AVITA Medical Establishes Proof of Concept for Novel Treatments Using Genetically-Modified Skin Cells

Data show promise for skin rejuvenation and treatment of epidermolysis bullosa

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VALENCIA, Calif. and MELBOURNE, Australia, 05 January 2022 — 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, today announced that preclinical data successfully established proof of concept in two key areas of cell-based gene therapy – skin rejuvenation and epidermolysis bullosa.

"We are very pleased to partner with leading scientists to explore opportunities for utilizing Spray-On Skin™ Cells in new and broad applications such as skin rejuvenation and genetic skin defects," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "These data, while early, demonstrate promise for skin regeneration from modified Spray-On Skin™ Cells, for treatment of aging skin with reverse-aged skin cells and for treatment of epidermolysis bullosa with gene-corrected skin cells."

A Novel RNA-Based Approach for Rejuvenation

In partnership with researchers at the Houston Methodist Research Institute (HMRI), preclinical data show successful regeneration of the skin by pairing AVITA Medical's proprietary Spray-On Skin Cells with HMRI's patented RNA technologies to reverse cellular aging. Personalized, cellular-level skin rejuvenation is an area of significant interest for consumers, with a total addressable market of $15 billion. More than three million aesthetic procedures are performed annually in the U.S., with approximately one million people undergoing facial lifting and tightening procedures. [i] [ii]

"We are encouraged by these early results and look forward to continuing to work with AVITA Medical to explore technologies for reversing aging of skin cells," said Dr. John Cooke, Chair of the Department of Cardiovascular Sciences, and Medical Director of the RNA Therapeutics department at Houston Methodist Research Institute. "Skin is the body's largest organ, and molecular signaling from aged cells can have a significant impact on the rest of the body. Therefore, reversing aging of skin could have significant implications for other systems in the body."

Epidermolysis Bullosa

In partnership with scientists at the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine, preclinical data show successful regeneration of skin from gene-modified skin cells to correct the mutation associated with recessive dystrophic epidermolysis bullosa, a rare and incurable skin disorder caused by mutations in the gene encoding structural proteins, resulting in skin fragility and blistering.

“These initial results are a meaningful step forward in the advancement of our epidermolysis bullosa program,” said director of the Gates Center for Regenerative Medicine Dr. Dennis Roop. “We’re looking forward to continuing to work with AVITA Medical on this novel approach to delivering gene-edited skin cells to patients.”

Epidermolysis bullosa can lead to chronic wounds and, in some sub-types, an increased risk of squamous cell carcinoma or death. There are no approved curative therapies, and current treatment is palliative, focused primarily on pain and nutritional management, itching relief, wound care and bandaging. As an orphan indication with 25,000-50,000 patients in the U.S., it is estimated that the current cost of palliative care ranges between $200K-$500K per year per patient. The total addressable U.S. market is estimated at $850 million.

For more information about the RECELL System, please visit www.RECELLSystem.com.

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ABOUT HOUSTON METHODIST
Houston Methodist is one of the nation’s leading health systems and academic medical centers. The health system consists of eight hospitals: Houston Methodist Hospital, its flagship academic hospital in the Texas Medical Center, six community hospitals and one long-term acute care hospital throughout the Greater Houston metropolitan area. Houston Methodist also includes a research institute; a comprehensive residency program; international patient services; freestanding comprehensive care, emergency care and imaging centers; and outpatient facilities. Houston Methodist employs approximately 27,000 people.

ABOUT THE UNIVERSITY OF COLORADO SCHOOL OF MEDICINE
Faculty at the University of Colorado School of Medicine work to advance science and improve care. These faculty members include physicians, educators, and scientists at UC Health University of Colorado Hospital, Children’s Hospital Colorado, Denver Health, National Jewish Health, and the Veterans Affairs Eastern Colorado Health Care System. The school is located on the Anschutz Medical Campus, one of four campuses in the University of Colorado system.

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. 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.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release 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 press release 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 press release 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 press release. 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 press release 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, Inc.

FOR FURTHER INFORMATION:

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[i] Estimates and data based on information on file at Avita Medical Limited

[ii] 2020 Plastic Surgery Statistics Report (Defined as Facelifts, Ablative Laser, Dermabrasion, Non-Surgical Skin Tightening)