



AVITA Medical Announces RECELL® Data Demonstrating Statistically Significant Reduction in Donor Skin Requirements and Pain, Increased Patient Satisfaction and Improved Donor Scar Outcomes for Second-Degree Burn Patients

RECELL Device presentations include data from pivotal trial and health economic results showing 44 percent reduction in total treatment costs compared to standard of care

Valencia, Calif., USA, and Melbourne, Australia, 11 April 2018 — AVITA Medical (ASX: [AVH](#), OTCQX: [AVMXY](#)) announced today that results from a pivotal clinical trial demonstrating the effectiveness and clinical benefits of the RECELL® Autologous Cell Harvesting Device in the treatment of deep partial-thickness (second-degree) burns were presented in the Top-Five Abstract plenary session of the American Burn Association (ABA) 50th Annual Meeting in Chicago. In the randomized, controlled clinical trial, burn sites treated with the RECELL Device required 97.5 percent less donor skin than burn sites treated with the standard of care, resulting in a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved donor scar outcomes. The results were presented by William Hickerson, MD, FACS, Firefighter Burn Center, Memphis, Tenn., and University of Tennessee Health Science Center, Memphis, Tenn.

“The RECELL Device requires significantly less skin for definitive closure of deep partial-thickness burns without any compromise to healing or safety outcome,” said Dr. Hickerson. “These results are an important advancement in the treatment of burns. As a result of the significant reduction in donor skin with the RECELL Device, the trial results showed increased donor-site healing, reduced pain and increased patient satisfaction.”

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 trial served as one of two pivotal trials used to support AVITA Medical’s U.S. PreMarket Approval (PMA) application for the treatment of burn injuries.

Also presented at the ABA meeting were results of a health economic model in which treatment with the RECELL Device was found to reduce total treatment costs compared to the standard of care. A third presentation provided a review of clinical outcomes obtained in the treatment of patients with extensive burn injuries with the RECELL Device under the Compassionate Use Investigational Device program. Patients in this study were severely injured with burns ranging from 43 percent to 95 percent of their total body surface areas (TBSA), and the RECELL Device was successfully added to each patient’s treatment to achieve definitive wound closures.

Pivotal Trial in Deep Partial-Thickness Burns; Treatment with the RECELL Device Required 97 Percent Less Donor Skin than Standard of Care

The presentation by Dr. Hickerson, "A Comparative Study of RECELL Device and Autologous Split-Thickness Meshed Skin Graft in the Treatment of Acute Burn Injuries," described outcomes from the controlled trial conducted at 12 U.S. burn centers. The pivotal trial evaluating 101 adult patients with thermal, partial-thickness burns covering 1 percent to 20 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 RECELL Device, while the other burn site was treated with the standard treatment, 2:1 meshed autograft.

During the pivotal trial, the patient donor skin required to be harvested to treat burn sites with the RECELL Device was 97.5 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 (four subjects were excluded from the analysis because they were treated with silver sulfadiazine, a contra-indicated cytotoxic agent). Clinical benefits of the significant reduction in donor skin harvested for RECELL treatment included:

- Significantly less donor-site pain ($p \leq 0.0025$).
- Significantly higher patient satisfaction with donor-site appearance ($p \leq 0.0025$)
- Significantly better donor-site scarring results ($p \leq 0.0025$)
- Significantly greater incidence of donor-site healing at two weeks ($p < 0.001$)
- At two weeks after treatment, a 4.4 greater rate of healing compared with conventional autograft donor sites

Consistent with the results of more than 7,000 uses of the RECELL Device worldwide, use of the RECELL Device in the trial was safe and well tolerated with adverse experiences typical for the type of burn injury sustained.

RECELL Device Could Reduce Cost of Treating Large Burns by 44 Percent or More

Kevin Foster, MD, of the Arizona Burn Center presented the results of a health economic model in "Cost-Effectiveness of an Autologous Cell Harvesting Device (ACHD) Versus Standard of Care (SOC) for Treatment of Severe Burns in the United States." Treatment with the RECELL Device was found to reduce total treatment costs compared to the standard of care, particularly for large burns and burns initially of indeterminate depth. The model determined that the RECELL Device could reduce the cost of treatment by 44 percent or greater for large burns.

"Management of severe burns is costly due to complex, individualized treatment, and the requirement for hospitalization and multiple procedures," said Dr. Foster. "The model discussed today highlights the potential of the RECELL Device to improve patient care in the treatment of severe burns, while also providing a technique for reducing the total cost of treatment."

The presentation described how a hospital-perspective cost-effectiveness model was developed, which uses sequential decision trees to depict the acute care pathway for burn patients, and then predicts how the RECELL Device would modify treatment for patients with burns ranging from 10 percent to 40 percent TBSA. Clinical inputs were derived from randomized controlled trials, burn surgeon surveys and interviews and the ABA National Burn Repository. An accompanying budget impact model builds on the cost-effectiveness calculations to evaluate overall cost impact to a burn center associated with incorporation of the RECELL

Device into patient care. This enables the model to be tailored to patient populations relevant to individual hospitals, healthcare systems and other organizations engaged in the treatment of burn patients around the world.

The model determined that treatment with the RECELL Device for deep partial-thickness burns reduced total treatment costs by an average of 33 percent, or approximately \$33,000, for patients with 10 percent TBSA and 44 percent, or approximately \$203,000, for patients with 40 percent TBSA. For full-thickness burns, treatment with the RECELL Device reduced total treatment cost by 7 percent, or approximately \$11,000, for patients with 10 percent TBSA, and by 20 percent or approximately \$154,000, for patients with 40 percent TBSA. The cost reductions are due to decreasing the length of hospital stay, the number of procedures required to close the burn wound, the donor site size and associated wound care, and number of downstream contracture release procedures. The cost reductions could be higher for patients with larger TBSAs.

The budget impact model was also used to calculate the annual budget impact of current management of burn treatment versus treatment with the RECELL Device for a burn center with 200 patients. The model determined that treatment with the RECELL Device would reduce annual total treatment costs from \$43.3 million to \$30.3 million, saving 30 percent or \$13.0 million.

The model was developed by AVITA Medical, IQVIA™ and the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services. Funding provided by BARDA, under Contract No. HHSO100201500028C, to support the development of the RECELL Device by AVITA Medical has included support of the health economic model, the pivotal clinical trial in partial-thickness burns and the Compassionate Use program encompassed by the three presentations from 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 the RECELL Device 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. The 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. The 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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