

## **AVITA Medical Announces Commencement of Randomized Controlled Clinical Study of RECELL® System in Treatment of Children with Burn Injuries**

*Clinical study is being conducted in Brisbane, Australia in collaboration with the Queensland University of Technology and Lady Cilento Children's Hospital*

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**Valencia, Calif., USA, and Melbourne, Australia, 25 October 2018** — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, today announced that the commencement of a randomized, controlled clinical study of the RECELL® Autologous Cell Harvesting Device (RECELL® System) in the treatment of significant superficial partial- and mid-thickness pediatric burns, including scald injuries. The clinical trial is being conducted by the Queensland University of Technology (QUT) in collaboration with the Pegg Leditschke Children's Burns Centre at Lady Cilento Children's Hospital in Brisbane, QLD. Treatment of children in the trial has commenced. The pediatric clinical trial is being led Dr Bronwyn Griffin, Child Health Research Centre, QUT, and Professor Roy Kimble, Roy M Kimble, Lady Cilento Children's Hospital · Department of Paediatric Surgery.

The protocol for the clinical trial was presented last week at the Australian & New Zealand Burn Association Annual Scientific Meeting in Brisbane by Dr. Anjana Bairagi, Honorary Research Fellow ( Paediatric Surgery ) at the Children's Burns Centre at Lady Cilento Children's Hospital. The current standard of care for children with partial-thickness burns is cleaning of the wound followed by a dressing application. Limitations of the standard of care include delay in healing of the burn injury, scarring, and pain. The clinical trial will include approximately 90 patients under 18 years old. Patients will be randomized into one of three groups and will be treated either with the RECELL System and Biobrane® dressing, the Biobrane dressing alone, or standard care (silver impregnated silicone lined dressing). The primary endpoint will be days to re-epithelization of the burn injury. Secondary endpoints include pain, patient satisfaction and scarring.

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.

## **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 indicated for use in the treatment of acute thermal burns in patients 18 years and older. 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. 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.

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:**

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