AVITA Medical Announces FDA 510(k) Clearance for Cohealyx, Expanding its Addressable Market

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- *New collagen-based dermal matrix designed for tissue generation, complementary to RECELL and PermeaDerm*
- *Cohealyx expected to triple AVITA Medical's addressable market in burns*

VALENCIA, Calif., Dec. 19, 2024 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a commercial-stage regenerative medicine company focused on first-in-class devices for wound care management and skin restoration, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for Cohealyx ™, a new collagen-based dermal matrix branded by AVITA Medical and co-developed with Regenity Biosciences. Cohealyx is designed for tissue integration and revascularization to facilitate wound healing, reduce treatment timelines, and improve patient outcomes in the treatment of full-thickness wounds.

Burns and full-thickness wounds penetrate all layers of the skin, resulting in significant tissue loss and structural damage. Unlike superficial wounds, full-thickness wounds lack the cellular components and structural support necessary to regenerate missing tissue. Without timely surgical intervention, there is heightened risk of delayed closure, infection, and severe scarring. Dermal matrices are essential in two-stage procedures for treating these wounds, as they support tissue generation for successful skin graft take and improve healing outcomes.

Cohealyx addresses this critical need in the treatment of full-thickness wounds with an advanced bovine collagen-based design engineered to facilitate cellular migration and blood vessel formation. Preclinical studies in porcine models demonstrated that Cohealyx generated robust tissue capable of consistently supporting a split-thickness skin graft in a two-stage procedure earlier than leading dermal matrices in the study. While animal model results do not necessarily translate to clinical results, this expedited timeline is anticipated to lead to quicker wound closure and streamlined clinician workflows, resulting in shorter hospital stays, reduced treatment costs, and better patient outcomes. These parameters will be evaluated in a clinical study.

"Cohealyx is a strategic addition to our RECELL-centric portfolio, unlocking the powerful synergies of RECELL and Cohealyx to address full-thickness wounds," said Jim Corbett, Chief Executive Officer of AVITA Medical. "This expansion to our product portfolio strengthens our ability to deliver superior patient outcomes and significantly expands our commercial potential in burns. By equipping clinicians with more comprehensive treatment options, we strengthen our competitive position, drive new growth opportunities, and further our commitment to advancing regenerative medicine."

Cohealyx strengthens AVITA Medical's portfolio by expanding its capabilities in the treatment of full-thickness wounds. Offered alongside RECELL and PermeaDerm®, Cohealyx enhances our comprehensive portfolio for addressing full-thickness wound care. This expanded portfolio is expected to triple AVITA Medical's addressable market in burns, as dermal matrices are a critical component of the standard two-stage surgical procedure for definitive closure of these wounds. We also anticipate Cohealyx will generate significant revenue as we penetrate the full-thickness skin defect market.

AVITA Medical plans to develop clinical data for Cohealyx in early 2025 to build on the preclinical success and support the product's commercial launch. The post-market clinical study will assess Cohealyx's performance in real-world settings, focusing on clinical efficacy and cost savings in the treatment of full-thickness wounds and burns. In the U.S., we expect to launch full commercialization efforts in the beginning of the second quarter of 2025.

About AVITA Medical, Inc.
AVITA Medical is a commercial-stage regenerative medicine company transforming the standard of care in wound care management and skin restoration with innovative devices. At the forefront of our platform is the RECELL System, approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient's own skin to create Spray-On Skin ™ Cells, delivering a transformative solution at the point-of-care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes. In the United States, AVITA Medical also holds the exclusive rights to market, sell, and distribute PermeaDerm, a biosynthetic wound matrix, and Cohealyx, an AVITA Medical-branded collagen-based dermal matrix.

In international markets, the RECELL System is approved to promote skin healing in a wide range of applications including burns, full-thickness skin defects, and vitiligo. The RECELL System, excluding RECELL GO ™, is TGA-registered in Australia, has received CE mark approval in Europe, and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

About Regenity Biosciences
Regenity Biosciences, a Linden Capital Partners portfolio company, is a leading global developer and manufacturer of bioresorbable technologies to repair and regenerate natural tissue and bone for a variety of markets including dental, spine, orthopaedic, sports medicine, advanced wound, neurosurgery, ENT, and nerve repair. Founded in 1997, Regenity (formerly Collagen Matrix, Inc.) is headquartered in Paramus, New Jersey, with manufacturing locations in Oakland and Allendale, New Jersey and Groningen, the Netherlands. Regenity's product portfolio includes a variety of collagen-based and synthetic polymer solutions that support the company's platform for tissue and bone regeneration. Regenity develops proprietary products that are sold to OEM customers on either a contract or private label basis and offers partnership opportunities including contract product development and manufacturing services. For more information, please visit www.regenity.com.

Forward-Looking Statements
This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-

looking statements are subject to significant risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements generally may be identified by the use of words such as "anticipate," "expect," "intend," "could," "would," "may," "will," "believe," "continue," "estimate," "look forward," "forecast," "goal," "target," "project," "outlook," "guidance," "future," and similar words or expressions, and the use of future dates. Forward-looking statements include, but are not limited to, statements relating to the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; anticipated market share growth and revenue generation from certain 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, as well as other economic or political conditions outside of the Company's control. These statements are made as of the date of this release, and the Company undertakes no obligation to publicly update or revise any of these statements, except as required by law. For additional information and other important factors that may cause actual results to differ materially from forward-looking statements, please see the "Risk Factors" section of the Company's latest Annual Report on Form 10-K and other publicly available filings for a discussion of these and other risks and uncertainties.

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

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