



ASX/News Release

## **AVITA Medical Announces Presentation of RECELL® Device Clinical Trial Results at Changhai Academic Week for Burns Treatment Conference in China**

*Also announces that Plastic Surgery Department of Peking Union Medical College Hospital (PUMCH) completes first national training session in treatment of vitiligo and scars*

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**Valencia, Calif., USA, and Melbourne, Australia, 27 June 2018** — AVITA Medical (ASX: AVH, OTCQX: AVMX) announced today that results from two U.S. pivotal clinical trials and the U.S. Compassionate Use program demonstrating the effectiveness and clinical benefits of the RECELL® Autologous Cell Harvesting Device were presented at the 2nd Changhai Academic Week for Burns Treatment in Shanghai, China. The results were presented by Jeffrey Carter, MD, FACS, Medical Director & Associate Professor of Surgery at University Medical Center Burn Center & Louisiana State University School of Medicine, New Orleans, LA.

"As Burn Surgeons we cannot choose our patients' severity of injury, age, nor any combination of other injuries or illness that complicate their course of care, said Dr. Carter. "Thanks to the RECELL device, we can choose to minimize the burden of patient donor sites, and offer a treatment that provides repigmented wounds capable of becoming subtle scars to the most discerning eye."

Key highlights of Dr. Carter's presentation included:

- The pivotal, controlled clinical trial of the RECELL Device in the treatment of second-degree burns demonstrated statistically significant reduction in donor skin requirements (97.5 percent reduction) and pain, increased patient satisfaction and improved donor scar outcomes.
- The pivotal trial in third-degree burns met its co-primary endpoints and demonstrated statistically significant reduction in donor skin requirements.
- Results from two patients enrolled under Compassionate Use with second-degree facial burns showed excellent cosmetic outcomes.

The presentation at the Changhai Academic Week follows the commencement this year of a government funded clinical trial of RECELL for the treatment of burns in China. The clinical trial entitled "Key Technique and Clinical Pathway for Burn Treatment" is a controlled clinical trial in which burn patients are being randomized for treatment with either standard of care, the RECELL Device, or one of two other treatments.

Also in 2018, the Company collaborated with the Plastic Surgery Department of Peking Union Medical College Hospital (PUMCH), one of the most renowned hospitals in China, to establish a RECELL Device training center based in Beijing. The training center is designed to standardize the protocol for the use of RECELL, train surgeons in the use of the RECELL Device nationwide, and encourage the expansion of the use of this innovative treatment to hospitals across China. The first national training course encompassing the treatment of vitiligo and scars with the RECELL Device was completed last month at PUMCH.

In the U.S., the RECELL Device is an investigational medical device that is designed to enable medical professionals to produce, at the point-of-care, a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™) using a

small sample of the patient's own skin. The autologous suspension contains cells necessary to regenerate epidermis and provides a new way to achieve permanent closure in burns and other wounds while reducing the amount of skin harvested at the time of surgery. Reduction in donor-site skin requirements has important benefits from both clinical and health economic perspectives. The two pivotal clinical trials presented by Dr. Carter were used to support AVITA Medical's U.S. Premarket Approval (PMA) application for the treatment of burn injuries.

The clinical trial underlying the results presented by Dr. Carter were conducted by a team of burn-care surgeons, medical professionals, and researchers at major burn centers throughout the U.S. The lead investigator of the two U.S. pivotal trials was James H. Holmes IV, MD FACS, Director, WFBMC Burn Center, Professor of Surgery, Wake Forest University School of Medicine, Winston-Salem, North Carolina, who has also treated multiple patients under the Compassionate Use program.

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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 EPITHELIAL SUSPENSION™, an autologous suspension comprised of the patient's skin cells and wound healing factors necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

In the United States, the RECELL Device is an investigational device limited by federal law to investigational use. In September 2017, AVITA Medical submitted to the U.S. Food and Drug Administration (FDA) a Premarket Approval (PMA) application for the RECELL Device for the treatment of burn injuries.

In all countries outside of Europe, our portfolio is marketed under the RECELL Device brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL Device 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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