



## **RECELL® System Feasibility Study Results for Treatment of Diabetic Foot Ulcers Presented at 11th Annual Congress of the Japanese Society of Limb Salvage & Podiatric Medicine**

June 30, 2019

*Innovative regenerative technology using patients' own skin cells significantly reduced size of wounds caused by diabetic foot ulcers in all patients*

**Valencia, Calif., USA, and Melbourne, Australia, 01 July 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY) a global regenerative medicine company, announced today favorable results from an open-label feasibility study of the RECELL® Autologous Cell Harvesting Device (RECELL® System) for the treatment of diabetic foot ulcers (DFUs). The data, presented by Mr. Tawqeer Rashid at the 11th annual meeting of the Japanese Society of Limb Salvage & Podiatric Medicine (JSLSPM) June 28-29, 2019, in Kobe, Japan, evaluated the clinical performance of the RECELL® System, which uses a small amount of a patient's own skin to prepare Spray-On Skin™ Cells at the point-of-care, in patients with DFUs that had not responded to standard care treatments.

"Chronic wounds, such as diabetic foot ulcers, significantly impact the lives of patients," said Mr. Rashid, Consultant Vascular and Endovascular Surgeon, Manchester Royal Infirmary. "There is a real need to find new ways of treatment, and the RECELL® System shows promise in potentially enhancing the healing of diabetic foot ulcers, including recalcitrant ulcers that have not responded to standard-of-care therapies."

The 26-week, single-arm, observational study included 16 patients treated at three hospitals in the United Kingdom, including Manchester Royal Infirmary, Kings College Hospital and Northwick Park Hospital. Patients enrolled in the study had chronic DFUs ranging in size from 5-33 cm<sup>2</sup>, with and without infection, and with varying depths, inclusive of bone and tendon exposure, that had failed to heal with standard-of-care treatments. Study investigators used the RECELL® System to prepare Spray-On Skin™ Cells using a small amount of each patient's own skin, that were then applied to the DFUs.

Key results from the study include:

- 100% of patients experiencing a reduction in DFU wound size following treatment with Spray-On Skin™ Cells, with an average wound size reduction of 83% at week 26
- 50% of the patients had DFU wounds heal completely, with a median time to healing of 14 weeks, despite the range of severity of ulcers
- Treatment using the RECELL® System provided an acceptable safety profile
- High patient and physician satisfaction scores were reported following treatment utilizing the RE-

CELL® System

"We are pleased with the results of the diabetic foot ulcer feasibility study, which demonstrate the potential versatility of the RECELL® System as a meaningful treatment option to heal chronic wounds," said Dr. Michael Perry, AVITA Medical's Chief Executive Officer. "AVITA is committed to continued exploration of how this innovative regenerative technology may further advance patient care in areas with significant unmet medical need."

According to recent data collected by the World Health Organization, the Harvard T.H. Chan School of Public Health, and Imperial College London, diabetes now affects 422 million adults globally at a cost of \$825 billion per year.<sup>1</sup> National Institute of Health data reports that approximately 25-30 million global diabetics suffer from DFUs, a widespread complication of poorly controlled diabetes.<sup>2</sup> DFUs can remain as open wounds for years, limiting patients' mobility and lifestyle, and risking infection, often leading to amputation if not treated effectively.

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### **ABOUT AVITA MEDICAL**

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™ (RESTM), 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, CFDA-cleared in China, and has 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*

1 Zhou, Bin et al. "Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants." *Lancet* 2016; 387: 1513–30. Published Online April 6, 2016. [http://dx.doi.org/10.1016/S0140-6736\(16\)00618-8](http://dx.doi.org/10.1016/S0140-6736(16)00618-8).

2 Raghav, Alok et al. "Financial burden of diabetic foot ulcers to world: a progressive topic to discuss always." *Therapeutic Advances in Endocrinology and Metabolism*: January 2018; 9(1): 29-31. U.S. National Library of Medicine: National Institutes of Health. Published Online December 12, 2017. doi: 10.1177/2042018817744513.

*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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