

RECELL® Pivotal Trial in Third-Degree Burns Meets Co-Primary Endpoints and Shows Statistically Significant Reduction in Donor Skin Requirements

Presentation today at American Burn Association Meeting highlights potential of RECELL to improve patient care in severe burns

Valencia, Calif., USA, and Melbourne, Australia, 13 April 2018 — AVITA Medical (ASX: AVH, OTCQX: AVMX) today announced that its pivotal, controlled clinical trial in the treatment of deep full-thickness (third-degree) burns with the RECELL® Autologous Cell Harvesting Device achieved its co-primary endpoints, demonstrating a statistically significant reduction in donor skin requirements versus standard of care while achieving comparable definitive wound closure. The results were presented at the American Burn Association (ABA) 50th Annual Meeting in Chicago by James H. Holmes, IV, MD, FACS, Wake Forest Baptist Medical Center, Winston-Salem, North Carolina.

“Treatment with the RECELL Device achieved comparable healing, long-term scar and patient satisfaction outcomes using significantly less donor skin with no safety concerns,” said Dr. Holmes. “I have had the opportunity to evaluate RECELL through several clinical trials and the FDA-approved Compassionate Use Program. I believe that the RECELL Device provides the opportunity to improve care for patients with severe burns.”

The RECELL Device is an investigational medical device in the U.S. that is designed to enable medical professionals to produce, at the point-of-care, a REGENERATIVE EPIDERMAL SUSPENSION™ (RES™) using a small sample of the patient’s own skin. The autologous suspension contains cells necessary to regenerate epidermis and provides a new way to achieve permanent closure in burns and other wounds while reducing the amount of skin harvested at the time of surgery. Reduction in donor-site skin requirements has important benefits from both clinical and health economic perspectives.

The presentation by Dr. Holmes, “Demonstration of the Safety and Effectiveness of Autologous Skin Cell Suspension Combined with Meshed Skin Grafts for the Reduction of Donor Area in the Treatment of Acute Burns,” described the outcomes from the controlled clinical trial conducted at seven U.S. burn centers. During the pivotal trial, the patient donor skin required to be harvested to treat burn sites with the RECELL Device was 32 percent less than the amount harvested to treat burn sites with the standard of care ($p < 0.001$). Despite the statistically significant reduction in donor skin required to treat with the RECELL Device, burn sites treated with the RECELL Device achieved definitive closure comparable to the burn sites treated with standard of care. At eight weeks post treatment, 92 percent of the burn sites treated with RECELL achieved complete healing versus 85 percent for the sites treated with the standard of care, demonstrating non-inferiority. Use of RECELL was safe and well tolerated with no treatment-related adverse events considered device related.

The pivotal trial evaluated 30 patients ranging in age from nine to 68 years old with thermal, mixed-

thickness burns, including full-thickness burns, covering five percent to 46 percent of their total body surface area. Patients served as their own control, and two comparable burn sites were selected for comparative testing on each patient. One burn site was treated with the standard treatment, meshed autograft, while the other was treated with the combination of the RECELL Device and more widely meshed autografted (for example, if a 2:1 meshed autograft was used to treat the control burn site, then a 3:1 meshed autograft was used to treat the RECELL site). The co-primary endpoints of the pivotal trial were reduction in donor skin requirements and non-inferiority in complete wound closure.

The Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the US Department of Health and Human Services has provided funding under Contract No. HHSO100201500028C to support the development of RECELL by AVITA Medical, including the Compassionate Use program included in the presentation today.

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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. Our medical devices work by preparing a REGENERATIVE EPITHELIAL SUSPENSION™, an autologous suspension comprised of the patient's own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This autologous suspension is then sprayed onto the areas of the patient to be treated.

In the United States, the RECELL Device is an investigational device limited by federal law to investigational use. In September 2017, AVITA Medical submitted to the U.S. Food and Drug Administration (FDA) a PreMarket Approval (PMA) application for RECELL for the treatment of burn injuries.

In all countries outside of Europe, our portfolio is marketed under the RECELL Device brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. RECELL Device is TGA-registered in Australia, and CFDA-cleared in China.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. RECELL Device is designed for the treatment of burns and plastic reconstructive procedures; REGENERCELL™ Autologous Cell Harvesting Device has been formulated for chronic wounds including leg and foot ulcers; and RENOVACELL™ Autologous Cell Harvesting Device is tailored for aesthetic applications including the restoration of pigmentation.

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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