ASX/News Release

First Patient Enrolled in AVITA Medical's Pivotal Study Evaluating RECELL System for Soft Tissue Reconstruction

Study to enroll a minimum of 65 patients across the United States to evaluate safety and effectiveness of treatment of acute, non-burn skin injuries

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Valencia, Calif., USA, and Melbourne, Australia, 3, 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 the pivotal study for soft tissue reconstruction with the enrollment of the first patient at the Arizona Burn Center at Valleywise Medical Health Center in Phoenix, AZ. This study will evaluate the safety and effectiveness of the RECELL® System when used as an adjunct to meshed autografts in patients undergoing reconstruction of skin defects not associated with a burn injury.

"The commencement of this pivotal trial is an important milestone for AVITA and a critical step toward making the RECELL System broadly available to help patients heal from traumatic or soft tissue wounds with the use of less donor skin than the standard of care," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "We are pleased to have initiated this registration trial and to have enrolled the first patient in this study."

Skin grafting is the standard of care for full-thickness, soft tissue reconstruction, including post-trauma and post-surgical skin reconstruction. Skin grafting requires the harvesting 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 donor site wounds. While skin grafting is commonly associated with burn treatment, in 2017 approximately 80% of acute wounds that required skin grafting were non-burn related injuries accounting for more than 200,000 procedures in the U.S.[(i)]

"We routinely treat acute non-burn wounds using conventional skin grafting, but that approach results in a donor site wound that adds to the patient's pain and to the cost of their care," said Dr. Kevin Foster, Director of the Arizona Burn Center at Valleywise Health Medical Center. "We are eager to evaluate use of the RECELL System as a way to reduce the amount of donor skin required. In burn care, where RECELL is currently FDA-approved, clinical and health economic benefits have been demonstrated. Relative to burn treatment, autografting for non-burn injuries occurs far more frequently, so this has the potential to be a significant treatment advancement for a large number of patients."

The prospective multi-center trial of at least 65 patients will compare the clinical performance of conventional skin grafting to the use of the RECELL System in combination with more widely meshed autografts on acute full-thickness non-burn skin defects. The study's two primary effectiveness endpoints are:

- Superior donor skin sparing, evaluated by comparing the actual expansion ratios of donor skin used to treat the wounds

- Non-inferior incidence of healing by eight weeks post treatment

Healing will be evaluated by a qualified clinician blinded to the treatment allocation. Additional long-term safety and effectiveness data collected over the course of the 52-week study will include blinded evaluation of scar outcomes and patient treatment preference.

Of note: Use of the RECELL System in patients undergoing reconstruction of skin defects not associated with a burn injury is limited by Federal law to investigational use.

The pivotal studies leading to the RECELL System's FDA premarket approval for the treatment of acute thermal burns demonstrated that the RECELL System treated burns using 97.5[(ii)] percent less donor skin when used alone in second-degree burns, and 32 percent less donor skin when used with autograft for third-degree burns.[(iii)] Despite the statistically significant reduction in donor skin required to treat burn patients with the RECELL System, burn wounds treated with the RECELL System achieved healing comparable to the burn wounds treated with standard of care.[(ii)]

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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[ii] Holmes JH, Molnar JA, Carter JE, et al. A comparative study of the RECELL® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. J Burn Care Res. 2018
[iii] Holmes JH, Molnar JA, Shupp JW, et al. Demonstration of the safety and effectiveness of the RECELL System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. Burns. 2019;45:772-782