# RECELL System Insurance Coverage Begins in Japan for Treatment of Acute Burns

September 1, 2022

**Reimbursement in Japan will be similar to that of pricing in the United States**

VALENCIA, Calif. and MELBOURNE, Australia, Sept. 01, 2022 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration, announced today that COSMOTEC, an M3 Group Company, received insurance coverage in Japan for the RECELL® System for the treatment of acute burns.

“We are very pleased that the Japanese MHLW (Ministry of Health, Labour and Welfare) has granted the RECELL System marketing approval with favorable reimbursement that will be aligned with pricing in the United States,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “We look forward to continuing to work with our partner, COSMOTEC, as they launch and promote RECELL in the Japanese market.”

The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient’s own skin, 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.

“We will utilize the capabilities of our robust team to support the successful launch of RECELL in Japan,” said Mr. Tatsuro Tsutsumi, CEO of COSMOTEC. “With this product in market, we look forward to contributing to the treatment of burn patients with the goal of returning them to their daily lives as soon as possible.”

**About M3**
M3 Inc. is a publicly traded company on the Tokyo Stock Exchange (TYO:2413) with subsidiaries in major markets including USA, UK, Japan, South Korea, and China. M3 Inc. provides services to healthcare and the life science industry. In addition to market research, these services include medical education, ethical drug promotion, clinical development, job recruitment, and clinic appointment services. M3 Inc. operates in the US, Asia, and Europe with over 4.5 million physician members globally via its portals including MDLinx.com, m3.com, Doctors.net.uk, medigate.net and medlive.cn. M3 has offices in Tokyo, Washington D.C., Fort Washington, PA, Oxford, London, Beijing, and Seoul. Please visit https://corporate.m3.com/en/ for more information.

**About COSMOTEC**
COSMOTEC Co., Ltd., established in 1992 specialises in sales and consulting of medical devices focusing on cardiac surgery, general surgery and endovascular treatment. COSMOTEC has 98% market share of the institutions conducting cardiovascular surgery in Japan. COSMOTEC has offices in Tokyo, Sapporo, Sendai, Nagoya, Osaka, Okayama and Fukuoka across Japan. COSMOTEC is an M3, Inc., group company. Please visit http://cosmotec.com/english/ for more information.

**About AVITA Medical, Inc.**
AVITA Medical is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The RECELL® System technology platform, approved by the FDA for the treatment of acute thermal burns in both adults and children, harnesses the regenerative properties of a patient’s own skin to create Spray-On Skin™ cells. Delivered at the point-of-care, RECELL enables improved clinical outcomes and validated cost savings. RECELL is the catalyst of a new treatment paradigm and AVITA Medical is leveraging its proven and differentiated capabilities to develop first-in-class cellular therapies for multiple indications, including acute traumatic wounds and repigmentation of stable vitiligo lesions.

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 approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

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 15,000 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 approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, acute traumatic wounds, vitiligo, and aesthetics. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval in Japan. 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 and realization 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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