Organogenesis Achieves Primary Endpoint in Randomized Controlled Trial of PuraPly®AM

April 6, 2026

- Statistically significant (p<0.0477) DFU wound closure at 12 weeks
- RCT compared PuraPly®AM plus standard of care to standard of care alone
- Results strengthen existing clinical evidence supporting future coverage

CANTON, Mass., April 06, 2026 (GLOBE NEWSWIRE) -- Organogenesis Holdings Inc. (Nasdaq: ORGO), a leading regenerative medicine company focused on the development, manufacture and commercialization of product solutions for the Advanced Wound Care and Surgical and Sports Medicine markets, today announced the completion of a randomized controlled trial (RCT) evaluating PuraPly®AM plus standard of care (SOC) versus SOC alone in the management of non-healing diabetic foot ulcers (DFUs).

The prospective, multi-center, randomized controlled trial of 170 patients evaluated the safety and efficacy of PuraPly® AM plus SOC. The trial achieved its primary endpoint, demonstrating statistically significant wound closure at 12 weeks, compared to SOC alone ($p < 0.0477$). These findings further demonstrate the clinical effectiveness of PuraPly®AM in the management of DFUs expanding the body of evidence supporting its use. Organogenesis plans to publish the study results soon in a peer-reviewed journal.

"We are pleased to report primary endpoint achievement in this important study underscoring the clinical efficacy of PuraPly®AM in the management of non-healing DFUs," said Patrick Bilbo, Chief Operating Officer of Organogenesis. "These wounds pose a significant burden to patients and are extremely costly to our healthcare system. We believe publication of these impactful results will strongly support PuraPly® AM's inclusion in future coverage policies, underscoring its critical role in the healing paradigm."

PuraPly® AM is a patent-protected product that is differentiated among all skin substitutes by combining a native, cross-linked collagen matrix with polyhexamethylene biguanide (PHMB) antimicrobial to manage bioburden within the product and support healing.

About Organogenesis Holdings Inc.
Organogenesis Holdings Inc. is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the advanced wound care and surgical and sports medicine markets. Organogenesis offers a comprehensive portfolio of innovative regenerative products to address patient needs across the continuum of care. For more information, visit www.organogenesis.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as "future," "plan," "believe," "intend," "seek," "anticipate," "expect," "outlook," and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Such forward-looking statements include statements relating to the Company's expectations and beliefs regarding PuraPly AM's inclusion in future coverage policies and opportunities for PuraPly AM to generate revenue for the Company. Forward-looking statements with respect to the operations of the Company, strategies, prospects, and other aspects of the business of the Company are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These factors include, but are not limited to: (1) the impact of coverage and reimbursement levels for PuraPly AM and the Company's other products, particularly in light of CMS' updated 2026 Medicare reimbursement and coverage changes; (2) the Company faces significant and continuing competition, which could adversely affect its business, results of operations and financial condition; (3) rapid technological change could cause the Company's products to become obsolete and if the Company does not enhance its product offerings through its research and development efforts, it may be unable to effectively compete; (4) to be commercially successful, the Company must convince physicians that its products are safe and effective alternatives to existing treatments and that its products should be used in their procedures; (5) the Company's ability to raise funds to expand its business; (6) the Company has incurred losses in the prior periods and may incur losses in the future; (7) changes in applicable laws or regulations; (8) the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors; (9) the Company's ability to maintain production or obtain supply of its products in sufficient quantities to meet demand; (10) the Company's ability to build out its Smithfield, Rhode Island facility on time and on budget; (11) whether the Company is able to obtain regulatory approval for and successfully commercialize ReNu; and (12) other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission, including Item 1A (Risk Factors) of the Company's Form 10-K for the year ended December 31, 2025 and its subsequently filed periodic reports. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so from time to time, the Company undertakes no commitment to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

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