



## **AVITA Announces Presentation of RECELL System Effectiveness and Safety at Eastern Great Lakes Burn Conference**

September 26, 2018

*Clinical results demonstrate point-of-care regenerative medicine technology benefits in treatment of second- and third-degree burns using Spray-On Skin™ Cells*

**Valencia, Calif., USA, and Melbourne, Australia, 27 September 2018** — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, today announced that the results from two U.S. pivotal clinical trials demonstrating the effectiveness and clinical benefits of the RECELL® Autologous Cell Harvesting Device (RECELL® System) were presented at the 46th Annual Eastern Great Lakes Burn Conference in Ann Arbor, Michigan. The results were presented by Jeffrey Carter, MD, FACS, Medical Director of University Medical Center New Orleans Burn Center & Associate Professor of Surgery at LSU Health New Orleans School of Medicine.

“The RECELL System technology provides a major advancement for burn care,” said Dr. Carter. “Within these studies we demonstrated comparable healing and scar outcomes to standard of care using significantly less skin. My team is excited to learn of the recent FDA approval and we are looking forward to treating our patients outside of the clinical trials.”

The U.S. Food and Drug Administration (FDA) approved on 20 September 2018 the RECELL System to treat acute thermal burns in patients 18 years and older. The RECELL System uses a small amount of a patient’s own skin to prepare Spray-On Skin™ Cells at the point of care in as little as 30 minutes, providing a new way to treat thermal burns. The two randomized, controlled clinical trials presented by Dr. Carter at the conference were used to support the FDA approval and demonstrated that treatment of acute burn wounds with the RECELL System required substantially less donor skin than required with conventional split-thickness autografts to achieve closure of burn wounds. Reduction in donor skin requirements provides key clinical benefits to patients and significant reductions in the cost of treatment.

In his presentation titled “Establishing the Safety and Effectiveness of RECELL as an Autograft-Sparing Technology for Definitive Closure of Burn Injuries,” Dr. Carter provided an overview of the key shortcomings of the current standard of care, split-thickness autografts. These include the large donor skin requirements, donor site pain and complications, and extended hospitalization and treatment cost. In the first of the pivotal randomized, controlled clinical trial presented by Dr. Carter, use of the RECELL System in the treatment of deep partial-thickness (second-degree) burns demonstrated statistically significant reduction in donor skin requirements (97.5 percent reduction) and pain, increased patient satisfaction and improved donor scar outcomes. In the second pivotal randomized, controlled clinical trial presented, use of the RECELL System in mixed and full-thickness (third-degree) burns met the trial’s co-primary endpoints and demonstrated statistically significant reduction in donor skin requirements (32.0 percent reduction).

The RECELL System is approved to be used at the point of care by licensed healthcare professionals to treat adult patients with acute thermal burn wounds. The RECELL System can be used alone in the treatment of

partial-thickness burns, or in combination with autografting for the treatment of full-thickness burns. A small skin sample is enzymatically and mechanically processed in the RECELL System at the point of care to isolate the skin cells to produce a suspension of Spray-On Skin Cells. The regenerative cell suspension includes keratinocytes, fibroblasts, and melanocytes, which play a critical role in wound healing. The suspension can be sprayed directly on a second degree burn or with an expanded skin graft on a third-degree burn, allowing for broad and even distribution of live cells across the entire wound bed. The RECELL System can be used to prepare enough suspension to treat a wound up to 80 times the size of the donor skin sample, so a skin sample approximately the size of a credit card can be used to treat a wound that covers a patient’s entire back.

Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device for a full description of important safety information including contraindications, warnings and precautions.

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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 EPIDERMAL SUSPENSION™ (RES™), an autologous suspension comprised of the patient’s skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Medical’s first FDA approved product, the RECELL® System, produces Spray-On Skin™ Cells using a small amount of a patient’s own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 7,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings.

In international markets outside of Europe, our portfolio is marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL System 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:**

##### **US Media**

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

Christian Pflaumer Phone +1-212-229-8412

Nicole Beckstrand Phone +1-858-431-9611

[AVITAMedicalTeam@syneoshealth.com](mailto:AVITAMedicalTeam@syneoshealth.com)

##### **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)

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

Dale A. Sander

Chief Financial Officer Phone +1-661-367-9178

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