



## AVITA Medical RECELL® Device Pivotal Trial Results in Second-Degree Burns Published in Journal of Burn Care & Research

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*Trial demonstrated statistically significant reduction in donor skin requirements and pain, increased patient satisfaction and improved donor scar outcomes*

**Valencia, Calif., USA, and Melbourne, Australia, 26 June 2018** — AVITA Medical (ASX:[AVH](#), OTCQX: [AVMX](#)) announced today that results from a pivotal clinical trial demonstrating the effectiveness and clinical benefits of the RECELL® Autologous Cell Harvesting Device in the treatment of deep partial-thickness (second-degree) burns were published for the first time in a major peer-reviewed journal, the *Journal of Burn Care & Research*. In the randomized, controlled clinical trial, burn sites treated with the RECELL Device required 97.5 percent less donor skin than burn sites treated with the standard of care, resulting in a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved donor scar outcomes.

"Reducing the amount of donor skin required to achieve complete and definitive burn wound closure opens the possibility for treating extensive and complex burns sooner than the current standard of care," said James H. Holmes IV, MD FACS, Director, WFBMC Burn Center, Professor of Surgery, Wake Forest University School of Medicine, Winston-Salem, North Carolina, first author of the publication. "These findings have potential implications for a paradigm shift in the approach used to achieve rapid and permanent closure of burn injuries. Furthermore, achieving definitive closure using less skin compared with standard autografting may decrease the number of surgical procedures as well as reducing hospital length of stay, thus decreasing the overall costs related to the treatment of burn injuries."

Each year nearly 500,000 Americans suffer acute thermal burns that require medical treatment, resulting in approximately 50,000 hospitalizations and over 3,000 deaths. Although the use of split-thickness skin grafts is considered standard treatment, grafting is associated with significant pain, delayed healing and scarring. Furthermore, in patients with large burn injuries, donor site availability is a limitation for rapid wound closure using traditional skin grafting.

The RECELL Device 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. The clinical trial in second-degree burns highlighted in the *Journal of Burn Care & Research* publication served as one of two pivotal trials used to support AVITA Medical's U.S. Premarket Approval (PMA) application for the treatment of burn injuries.

The *Journal of Burn Care & Research* article, "A Comparative Study of the RECELL Device and Autologous Split-Thickness Meshed Skin Graft in the Treatment of Acute Burn Injuries," describes the controlled trial

conducted in 101 adult patients with thermal, partial-thickness burns covering 1 percent to 20 percent of their total body surface area. Patients served as their own control, and two comparable burn sites were selected for comparative testing on each patient. One burn site was treated with the RECELL Device, while the other burn site was treated with 2:1 meshed autograft.

During the pivotal trial, burn sites treated with the RECELL Device and proper wound care for newly regenerated epidermis achieved definitive closure comparable to the burn sites treated with standard of care. The amount of donor skin required to treat burn sites with the RECELL Device was on average 97.5 percent less than the amount harvested to treat burn sites with the standard of care ( $p < 0.001$ ). Benefits experienced by patients as a result of the significant reduction in donor skin harvested for RECELL treatment included:

- Significantly less donor-site pain ( $p \leq 0.0025$ )
- Significantly higher patient satisfaction with donor-site appearance ( $p \leq 0.0025$ )
- Significantly better donor-site scarring results ( $p \leq 0.0025$ )
- Significantly greater incidence of donor-site healing at two weeks ( $p < 0.001$ )

Funding for the pivotal trial was provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C. Funding was also provided by the U.S. Department of the Army, AFIRM 1 Contract #W81XWH-08-2-0032.

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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. The medical devices work by preparing a REGENERATIVE EPITHELIAL SUSPENSION™, an autologous suspension comprised of the patient's skin cells and wound healing factors necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

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 the RECELL Device 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 Autologous Cell Harvesting 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](http://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:**

##### **OUS Media**

###### **Monsoon Communications**

Sarah Kemter

Phone: +61 (0)3 9620 3333

Mobile: +61 (0)407 162 530

[sarahk@monsoon.com.au](mailto:sarahk@monsoon.com.au)

###### **Investors:**

###### **Westwicke Partners**

Caroline Corner

Phone +1 (415) 202-5678

[caroline.corner@westwicke.com](mailto:caroline.corner@westwicke.com)

##### **US Media**

###### **Syneos Health Public Relations**

David Polk

Phone: +1 (310) 309 1029

Mobile +1 (805) 428 5775

[david.polk@syneoshealth.com](mailto:david.polk@syneoshealth.com)

##### **AVITA Medical Ltd**

Dale A. Sander

Chief Financial Officer Phone +1 (858) 663-6993

[dsander@avitamedical.com](mailto:dsander@avitamedical.com)