ASX/News Release

AVITA Medical Receives U.S. FDA Investigational Device Exemption Approval of Pivotal Study Evaluating RECELL System for Soft Tissue Reconstruction

First RECELL System clinical trial in the U.S. focused on acute soft tissue injuries, defects, and reconstruction; study expected to commence within next 6 months

---

Valencia, Calif., USA, and Melbourne, Australia, 17 September 2019 — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a regenerative medicine company focused on the development and commercialization of innovative therapies leveraging the healing properties of a patient's own skin, announced today that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) application to conduct a pivotal trial evaluating the safety and effectiveness of the RECELL® Autologous Cell Harvesting Device (RECELL® System) in combination with meshed autografting for the treatment of acute full-thickness skin defects, such as degloving (a type of injury where the skin is ripped from the underlying tissue), crush wounds (a break in the external surface of the body), abrasions, lacerations, and surgical wounds.

"FDA approval of our IDE for a soft tissue reconstruction pivotal clinical trial is an important next step in expanding the potential indications of our RECELL System technology platform. We are pleased with the strong interest expressed by the clinical community in participating in this study and we look forward to working with physicians and their patients upon study commencement," said Dr. Michael Perry, Chief Executive Officer of AVITA Medical. "Many burn specialists who have experience treating burn patients with the RECELL System also treat patients with trauma injuries in their clinics. The treatment protocols for burns and trauma are well-aligned and as such, we anticipate a positive transfer of clinical experience to benefit this patient population during the clinical trial."

Skin grafting is the standard of care for 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 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]

"Based on the compelling safety and effectiveness of the RECELL System in treating burn wounds, we believe our innovative technology is ideally positioned to be evaluated as a treatment to heal trauma- and surgery-related wounds," said Andy Quick, Chief Technology Officer of AVITA Medical. "With a clear opportunity to improve the standard-of-care, we look forward to sharing results upon completion of this pivotal trial."

AVITA Medical will initiate a prospective, multi-center, randomized controlled study to compare the clinical performance of conventional skin grafting with and without the use of the RECELL System on acute non-burn full-thickness skin defects. Each patient will have a control wound treated with

conventional skin grafting and a wound treated with expanded skin grafting in combination with the RECELL System. The study's two primary effectiveness endpoints are:

- Incidence of healing by eight weeks post treatment
- Donor skin sparing, evaluated by comparing the ratios of donor skin required to treat the wounds

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.

The pivotal studies leading to the RECELL System's FDA premarket approval (PMA) 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. Donor site outcomes from the clinical trial for second-degree burns also revealed a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved scar outcomes.[ii]

# # #

ABOUT AVITA MEDICAL

ABOUT AVITA MEDICAL LIMITED

AVITA Medical is a regenerative medicine company focused on the development and commercialization of innovative therapies leveraging the healing properties of a patient's own skin. With its novel technology platform, AVITA Medical is advancing the standard-of-care for burn patients and is poised to address unmet medical needs across a range of dermatological indications, including vitiligo, wounds and aesthetic rejuvenation. The company's patented and proprietary collection and application technology prepares a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™) comprising the patient's skin cells necessary to regenerate a natural healthy epidermis that can then be sprayed onto the areas of the patient's skin requiring treatment. More information about AVITA Medical is available at www.AvitaMedical.com

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, acute wounds, scars and vitiligo. The RECELL System is TGA- registered in Australia, CFDA-cleared in China, and has 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.

FOR FURTHER INFORMATION:

U.S. Media Sam Brown, Inc. Christy Curran Phone +1-615.414.8668 christycurran@sambrown.com **O.U.S Media** Monsoon Communications Sarah Kemter Phone +61 (0)3 9620 3333 Mobile +61 (0)407 162 530 sarahk@monsoon.com.au	**Investors** Westwicke Partners Caroline Corner Phone +1-415-202-5678 caroline.corner@westwicke.com

PR 20190917

# # #

[i] 2017 Procedural Data. © 2019 DR/Decision Resources, LLC

[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.