



## AVITA Medical Announces U.S. National Market Launch of RECELL® System

January 7, 2019

*Strong market response to the RECELL System approval in advance of U.S. launch with 36 burn centers actively reviewing the product or placing commercial orders*

**Valencia, Calif., USA, and Melbourne, Australia, 8 January 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, today announced that it has commenced the U.S. national market launch of the RECELL® Autologous Cell Harvesting Device (RECELL® System) for the treatment of acute thermal burns in patients 18 years and older. The U.S. sales team of Regenerative Tissue Specialists and Clinical Training Specialists that joined AVITA Medical in November 2018 has been trained and fully deployed across the U.S. in support of the nationwide launch of the RECELL System.

In advance of the national launch, AVITA Medical has been actively fulfilling orders in response to strong market demand. Clinical evidence, years of successful patient outcomes and favorable health economic results have created ideal market conditions for the RECELL System. AVITA's new commercial team is now in active discussions with nearly half of the total number of burn centers across the U.S. The Company also announced the successful commercial results that have been achieved in advance of the national market launch:

- 36 burn centers have begun the purchase authorization process with their hospital
- 25 burn centers have been trained and certified in the use of the RECELL
- 12 accounts have already placed orders and have received commercial

"We are pleased that in advance of our market launch and without any direct promotional effort the clinical and economic benefits of the RECELL System have generated strong interest and sales orders," said Erin Liberto, Chief Commercial Officer. "Based on the pre-promotion demand, we are excited to see the response now that our full sales team of 20 has been deployed."

AVITA Medical's U.S. commercial team brings extensive surgical and operating room experience to support the RECELL market adoption. Each member of the sales team has burn care experience with an average of 16 years of experience in the field, and 100 percent of the team members have previously launched a new product. The team's Clinical Training Specialists are all credentialed clinicians with first-hand burn experience, and the Regenerative Tissue Specialists are adept at effectively navigating hospital approval processes. With the continued scientific and clinical support of a distinguished Medical Affairs staff, the AVITA team is well positioned to drive the market success of the RECELL System.

"I could not be more pleased with the quality of individuals and the collective focus they have all devoted to the RECELL System launch," said Terry Bromley, Vice President of Commercial Operations. "We are very delighted with the enthusiasm our highly experienced sales team has expressed for the RECELL System, and how quickly this team of professionals has prepared for the U.S. launch."

Key commercial achievements after the U.S. Food and Drug Administration (FDA) approved the RECELL System in September 2018 include:

- American Burn Association (ABA) issued reimbursement coding guidelines within one week of approval.
- Commercial product availability within two weeks of
- First commercial sale within two days of product
- Entire U.S. sales team in place within eight weeks of
- National sales launch commenced in January

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

### 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.

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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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