

RECELL® Study in Facial Burns Shows Excellent Cosmetic Outcomes

Two presentations today at American Burn Association Meeting highlight potential of RECELL to improve patient care in difficult-to-treat burns

Valencia, Calif., USA, and Melbourne, Australia, 12 April 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMY) announced today results from a clinical study highlighting the potential benefits of the RECELL® Autologous Cell Harvesting Device in the treatment of deep partial-thickness (second-degree) facial burns. The results showed excellent cosmetic outcomes when RECELL was used on deep partial-thickness facial burns, an injury for which treatment with standard of care often results in dyspigmentation and hypertrophic scarring at the seams of skin grafts. The results were presented by Nicholas Walker, MD, Wake Forest University School of Medicine, North Carolina, at the American Burn Association (ABA) 50th Annual Meeting in Chicago.

RECELL is an investigational medical device in the U.S. that is designed to enable medical professionals to produce, at the point-of-care, a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™) using a small sample of the patient's own skin. The autologous suspension contains cells necessary to regenerate epidermis and provides a new way to achieve permanent closure in burns and other wounds while reducing the amount of skin harvested at the time of surgery. Reduction in donor-site skin requirements has important benefits from both clinical and health economic perspectives.

Deep partial-thickness facial burns present a challenge in reconstructive surgery. Standard of care typically includes excision and allograft followed by split-thickness skin graft. Limitations of the current treatment regimen includes dyspigmentation at the sites of the skin grafts and hypertrophic scarring at the seams of the grafts, resulting in substantial patient dissatisfaction with the outcome. In this study, treatment with RECELL provided equivalent or superior results to current treatments in facial burn care in terms of wound healing, and excellent cosmetic outcomes.

"These preliminary results demonstrate excellent cosmetic outcomes when RECELL was used on deep partial-thickness facial burns," said Joseph A. Molnar, MD, PhD, Wake Forest University School of Medicine, North Carolina, senior author of the presentation. "Patient satisfaction with the cosmetic outcome is critically important for these injuries, and I look forward to further evaluating how and where RECELL can be best utilized to treat patients with facial burns."

The presentation by Dr. Walker, "Initial Experience with Autologous Cell Suspension for Treatment of Partial Thickness Facial Burns," provided a retrospective review of clinical outcomes obtained in the treatment with the RECELL Device of patients with acute deep partial-thickness facial burn injuries under the Compassionate Use Investigational Device program. The Compassionate Use program was approved for patients with life-threatening wounds requiring grafting with no suitable alternative therapy that would be adequate to meet the patient's medical need.

A total of 26 patients were treated at Wake Forest University School of Medicine, North Carolina, under the Compassionate Use program, five of whom had deep partial-thickness facial burns and were evaluated in this study. Patients in the facial burn study ranged from 2 to 40 years of age and had burns covering 35 percent to 62 percent of their total body surface area (TBSA).

Researchers led by Dr. Walker performed a retrospective review of outcomes of the patients in the study, including subjective cosmetic parameters, complications and number of reoperations. Detailed photographic documentation at multiple stages of the treatment procedures, and at multiple points in time post-procedure, were presented.

Jongwon Genevieve Park, MD, PhD, Wake Forest Baptist Medical Center, North Carolina, also presented “Validation and Characterization of an Immediate, One-Stage Technique to Treat Full-Thickness Wounds in Swine,” at the ABA Meeting, detailing the results of a preclinical model demonstrating the potential benefits of RECELL in combination with dermal substitutes in the treatment of full-thickness (third-degree) burns. The results of the study demonstrated that the addition of RECELL to either of two dermal substitutes accelerates epithelialization. Full-thickness burns are sometimes treated in a two-step process in which a dermal substitute is placed first, followed approximately two weeks later by a skin graft. This technique improves scarring but has the disadvantages of the need for multiple operations and the potential for donor site morbidity.

The goal of the preclinical study was to validate in a swine model a technique using RECELL and a dermal substitute to replace dermis and epidermis in a single surgery, and to minimize donor site morbidity. In the study, full-thickness wounds were treated with one of two dermal substitutes, RECELL alone, or RECELL in combination with each of the dermal substitutes. The study suggests that a dermal matrix combined with RECELL could be used as a one-stage procedure in the management of full-thickness burns.

“We are pleased to see researchers evaluate additional ways in which RECELL may potentially be used to treat patients with severe burn injuries,” said Dr. Michael Perry, AVITA Medical’s Chief Executive Officer. “These earlier-stage studies complement the broader body of scientific evidence supporting the benefits of RECELL, including our pivotal clinical trials presented this week, and we look forward to the continued exploration of the benefits of RECELL in high-unmet-need burns.”

The Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the US Department of Health and Human Services has provided funding under Contract No. HHSO100201500028C to support the development of RECELL by AVITA Medical, including the Compassionate Use program included in the presentation today.

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ABOUT AVITA MEDICAL LIMITED

AVITA Medical is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical’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™, an autologous suspension comprised of the patient’s own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This autologous suspension is then sprayed onto the areas of the patient to be treated.

In the United States, the RECELL Device is an investigational device limited by federal law to investigational use. In September 2017, AVITA Medical submitted to the U.S. Food and Drug Administration (FDA) a PreMarket Approval (PMA) application for RECELL for the treatment of burn injuries.

In all countries outside of Europe, our portfolio is marketed under the RECELL Device brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL Device is TGA-registered in Australia, and CFDA-cleared in China.

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

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.

FOR FURTHER INFORMATION:

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