Organogenesis Announces Successful FDA Meeting and Plan to File BLA for ReNu® for Knee Osteoarthritis Pain

December 15, 2025

Clinical Development Program Appropriate for Rolling BLA

Submission Expected by the End of 2025

CANTON, Mass., Dec. 15, 2025 (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 successful completion of a planned Type-B meeting with the Food and Drug Administration (FDA) resulting in confirmation to initiate a rolling Biologics Licenses Application (BLA) for ReNu planned before the end of December.

"We are excited about the outcome of our FDA meeting and reaching this important milestone in the ReNu program," said Patrick Bilbo, Chief Operating Officer of Organogenesis. "We are pleased the ReNu clinical development program consisting of two large Phase 3 randomized controlled trials (RCT), a separate 200-patient RCT, extensive commercial history and Regenerative Medicine Advanced Therapy (RMAT)-designation is appropriate for BLA submission. If approved, we believe that ReNu will address a significant medical need for a large and growing patient population."

Knee OA is a degenerative joint disease that is estimated to affect nearly 31.1 million Americans and projected to grow to 34.4 million Americans by 2027. It is ranked among the most common causes of disability and poor quality of life, generally characterized by pain and functionality deficits. End stage management of the disease in these patients is typically a total knee replacement when all other treatment options are exhausted.

About ReNu®
ReNu is a cryopreserved, amniotic suspension allograft developed for the management of symptomatic knee osteoarthritis. ReNu consists of amniotic fluid cells and micronized amniotic membrane and contains cellular, growth factor, and extracellular matrix components. ReNu has been studied in three large RCTs consisting of more than 1,300 patients and received FDA RMAT designation for Knee OA in 2021. ReNu was previously marketed under Section 361 of the Public Health Service Act and was commercially available for approximately six years.

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 “planned,” “intend,” “seek,” “anticipate,” “believe,” “expect,” “estimate,” “potential” and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters, including statements regarding the anticipated timing of regulatory submissions and interactions. These statements concern, and these risks and uncertainties include, among others: the risks and uncertainties inherent in clinical development; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to develop or commercialize ReNu; the likelihood and timing of possible regulatory approval and commercial launch of ReNu: the FDA may conclude the data we submit for ReNu is not sufficient for BLA approval; the FDA may require additional evidence for ReNu before we can get a BLA approved, which we may not be able to obtain; that other clinical trials of ReNu may produce different results; ongoing regulatory obligations and oversight impacting ReNu; unforeseen safety issues resulting from the administration of ReNu in patients; competing products and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of ReNu and the impact of studies (whether conducted by us or others and whether mandated or voluntary) on the commercial success of ReNu; our ability to manufacture and manage supply components for ReNu; the availability and extent of reimbursement of ReNu from third-party payers, including private payer healthcare and insurance programs and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers, including local coverage determinations by Medicare Part A/B Medicare Administrative Contractors; new policies and procedures adopted by such payers; unanticipated expenses; the costs of developing, producing, and selling ReNu; our ability to meet our sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; and 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, 2024 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.

Investor Inquiries: ICR Healthcare Mike Piccinino, CFA OrganoIR@westwicke.com Press and Media Inquiries: Organogenesis Communications@organo.com