



## **AVITA Medical Announces Nine RECELL® System Abstracts Accepted for Presentation at American Burn Association (ABA) 51st Annual Meeting**

January 28, 2019

*RECELL System clinical benefits and cost savings featured in 26 presentations at four burn conferences in early 2019*

**Valencia, Calif., USA, and Melbourne, Australia, 29 January 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, today announced that 26 abstracts highlighting the clinical and cost savings benefits of the RECELL® Autologous Cell Harvesting Device (RECELL® System) have been selected for presentation at four burn conferences in early 2019. Nine of the presentations will be made at the largest burn conference, the American Burn Association (ABA) 51st Annual Meeting to be held in Las Vegas April 2-5, 2019, including a Top-Five Abstract presentation in plenary session. Each of the presentations will be made by clinical investigators who will share their experiences and observations treating patients with the RECELL System.

### **NINE PRESENTATIONS AT ABA MEETING**

The nine presentations at the ABA meeting include the clinical results and benefits of the RECELL System in the treatment of burns in specific subgroups of patients and types of burn injuries, including:

- Pediatric patients (selected as a Top-Five Abstract to be presented in plenary session)
- Extensive burn injuries in an adult population (life threatening burns greater than 50 percent total body surface area or TBSA)
- Burn injuries of the hands
- Burn injuries of joints and rehabilitation considerations
- Budget impact of use of the RECELL System versus standard of care in treatment of severe burns at Arizona Burn Center
- Post-operative wound management following treatment with the RECELL System
- Treatment and healing of donor sites with the RECELL System in patient with large TBSA burns
- Case study of 60% TBSA patient with life-threatening burn injuries and limited donor skin
- A summary of ten years of clinical experience using RECELL System in the point-of-care treatment of burn injuries

The U.S. Food and Drug Administration (FDA) approved the RECELL System in September 2018 for the treatment of acute thermal burns in patients 18 years and older. Patients included in seven of the ABA presentations were treated as part of the Compassionate Use and Continued Access Investigational Device Exemption (IDE) programs made available to more than 150 burn patients prior to the FDA approval. Several of the presentations include classes of burns or patients that fall outside of the currently approved U.S. product labeling. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device (<https://recellsystem.com/>) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

"These abstracts build upon and greatly advance the pivotal clinical trial results and health economic data presented at last year's ABA meeting," said Dr. Michael Pery, Avita Medical's Chief Executive Officer. "The presentations to be made this April at the 2019 ABA meeting highlight the positive clinical outcomes that burn surgeons have observed in a broad range of patients and burn types. The clinical results demonstrate that the RECELL System is a major innovation in the treatment of burn patients as evidenced by the prominent featuring of this product candidate at the ABA conference. We appreciate the strong support we have received from the medical professionals and patients participating in these studies and thank them for their efforts in advancing the care of burn patients."

### **NINE ADDITIONAL PRESENTATIONS MADE AT TWO BURN CONFERENCES LAST WEEK**

During the North American Burn Society 37th Annual Conference (NABS) held 20-23 January 2019 in Park City, Utah, eight presentations were made supporting the clinical and economic benefits of the RECELL System. Kevin Foster, MD, MBA, FACS, Arizona Burn Center, made a series of presentations detailing the results from two U.S. pivotal clinical trials which demonstrated the effectiveness, safety and clinical benefits of the RECELL System, and which were used as the primary basis for the FDA approval. Dr. Foster also presented a case study of the successful treatment with the RECELL System of a patient with a large soft-tissue defect caused by necrotizing fasciitis, or flesh-eating bacteria. Other presentations at the NABS conference included:

- An overview of the protocols for two randomized controlled U.S. trials of the RECELL System in the treatment of pediatric patients

- A case study of the successful treatment of a 60% TBSA burn patient with the RECELL System in combination with a biodegradable temporizing matrix

At the LA-ACS/SAL Annual Meeting held 18-20 January 2019 in New Orleans, Louisiana, Blake Platt, MD, University Medical Center New Orleans Burn Center and LSU Health New Orleans School of Medicine, presented data demonstrating a reduction in length of stay for burn patients treated with the RECELL System. Dr. Platt presented the results of 18 patients treated in the Compassionate Use and Continued Access programs who had a mean length of stay of 24 days compared to the expected mean length of stay of 55 days based on data from the American Burn Association National Burn Repository, a greater than 50 percent reduction.

## EIGHT PRESENTATIONS AT UPCOMING JOHN A BOSWICK BURN & WOUND SYMPOSIUM

An additional eight presentations have been accepted for presentation at the John A Boswick Burn & Wound Symposium to be held 2-7 February 2019 in Maui. These describe the clinical and cost savings benefits of treatment with the RECELL System, and the presentations include:

- Pivotal trials in 2nd and 3rd degree burns
- Health economic model demonstrating cost savings benefit of the RECELL System
- Treatment with the RECELL System combined with dermal substitutes

## ABOUT THE RECELL SYSTEM

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. 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 an adult patient's entire back. Randomized, controlled trials have demonstrated that treatment of acute burn wounds with the RECELL System requires 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.

Funding and technical support for the development of the RECELL System 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. Programs discussed above which were funded under the BARDA contract include the two randomized, controlled pivotal clinical trials, the Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients.

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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 U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL System is indicated for use in the treatment of acute thermal burns in patients 18 years and older. The RECELL System is used to prepare 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 products are 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, CFDA-cleared in China, and received CE-mark approval in Europe.

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.*

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