



## **Avita Medical Announces Collaboration with COSMOTEC, an M3 Group Company, to Commercialize the RECELL® System in Japan**

March 3, 2019

*COSMOTEC has filed a JPMDA application for approval to market the RECELL System in Japan*

**Valencia, Calif., USA, and Melbourne, Australia, 4 March 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY), a global regenerative medicine company, announced that it has collaborated with COSMOTEC, an M3 Group company, to market and distribute the RECELL® Autologous Cell Harvesting Device (RECELL® System) for the treatment of burns and other wounds in Japan. In addition, COSMOTEC filed on 25 February 2019 a Japan's Pharmaceuticals and Medical Devices Act ("JPMDA") application for approval to market the RECELL System in Japan. The JPMDA has accepted the application and review is expected to take nine months to a year.

"The number of patients suffering from chronic wounds and decubitus ulcers is increasing in Japan due to aging. Japan is also planning for the Tokyo Olympic Games in 2020 and must be prepared for major disasters such as a large earthquake. We are very proud to add the RECELL System to our product lineup," said Mr.

Kiyoshi Takei, President of COSMOTEC. "With over 30 years since our foundation, COSMOTEC has been doing business in 90-100% of high acute care hospitals in Japan in the fields of cardiac surgery, vascular surgery, and wound care. As a member of the M3 Group, we can deliver the RECELL System's benefits to at least 90% of Japanese plastic surgeons and dermatologists through the portal site "m3.com." With this opportunity, we would like to contribute to the advancement of burn injury and wound care in Japan."

"We are very excited to partner with COSMOTEC on the commercialization of the RECELL System in Japan, a key global market," said Dr. Michael Pery, AVITA Medical Chief Executive Officer. "COSMOTEC's experience marketing medical devices and other products into hospitals and surgical suites throughout Japan, including specialties required a high level of training such as cardiovascular treatment, make them an ideal partner for us. We are also pleased that they are backed by the M3 Group, a major healthcare company with great physician access in Japan and other markets. The filing of the JPMDA application is a major milestone, and we look forward to making the RECELL System available to patients in Japan."

Japan is the second largest healthcare market in the world and represents a valuable market for the RECELL System with more than 6,000 patients with severe burns treated in hospitals each year. Over two million people in Japan are estimated to have vitiligo, a disease that causes the loss of skin color in blotches and can affect the skin on any part of a patient's body. Financial terms of the collaboration were not disclosed.

### **About M3**

M3 Inc. is a publicly traded company on the Tokyo Stock Exchange (TYO:2413) with subsidiaries in major markets including USA, UK, Japan, South Korea, and China. M3 Inc. provides services to healthcare and the life science industry. In addition to market research, these services include medical education, ethical drug promotion, clinical development, job recruitment, and clinic appointment services. M3 Inc. operates in the

US, Asia, and Europe with over 4.5 million physician members globally via its portals including MDLinx.com, m3.com, Doctors.net.uk, medigate.net and medlive.cn. M3 has offices in Tokyo, Washington D.C., Fort Washington, PA, Oxford, London, Beijing, and Seoul. Please visit <https://corporate.m3.com/en/> for more information.

### **About COSMOTEC**

COSMOTEC Co., Ltd., established in 1992 specialises in sales and consulting of medical devices focusing on cardiac surgery, general surgery and endovascular treatment. COSMOTEC has 98% market share of the institutions conducting cardiovascular surgery in Japan. COSMOTEC has offices in Tokyo, Sapporo, Sendai, Nagoya, Osaka, Okayama and Fukuoka across Japan. COSMOTEC is an M3, Inc., group company. Please visit <http://cosmotec.com/english/> for more information.

### **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 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 (<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 and CFDA-cleared in China.

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.*

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