



First Patient Enrolled in AVITA Medical's Pivotal Study Evaluating RECELL® System for Pediatric Scald Injuries

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Study to evaluate treatment with the RECELL System within 72-hours of a pediatric scald burn injury

Valencia, Calif., USA, and Melbourne, Australia, 05 March 2020 — AVITA Medical Limited (ASX: AVH, NASDAQ: RCEL), a regenerative medicine company with a technology platform positioned to address unmet medical needs in therapeutic skin restoration, announced today the initiation of a pivotal trial for the treatment of pediatric scald injuries with enrollment of the first patient at the Arizona Burn Center at Valleywise Medical Health Center in Phoenix, AZ. This study seeks to demonstrate that treatment with the RECELL System of partial-thickness burn injuries within 72-hours can safely and effectively increase the incidence of healing at day 10 when compared to a standard wound dressing.

"The immediate treatment of scald injuries in pediatric patients represents a shift in thinking as surgeons currently favor a delayed approach to avoid the additional trauma associated with conventional skin grafting. With the commencement of this pivotal trial, we intend to demonstrate that treatment with the RECELL System within the first three days of a pediatric burn improves healing and decreases the need for autografting," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "Building on the success surgeons have had in treating burns in adult patients, we look forward to potentially expanding the use of the RECELL System to benefit pediatric patients with burns and are pleased to progress toward this with the commencement of this pivotal trial."

In the U.S., it is estimated that 30-percent of burn patients are within the ages of one to 15 years old, and approximately 45-percent of the pediatric burn injuries are from scald burns¹. The standard of care for pediatric patients with second-degree burns, such as scald burns, is to apply dressings and assess the injury over time to determine if skin grafting is required. Skin grafting results in scar formation in the area treated and involves the harvesting of substantial amounts of donor skin, resulting in an additional wound to the patient. Significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring are all associated with skin graft donor site wounds.

"Second-degree burn injuries among children are often the result of an accident, such as a child grabbing and tipping over a pot of boiling water, causing a scald burn of varying depths across the body. We typically dress the injury, then watch it for 10-14 days to determine if the wound requires autografting," said Dr. Kevin Foster, Director of the Arizona Burn Center at Valleywise Health Medical Center. "We are eager to evaluate the RECELL System as an early treatment option as it may speed up the healing process as well as reduce the frequency with which we turn to conventional autografting for treatment of pediatric scalds."

The primary endpoint of this prospective multi-center trial is to demonstrate that treatment of partial-thickness burn injuries with the RECELL System increases the incidence of healing at day 10

compared with a standardized wound dressing. Additionally, the effects of both treatments on time to healing, the incidence of conventional autografting, pain, itching, scarring, health-related quality of life and resource utilization will be investigated. Enrollment of 160 pediatric patients, ages one to 16 years old, is planned. This study utilizes an adaptive design with an interim analysis.

Healing will be evaluated by a clinician blinded to the treatment allocation. Additional data collected over the course of the 52-week study will include blinded evaluation of scar outcomes, evaluation of disease-specific quality of life, and healthcare resource utilization.

BARDA Funding Supports Development of RECELL System

Funding 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.

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Authorized for release by the Chief Executive Officer of AVITA Medical Limited.

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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 8,000 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 (<https://recellsystem.com/>) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

In international markets, 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 and received CE-mark approval in Europe. To learn more, visit 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.

This press release was authorized by the review committee of AVITA Medical Limited.

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