



## **AVITA Medical RECELL® System Health Economic Data Projects USD \$28 Million in Annual Savings at a Single Major Burn Center Versus Standard of Care**

April 5, 2019

*Additional data presented at ABA Annual meeting include results demonstrating that donor sites treated using the RECELL System could be reharvested in as little as seven days after treatment*

*Patients with burns covering more than 50% of their bodies treated using the RECELL System in combination with widely meshed autografts healed as quickly as patients with smaller burn injuries with the same treatment*

**Valencia, Calif., USA, and Melbourne, Australia, 5 April 2019** — AVITA Medical (ASX: AVH, OTCQX: AVMXY) a global regenerative medicine company, announced health economic data projecting that use of the RECELL System to treat patients with severe burns could save a major U.S. burn center up to USD \$28 million annually compared to treatment with the standard of care. The health economic results were presented at the American Burn Association (ABA) 51st Annual Meeting in Las Vegas by Kevin Foster, MD, MBA, FACS, of the Arizona Burn Center, and were calculated based on the demographic mix of patients treated at that institution in 2018.

An additional presentation at the ABA meeting, awarded best in category at the conference, highlighted preliminary study results demonstrating that donor sites treated with the Spray-On Skin™ Cells prepared using the RECELL System could be reharvested in as little as seven days after treatment. Also presented were data showing that patients with extensive burns, greater than 50% total body surface area (TBSA), treated with Spray-On Skin Cells in combination with widely meshed autografts healed as quickly as patients with smaller burn injuries provided the same treatment combination. Patients from both the donor site and large TBSA presentations were treated under Compassionate Use and Continued Access programs which allowed treatment of patients with life-threatening burns in advance of the September 2018 approval to market the RECELL System in the U.S.

The RECELL System uses a small amount of a patient's own skin to prepare Spray-On Skin Cells at the point of care in as little as 30 minutes, providing a new way to treat thermal burns. Two randomized, controlled clinical trials demonstrated that treatment of acute burn wounds using the RECELL System required substantially less donor skin than conventional treatment to achieve closure of burn wounds. Reduction in donor skin requirements provides key clinical benefits to patients and significant reductions in the cost of treatment. The RECELL System was approved by the U.S. Food and Drug Administration (FDA) in September 2018 for the treatment of acute thermal burns in patients 18 years and older. The donor site and large TBSA presentations include classes of burns or injuries that are unapproved indications that fall outside of the currently approved U.S. product labeling. 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

### **RECELL Projected to Reduce Cost of Treating Severe Burns at Major Center by USD \$28 Million Annually**

The results of the health economic model were highlighted by Dr. Foster in a presentation titled "Budget impact of autologous cell harvesting device (ACHD) use versus standard of care (SOC) for treatment of severe burns: A case study for the Arizona Burn Center" and demonstrated:

- The Arizona Burn Center would save approximately USD \$28 million (16%) per year using the RECELL System versus the current standard of care (net of the cost of the RECELL System)
- The largest driver of the predicted cost savings is reduction in length of stay per patient, comprising 70% of the savings
- Also contributing to the estimated cost savings is an approximate 67% less autografting procedures, with reduction in operating room time contributing another 13% to the estimated cost savings

The Arizona Burn Center is part of the Maricopa Integrated Health System (MIHS), a major public teaching hospital and safety net system of care based in Phoenix.

"We now have a tool to economically assess any new intervention into the burn market, which can be used in our hospitals to determine fiscal responsibility of new treatments," said Kevin Foster, MD, MBA, FACS, of the Arizona Burn Center. "Based on the characteristics of our burn center and the patients we treated in 2018, use of the RECELL System is estimated to produce significant cost savings of about 16% of our total center costs, or approximately \$28 million per year. Key drivers of projected cost savings were decreased length of hospital stay, fewer autograft surgeries, reduced donor site size and associated wound care, and reduced rehabilitation needs."

To investigate the value proposition and potential transformative impact of Biomedical Advanced Research and Development Authority (BARDA) investments in burn care such as the RECELL System, an evaluation and modeling tool which emulated the cost-effectiveness in routine care was developed by IQVIA™, BARDA, and AVITA Medical. The BEACON model evaluates how practice patterns, interventions and patient characteristics interact across all phases of care (wound assessment, debridement/excision, temporary coverage and permanent closure) to understand how patient

and burn center outcomes change given the incorporation of a new burn care treatment, such as the RECELL System. Results from the model demonstrate that the RECELL System would reduce treatment costs for patients with burns ranging from 10 percent to 40 percent TBSA were presented last year at the 2018 ABA Annual Meeting and at a series of other burn and health economic meetings. As described in this week's presentation, the patient characteristics for the Arizona Burn Center (for example, age, burn depth, TBSA) were input into the BEACON model based on the 800 patients with 10% TBSA and greater burns treated in 2018 at the institution.

"Our ability to run this economic model based on the specific demographics of an individual burn center is a great resource to them as they evaluate the potential benefits of the RECELL System," said Dr. Michael Perry, Chief Executive Officer. "We thank Dr. Foster, IQVIA, BARDA and others who have participated in the development of the BEACON model. The cost savings benefits of the RECELL System demonstrated by the model complement the clinical benefits which are also being prominently featured in a series of ten presentations at the ABA meeting this week."

Funding and technical support for the development of the RECELL System is provided by 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, under ongoing USG Contract No. HHSO100201500028C. Programs funded under the BARDA contract include two randomized, controlled

pivotal clinical trials, the Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients.

## **Healing of Donor Sites after Treatment Using the RECELL System**

Another presentation by Dr. Foster, "Healing of Donor Sites with Autologous Skin Cell Suspension Enables Early Reharvesting for Large TBSA Burn Injuries: A Prospective Evaluation" described the treatment of donor sites in patients with large TBSA burn injuries. In large TBSA injuries the patient may not have enough donor skin available to allow for immediate treatment of the entire area of burn injuries with traditional autografting techniques. In severely burned patients with extensive injuries, surgeons often must wait until the donor sites have healed so that they can reharvest from the site, resulting in delays in treatment and healing and the need for multiple procedures and extended hospital time.

In the prospective observational study of 73 subjects with life-threatening thermal burn injuries treated under the Compassionate Use program, 426 donor sites wounds were treated with Spray-On Skin™ Cells prepared using the RECELL System. The mean TBSA of the patients in the study was 54% with burns ranging from 20% to 91% TBSA. Two weeks after treatment, 91% of the donor sites had healed in this compromised patient population, and 98% had healed by week eight. Donor sites treated using the RECELL System were able to be reharvested as early as seven days after treatment. No infection or delayed healing were reported for donor sites treated with Spray-On Skin™ Cells.

"The ability to reharvest additional donor skin from a site in as little one week after treatment with the RECELL system is extremely beneficial in this population of patients with extensive life-threatening injuries and limited available donor skin," said Kevin Foster, MD, MBA, FACS, of the Arizona Burn Center. "Treatment of donor sites using the RECELL System may provide improved healing rates as well as pain reduction and additional exploration of the potential benefits of the RECELL System should be undertaken."

## **Treatment of Patients with Burns Greater than 50% TBSA**

William Hickerson, MD, FACS, Firefighter Burn Center and University of Tennessee Health Science Center presented data showing that the use of the RECELL System in combination with meshed autografts achieves definitive closure for patients with burn injuries greater than 50% TBSA and achieved comparable outcomes to patients with less severe injuries in a presentation was titled "Evaluation of Autologous Skin Cell Suspension (ASCS) for Definitive Closure of Extensive Burn Injuries in an Adult Population." In patients with extensive burn injuries, lack of available donor skin is a major limitation in achieving permanent closure, and the longer a wound remains open the more susceptible a patient is to infection. The use of the RECELL System, a donor skin sparing technology that enables rapid definitive closure, has the potential to improve patient outcomes. The purpose of this study was to evaluate clinical outcomes for patients with life-threatening, greater than 50% TBSA burn injuries, in which the RECELL System was used in combination with widely meshed split-thickness autografts.

In this study of 35 patients with life-threatening thermal burn injuries, the RECELL System was used in combination with widely meshed split-thickness autografts to achieve definitive closure using minimal donor skin. For patients with greater than 50% TBSA burns, 150 burn wounds were treated with the combination of Spray-On Skin™ Cells and widely meshed split-thickness autografts, with 95% of the wounds achieving complete wound closure two months after treatment. For patients with equal to or less than 50% TBSA burns, 53 burn wounds were treated with the same combination and the rate of healing was similar to the large TBSA patients, with 92% of wounds achieving full healing two months after treatment

"The RECELL System combined with widely meshed split-thickness autografts achieved definitive closure and achieved healing outcomes for patients with life-threatening injuries greater than 50% TBSA, largely equivalent to those with less severe injuries equal to or less than 50% TBSA," said William Hickerson, MD, FACS, Firefighter Burn Center and University of Tennessee Health Science Center. "There were no device related adverse events and long-term durability was excellent."

###

## **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™ (RES™), 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 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://avitamedical.com>) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

In international markets, AVITA Medical's products are marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, acute wounds, scars and vitiligo. The RECELL System is TGA-registered in Australia and CFDA-cleared in China.

To learn more, visit [www.avitamedical.com](http://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:**

##### **U.S. Media**

##### **Sam Brown, Inc.**

Christy Curran

Phone +1-615.414.8668

[christycurran@sambrown.com](mailto:christycurran@sambrown.com)

##### **O.U.S Media**

##### **Monsoon Communications**

Sarah Kemter

Phone +61 (0)3 9620 3333

Mobile +61 (0)407 162 530

[sarahk@monsoon.com.au](mailto:sarahk@monsoon.com.au)

##### **Investors:**

##### **Westwicke Partners**

Caroline Corner

Phone +1-415-202-5678

[caroline.corner@westwicke.com](mailto:caroline.corner@westwicke.com)

##### **AVITA Medical Ltd**

Dale A. Sander

Chief Financial Officer Phone +1-661-367-9178

[dsander@avitamedical.com](mailto:dsander@avitamedical.com)