



## AVITA Medical Files RECELL® System Investigational Device Exemption (IDE) Application with the U.S. Food and Drug Administration for Treatment of Vitiligo

June 1, 2020

Valencia, Calif., USA, and Melbourne, Australia, 01 June 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, today announced that it has submitted an Investigational Device Exemption (IDE) supplement with the U.S. Food and Drug Administration (FDA) for the initiation of a pivotal clinical trial to investigate the RECELL® System for the treatment of vitiligo.

"We are very pleased to have filed the supplement and look forward to advancing the RECELL® System into the clinic for treatment of vitiligo following acceptance of the application," said Andrew Quick, Chief Technology Officer of AVITA Medical. "The data from the pivotal trial will form the basis of the FDA submission for consideration to expand use of the RECELL® System for repigmentation of depigmented lesions associated with stable vitiligo. In parallel, and as previously announced, we are also conducting a complementary and more scientifically-oriented feasibility study."

"Globally, the RECELL® System is approved for additional skin applications, including vitiligo, which is supported by a substantive body of clinical evidence with patients internationally and in peer-reviewed publications, providing us with valuable experience and confidence in pursuing expanded labelling in the U.S.," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "The submission of this pivotal IDE is an important milestone as we continue to explore opportunities to expand the patient populations who can benefit from treatment with the RECELL® System platform."

### About Vitiligo

Vitiligo affects approximately 6.5 million people in the United States (i), rivalling the prevalence of psoriasis (ii); however, there are limited treatment options available to patients to permanently restore skin pigmentation.

Vitiligo is a disease resulting in loss of color, or pigmentation, in patches of skin that impacts the quality of life for those living with the condition. (iii) There is currently no cure for vitiligo, nor a universally accepted method for limiting the spread of the disease. Although many treatments are being used for the management of vitiligo, they are often temporary with a high rate of recurrence. (iv)

Authorized for release by the Chief Financial 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 RES® REGENERATIVE EPIDERMAL SUSPENSION, 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](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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