Organogenesis Provides Update on Second Phase 3 ReNu® Study

September 25, 2025

Company maintains confidence in ReNu as innovative pain management therapy

- Second Phase 3 trial demonstrates numerical improvement in baseline pain reduction over the first Phase 3 trial despite not meeting the primary endpoint
- Statistically significant maintenance of function (p<0.0001)
- Company will request pre-BLA meeting with FDA to discuss submission pathway

CANTON, Mass., Sept. 25, 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 that the second Phase 3 randomized controlled trial (RCT) of ReNu, a cryopreserved amniotic suspension allograft (ASA) for the management of symptoms associated with knee osteoarthritis (OA), did not achieve statistical significance for its primary endpoint, despite the ReNu results demonstrating a numerical improvement in baseline pain reduction over the first Phase 3 trial. Baseline pain reduction at six months for ReNu was -6.9 for the second Phase 3 study compared to -6.0 in the first Phase 3 study. Additionally, the ReNu results continued to demonstrate a favorable safety profile.

The primary endpoint for the study is the difference between ReNu and Saline groups in the reduction in knee pain at six months assessed by the Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain scale. The study demonstrated a numerical improvement of -0.5[1] favoring ReNu (p=0.0393 one-sided p-value, compared to p=0.023 target threshold). The first Phase 3 trial achieved improvement of -0.7[2] favoring ReNu, which was statistically significant (p=0.0177, one sided p-value, compared to p=0.023 target threshold).

“Given the first Phase 3 trial achieved a statistically significant reduction in pain compared to Saline and the second Phase 3 trial demonstrated a numerical improvement in baseline pain reduction over the first Phase 3, we believe these results support the potential approval of ReNu for pain symptoms associated with knee OA, including those patients classified as most severe,” said Patrick Bilbo, Chief Operating Officer of Organogenesis. “As a next step, we will request a pre-BLA meeting with the FDA by the end of October to discuss the submission pathway, including using the combined efficacy analysis from both Phase 3 studies to support a BLA approval.”

ReNu has now been studied in three large RCTs of more than 1,300 patients combined. Organogenesis believes the totality of this data is compelling evidence for the FDA to review in a Biologics License Application (BLA). Additionally, the FDA granted ReNu Regenerative Medicine Advanced Therapy (RMAT) designation based on ReNu demonstrating the potential to treat an unmet medical need related to a serious condition.

“The results for ReNu support our continued confidence in the potential of ReNu as an innovative pain management product,” said Gary S. Gillheeney, Sr., President, Chief Executive Officer and Chair of the Board for Organogenesis. “We believe ReNu, if approved, will address a significant unmet medical need for the millions of Americans suffering from symptomatic knee OA.”

Knee OA is a degenerative joint disease that is estimated to affect more than 30 million Americans. 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.

The fully enrolled 594 patient second Phase 3 trial is a prospective, double-blind, multicenter, saline-controlled, parallel group, RCT of ReNu ASA, for the treatment of subjects with mild to severe symptomatic knee OA. Patients were randomized to receive a single intra-articular (IA) injection of either saline control or ReNu.

Additional top-line data tables from both Phase 3 studies are available in a Current Report on Form 8-K, which the Company filed today with the SEC and can be found at SEC.gov.

About ReNu®
ReNu is a cryopreserved, amniotic suspension allograft (ASA) 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 received FDA Regenerative Medicine Advanced Therapy (RMAT) designation for Knee OA in 2021.

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 “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. These statements concern, and these risks and uncertainties include, among others: the risks and uncertainties inherent in clinical development; the FDA may require additional evidence for ReNu before we can submit a BLA or get a BLA approved, which we may not be able to obtain; that other clinical trials of ReNu may produce different results; the likelihood and timing of possible regulatory approval and commercial launch of ReNu; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to develop or commercialize ReNu; 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.

[1] Second Phase 3 Reduction in baseline knee pain at six months assessed by WOMAC pain scale: ReNu -6.9 & Saline -6.4

[2] First Phase 3 Reduction in baseline knee pain at six months assessed by WOMAC pain scale: ReNu -6.0 & Saline -5.3

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