



## AVITA Medical Announces First U.S. Sales of RECELL® System and Commencement of Commercial Shipping

October 17, 2018

*Multiple U.S. burn centers incorporating RECELL System into their practices in advance of national U.S. market launch*

**Valencia, Calif., USA, and Melbourne, Australia, 18 October 2018** — AVITA Medical (ASX:AVH, OTCQX: [AVMXY](#)), a global regenerative medicine company, today announced that it has received the first commercial sales orders from U.S. burn centers for the RECELL® Autologous Cell Harvesting Device (RECELL® System) and has commenced commercial shipment of the product. 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.

"We are pleased to have fulfilled multiple orders for the RECELL System in such a short period of time following FDA approval and in advance of our national U.S. market launch," said Erin Liberto, Chief Commercial Officer. "Our immediate commercial focus is completing the recruitment and training of our

U.S. field force. However, we are in a unique position as many large burn centers already have substantial experience using our product through our clinical trials and Compassionate Use and Continued Access Programs. Moreover, some burn centers have indicated their desire to adopt the RECELL System in advance of our national market launch. In general, we expect most burn centers will adhere to the standard process for novel devices of initially evaluating the product and thereafter advancing it through their Hospital's Value Analysis Committee prior to purchasing for regular use. This process can sometimes be a lengthy one and may take 6 months or more to complete. That said, we are excited to see some of the larger burn centers accelerate this process and commence incorporating the RECELL System into their practice."

Of the 134 burn centers in the U.S., 24 already have experience using the RECELL System through participation in clinical trials and the Compassionate Use and Continued Access programs. Notably, these 24 burn centers are estimated to treat over 30 percent of the U.S. burn patients annually.

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

The two randomized, controlled clinical trials used to support the FDA approval 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.

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.*

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