



## **AVITA Medical Announces Presentation at ABA Meeting Highlighting Results of Study Using RECELL® System to Treat Third-Degree Burns in Pediatric Patients**

April 8, 2019

*Professor Fiona Wood, co-inventor of the RECELL System, described her experience treating more than 3,500 patients using RECELL and resulting benefits including reduced time to healing and decreased length of hospitalization*

*The publication of the RECELL System pivotal trial in the treatment of second-degree burns was selected as a top journal publication for 2018*

**Valencia, Calif., USA, and Melbourne, Australia, 8 April 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY) a global regenerative medicine company, announced that interim results describing clinical outcomes for pediatric patients treated using the RECELL® System were presented at the American Burn Association (ABA) 51st Annual Meeting in Las Vegas by Jeffrey Carter, MD, FACS University Medical Center New Orleans Burn Center and LSU Health New Orleans School of Medicine. Patients enrolled in the Investigational Device Exemption (IDE) Compassionate Use and Continued Access studies had mixed-depth and full-thickness

(third-degree) burns and were treated with the combination of Spray-On Skin™ Cells prepared using the RECELL system and widely meshed autografts. Patients in the studies experienced excellent healing outcomes, with 98% of wounds healed four weeks after treatment. Dr. Carter's presentation describing the treatment of pediatric patients was selected as a "Best of the Best Abstract" out of more than 500 abstract submissions to the ABA meeting.

Another one of the ten presentations related to the RECELL System at the ABA meeting was a long-term review of patient outcomes by the co-inventor of the technology, Professor Fiona Wood, AM, Burns Service of Western Australia, Fiona Stanley and Perth Children's Hospitals. Professor Wood described her experience treating more than 3,500 patients with burns and other cutaneous injuries. In addition, the 2018 publication of the RECELL System pivotal trial in second-degree burns in the *Journal of Burn Care & Research* was recognized during the "The Year in Review: The Top Journal Publications" session of the ABA meeting.

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 RECELL System was approved by the U.S. Food and Drug Administration (FDA) in September 2018 for the treatment of acute thermal burns in patients 18 years and older. The pediatric presentation includes a class of 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.

### **Best of the Best Abstract – Pediatric Burn Care**

Dr. Carter presented data showing that 98% of mixed-depth/full-thickness burn Injuries in pediatric patients treated using Spray-On Skin Cells in combination with widely spaced meshed autografts were healed within four weeks of treatment. The presentation titled "Evaluation of a Pediatric Population Treated for Burn Injuries Using an Autologous Skin Cell Suspension: Interim Analysis" described the interim outcomes for 23 pediatric patients with a median age of 6.7 years old (ranging from 0.8 to 16.0) treated under FDA-IDE approved Compassionate Use and Continued Access programs. In patients with extensive burn injuries, lack of available donor skin is a major limitation achieving permanent closure, and the longer a wound remains open the more susceptible a patient is to infection. In the U.S., one-third of burn injuries occur in children, and the availability of donor skin for traditional meshed autografts is even more limited in pediatric patients with extensive injuries. The use of the RECELL System, a donor skin sparing technology that enables rapid definitive closure of burn wounds, has the potential to improve patient outcomes.

In this study of pediatric patients which included those with life-threatening thermal burn injuries, Spray-On Skin Cells prepared using the RECELL System were applied in combination with widely meshed split- thickness autografts to achieve definitive closure using minimal donor skin. A total of 107 burn injuries were treated in the study, and 98% achieved definitive healing within four weeks of treatment. Importantly, for patients with greater than 50% total body surface area (TBSA) burns, treatment with the combination of Spray-On Skin Cells and widely meshed split-thickness autografts achieved the same high rate of healing at week four as patients with smaller burns (burns equal to or less than 50% TBSA) treated with the same combination. In addition, in the study the donor sites on all patients were treated with Spray-On Skin Cells, and 62.5% of the donor sites were healed within a week of treatment, and 100% were completely healed within two weeks of treatment.

"This interim analysis supports the use of the RECELL System as a viable option for treatment in these deeper burn injuries in pediatric patients," said Jeffrey Carter, MD, FACS University Medical Center New Orleans Burn Center and LSU Health New Orleans School of Medicine. "In this vulnerable patient population, we observed excellent clinical outcomes with 98% of wounds healing within four weeks of treatment, and with the majority of burn sites having cosmetic outcomes rated as satisfactory or equivalent compared to uninjured skin. The early healing of donor sites contributed to a decrease between harvest times for patients with limited donor skin availability."

### **Co-Inventor of the RECELL System Describes More than Ten years of Experience with the RECELL System**

Professor Wood described her long-term experience treating more than 3,500 patients using the RECELL System in a presentation titled "10 years of clinical experience using point of care non cultured autologous skin cell suspension harvested using the RECELL System." Professor Wood, the co-inventor of the technology forming the basis for the RECELL System, provided an analysis of the long-term impact of the integration of the RECELL System as the standard of care in a health system providing burn care to a population of 2.6 million in Western Australia. For more than a decade the

RECELL System was used in the treatment of more than 3,500 patients, 90% of which had acute burn injuries, 9% were treated for scar revision, and 1% had other wounds. More than 700 of these patients were pediatric patients, with approximately 50% suffering scald injuries.

“Our use of cell-based therapies which ultimately evolved into the RECELL System was driven by our desire to reduce the time to healing and improve the outcomes for our burn patients. The quality of life must be worth the pain of survival,” said Professor Fiona Wood, AM, Burns Service of Western Australia, Fiona Stanley and Perth Children’s Hospitals. “Treatment using the RECELL System was associated with a reduction

in the number of surgical procedures, earlier intervention, and reduction in time to healing and length of stay. The RECELL System facilitated early intervention and wound healing as a solo treatment in partial- thickness injuries, and in combination with traditional techniques in deeper injuries with limited donor sites. Using a cumulative outcome index, intervention within one week of injury was associated with significantly improved outcome at three months which was maintained at one-year post injury.”

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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 Spray-On Skin™ Cells, 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 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. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device (<https://avitamedical.com>) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

Funding and technical support for the development of the RECELL System is 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 funded under the BARDA contract include 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.

In international markets, AVITA Medical’s products are marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, acute wounds, scars and vitiligo. The RECELL System is TGA-registered in Australia and CFDA-cleared in China.

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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