



**ASX/News Release** 

# AVITA Medical and the Gates Center for Regenerative Medicine at the University of Colorado Anschutz Medical Campus Enter into Collaboration to Explore Potential Spray-On Treatment of Genetically Modified Cells for Epidermolysis Bullosa

AVITA Medical secures option for exclusive licensing of emerging technologies

Preclinical research will pair AVITA Medical's Spray-On Skin™ Cells technology and expertise with the Gates Center's patent pending combined reprogramming and gene editing methodology

Valencia, Calif., USA, Melbourne, Australia, and Aurora, Colo., USA, 25 November 2019 — AVITA Medical (ASX: AVH, NASDAQ: RCEL), a regenerative medicine company with a technology platform positioned to address unmet medical needs in therapeutic skin restoration, and scientists at the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine announced today a preclinical research collaboration to establish proof-of-concept and explore further development of a spray-on treatment of genetically modified cells for patients with epidermolysis bullosa (EB), with potential applicability to other genetic skin disorders.

The partnership will pair AVITA Medical's patented and proprietary Spray-On Skin™ Cells technology and expertise with the Gates Center's innovative, patent pending combined reprogramming and gene editing technology to allow cells to function properly. Under the terms of the Sponsored Research Agreement (SRA), AVITA Medical retains the option to exclusively license technologies emerging from the partnership for further development and commercialization. The Gates Center team is further supported by the EB Research Partnership in New York, the Los Angeles-based EB Medical Research Foundation, the London-based Cure EB Charity and government grants, in a collaborative effort to rapidly develop and translate this technology to the clinic for meaningful impact on patient lives.

"The Gates Center is a leader in developing therapeutic approaches for genetic skin diseases. Researchers at the Gates Center have developed a powerful new approach for treating genetic skin disorders and improving the lives of patients with epidermolysis bullosa," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical and adjunct professor at the Gates Center for Regenerative Medicine. "We look forward to collaborating with the team at the Gates Center on the expanded use of our technology. This agreement marks an important milestone in AVITA's mission to harness the potential of regenerative medicine to address unmet medical needs across a broad range of dermatological indications, including genetic disorders of the skin."

Epidermolysis bullosa is a group of rare and incurable skin disorders caused by mutations in genes encoding structural proteins resulting in skin fragility and blistering, leading 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.

"It's very exciting to partner with AVITA Medical to help advance our epidermolysis bullosa program," said Director of the Gates Center for Regenerative Medicine Dr. Dennis Roop. "We're looking forward to exploring a novel approach to delivering gene-edited skin cells to patients that addresses current treatment challenges."

"We believe that Spray-On Skin™ Cells technology combined with our genetically corrected cells has the potential to be game changing in the treatment of this disease. This combination could reduce time to treatment, lower manufacturing complexity, reduce costs and improve patient outcomes," said Dr. Ganna Bilousova, assistant professor of dermatology, who is a co-principal investigator on this research program.

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#### ABOUT THE CHARLES C. GATES CENTER FOR REGENERATIVE MEDICINE

The Charles C. Gates Center for Regenerative Medicine was established in 2006 with a gift in memory of Denver industrialist and philanthropist, Charles C. Gates, who was captivated by the hope and benefit stem cell research promised for so many people in the world. The Gates Center aspires to honor what he envisioned—by doing everything possible to support the collaboration between basic scientific researchers and clinical faculty to transition scientific breakthroughs into clinical practice as quickly as possible.

Led by Founding Director Dennis Roop, Ph.D., the Gates Center is located at the University of Colorado's Anschutz Medical Campus, the largest new biomedical and clinical campus in the United States. Operating as the only comprehensive Stem Cell Center within a 500-mile radius, the Gates Center shares its services and resources with an ever-enlarging membership of researchers and clinicians at the Anschutz Medical Campus, which includes University of Colorado Hospital, Children's Hospital Colorado and the Veterans Administration Medical Center, as well as the Boulder campus, Colorado State University, the Colorado School of Mines, and business startups. This collaboration is designed to draw on the widest possible array of scientific exploration relevant to stem cell technology focused on the delivery of innovative therapies in Colorado and beyond.

#### 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 University of Colorado Hospital, Children's Hospital Colorado, Denver Health, National Jewish Health, and the Denver Veterans Affairs Medical Center. The school is located on the <a href="Anschutz Medical Campus">Anschutz Medical Campus</a>, one of four campuses in the University of Colorado system. To learn more about the medical school's care, education, research and community engagement, visit its web site.

#### **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  $^{\text{TM}}$  (RES $^{\text{TM}}$ ), 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.

#### **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.

## FOR FURTHER INFORMATION:

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