor skin

expansion with ReCell® was found to be significant ($p<0.001$) and resulted in use of an average of just over 30% less donor skin than the Control and a commensurate reduction in donor site size.

The second co-primary effectiveness endpoint explored the incidence of healing within 8 weeks, which was similar in wounds that received ReCell® compared to those that received control treatment. Healing with ReCell® was found to be statistically non-inferior relative to conventional treatment.

Three secondary endpoints evaluated (1) patient preference of scar outcomes along with (2) patient- and (3) blinded-observer overall opinion ratings using a standardized scar assessment scale and no statistical difference was observed between ReCell® and Control on these measures. The Company said it was encouraged by the equivalent secondary endpoint data because more expanded meshed skin grafts are expected to result in a worse long-term scar outcome, but this was not the case with the adjunctive use of ReCell® with these autografts.

The results of the co-primary endpoints suggest the use of ReCell®, relative to conventional autografting, can result in use of over 30% less donor skin to achieve comparable short-term healing and long-term scar outcomes. This is important for patients dealing with burn injuries, because the harvesting of donor skin adds discomfort and increases the effective size of their injury.

The Biomedical Advanced Research and Development Authority (BARDA) has supported Avita's late- stage clinical development of ReCell® through a USD 61.9m contract. The successful completion of this trial is a major Avita milestone under the BARDA contract supporting the Department of Health and Human Services mission toward burn care preparedness in the response to a mass casualty event.

The other U.S. trial was conducted between 2010 and 2014, and involved 101 burns patients treated under the same Investigational Device Exemption (IDE) as used for the PMA pivotal trial. Participants in this trial were treated under a different protocol that compared the effectiveness of the cell suspension alone, to that of conventional meshed autografting on partial-thickness injuries. These data showed superiority in healing of donor sites used for ReCell®. It also showed superiority of scar outcomes in terms of scar height, in the straight comparison between ReCell® and autografting. The data did not show statistical non-inferiority of burn injury healing using ReCell® compared to standard treatment, although analysis of the group concluded this outcome was due to post-operative care, rather than treatment. The Company said this earlier work could support Avita's PMA submission, by providing additional safety and effectiveness information. Avita received support for this trial from the Armed Forces Institute of Regenerative Medicine (AFIRM) a six-way partnership among the U.S. Army, Navy, Air Force, Veterans Administration, the Defense Health Program and the National Institutes of Health.

"Both studies validate our broader view that this unique regenerative approach will transform the way burns are treated in the U.S., a sector that has been starved of innovation for many years," said Andy Quick, Avita's Senior VP of Clinical Development. "The successful trial data represents years of hard work and commitment from patients and physicians across the U.S., all of whom we would like to thank for their participation. We look forward to

publication of the complete data set in a peer-reviewed journal."

Avita CEO Adam Kelliher agreed, saying; "This significant data readout, from a total of 131 burns patients evaluated under randomized controlled settings, takes us one step further along the approval pathway. The Avita team will now push ahead with completing and submitting the PMA, our next big milestone as we work towards launching ReCell® into the U.S. burns market."

To learn more, visit www.avitamedical.com.

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ABOUT AVITA MEDICAL LIMITED

Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our medical devices work by preparing a Regenerative Epithelial Suspension (RES™), an autologous suspension comprised of the

patients' own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated.

In all countries outside of Europe, our portfolio is marketed under the ReCell® brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics.

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 and compassionate use.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. ReCell® is designed for the treatment of burns and plastic reconstructive procedures; ReGenerCell™ has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCell™ is tailored for aesthetic applications including the restoration of pigmentation.

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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FOR FURTHER INFORMATION"

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