Organogenesis Announces Publication of Randomized Clinical Trial Results Demonstrating the Safety and Efficacy of NuShield for Diabetic Foot Ulcers

October 1, 2024

- Robust 218-patient RCT demonstrates statistically superior frequency of wound closure at 12 weeks compared to standard of care (p=.04)
- Organogenesis believes published study satisfies requirements for Medicare coverage under proposed Local Coverage Determination (LCDs)

CANTON, Mass., Oct. 01, 2024 (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 publication of "Dehydrated Amnion Chorion Membrane Versus Standard of Care for Diabetic Foot Ulcers: A Randomised Controlled Trial" in the *Journal of Wound Care*.

NuShield, a dehydrated amnion chorion membrane, demonstrated statistically superior frequency of wound closure (p=0.04) compared to standard of care (SoC) at weeks 4, 6, 8, 10, and 12 as determined by a Cox analysis that adjusted for both wound duration and wound area in a challenging patient population with complex diabetic foot ulcers (DFUs). A total of 218 patients with Wagner 1 or 2 grade DFUs were randomized into two treatment groups: NuShield plus SoC or SoC alone. The NuShield group demonstrated a 48% greater probability of wound closure and decreased median time to complete wound closure when compared to SoC alone.

"We are pleased this data demonstrates NuShield provides a significant advantage when managing DFUs, a severe medical crisis that often leads to amputations and associated higher mortality rates, especially in underserved populations," said Gary S. Gillheeney, Sr., President and Chief Executive Officer of Organogenesis. "As a leader in this field, we support CMS's evidence-based approach to coverage for these serious wounds and believe this large, peer-reviewed published RCT satisfies the requirements for Medicare coverage under the proposed LCDs."

Patients with diabetes are estimated to be at a 34% lifetime risk of developing a DFU and 20% of people with a DFU will require a lower extremity amputation[i]. DFUs disproportionately affect racial and ethnic minority populations and the rate of lower extremity amputation is significantly higher among these groups[ii]. According to the American Diabetes Association, the 5-year mortality rate for patients who receive an DFU-related amputation is higher than coronary artery disease, colorectal cancer or breast cancer.

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.

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 "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "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 whether the recently announced data from the NuShield RCT would satisfy the requirements for Medicare coverage under LCDs proposed by Novitas, FCSO and CGS, which LCDs remain subject to change. 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 any changes to the coverage and reimbursement levels for the Company's products (including as a result of the recently proposed LCDs or any changes to those proposed LCDs); (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 current period and 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) any resurgence of the COVID-19 pandemic and its impact, if any, on the Company's fiscal condition and results of operations; and (11) 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, 2023 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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[i] McDermott K, Fang M, Boulton AJM, Selvin E, Hicks CW. Etiology, Epidemiology, and Disparities in the Burden of Diabetic Foot Ulcers. Diabetes Care. 2023 Jan 1;46(1):209-221. doi: 10.2337/dci22-0043. PMID: 36548709; PMCID: PMC9797649

[ii] https://diabetes.org/advocacy/amputation-prevention-alliance/resources

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