



## **RECELL® System Data Presented at American Burn Association Fall Regional Burn Conferences**

December 15, 2020

*Abstracts Highlighting Clinical and Health Economic Data Reinforce Effectiveness of Treatment with RECELL System*

*More than 10,000 Patients treated with RECELL System globally*

VALENCIA, Calif. and MELBOURNE, Australia, Dec. 15, 2020 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, announced today the presentation of RECELL® System data recently presented at the Northeast Regional Burn Conference and Southern Regional Burn Conference of the American Burn Association.

"Since the U.S. Food and Drug Administration approval of the RECELL System in September 2018, 93 U.S. burn centers have ordered the RECELL System, with more than 80% of burn surgeons throughout the United States certified on the use of the system. There have now been more than 10,000 patients treated globally, with U.S. RECELL System sales topping \$27 million in the two years since FDA approval," said Dr. Mike Perry, AVITA Medical's Chief Executive Officer. "As burn surgeons continue to gain experience with the RECELL System and increasingly use it across a range of burn sizes, we are encouraged to see the utility, positive clinical outcomes, and health economic benefits of the RECELL System highlighted at medical conferences. We remain committed to advancing burn care in collaboration with burn surgeons and look forward to expanding the benefit of the RECELL System to additional indications, including soft tissue defects and vitiligo, amongst others."

### **Recent RECELL® System Data Abstracts:**

- Carney. A Pilot Study of Negative Pressure Therapy with Autologous Skin Cell Suspensions in a Porcine Model. Presented at Northeast Region Burn Conference; 2020 November 6; Virtual.
- Chihade. Autologous Epidermal Skin Cell Suspension: A Cost-Effective Treatment for Burns >20% TBSA in a County Hospital with Limited Resources. Southern Region Burn Conference; 2020 December 6; Virtual.
- Desai. Aesthetic superiority of autologous cell suspension device in treating deep partial and full thickness burn compared to skin graft in a single case. Southern Region Burn Conference; 2020 December 6; Virtual.

The RECELL System is FDA-approved for the treatment of acute thermal burns in patients 18 years and older. Used by a trained healthcare professional at the point of care, the RECELL System is used to prepare Spray-On Skin™ Cells to be sprayed directly on second-degree burn injuries or applied in combination with meshed autografts for third-degree burn injuries. The pivotal studies leading to the RECELL System's FDA premarket approval for the treatment of acute thermal burns demonstrated that the RECELL System treated burns using 97.5<sup>i</sup> 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.<sup>ii</sup> This statistically significant reduction in donor skin required to treat burn patients with the RECELL System produced healing comparable to the standard of care while providing a significant reduction in donor site pain and improved donor site healing.<sup>i</sup>

For more information about the RECELL System, please visit [www.RECELLSystem.com](http://www.RECELLSystem.com).

### **ABOUT AVITA MEDICAL, INC.**

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 10,000 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.avitammedical.com](http://www.avitammedical.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.

This press release was authorized by the review committee of AVITA Medical Limited.

**FOR FURTHER INFORMATION:**

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<sup>i</sup> 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

<sup>ii</sup> 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