Organogenesis Reports Positive Interim Analysis of Phase 3 Clinical Trial of ReNu for Knee Osteoarthritis

March 1, 2023

CANTON, Mass. , March 01, 2023 (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 reported the favorable outcome of the interim analysis of its Phase 3 clinical trial for the management of symptoms associated with knee osteoarthritis.

The pre-specified interim analysis on 50% of the 474 required patients with moderate to severe knee osteoarthritis (Kellgren-Lawrence [KL] severity grade 2 to grade 4) focused on the 6-month primary endpoint for potential sample size re-estimation. The Independent Data Monitoring Committee (DMC) for the trial provided directional guidance on the results of the interim analysis, while rigorously maintaining all aspects of study blinding. The DMC recommended that the trial proceed without modification and without increase to sample size. Additionally, the DMC found the safety data to be consistent with the known safety profile for ReNu.

"We are very pleased with the outcome of the interim analysis," said Patrick Bilbo, Chief Operating Officer of Organogenesis. "Based on these statistical results in the favorable zone, we believe the positive clinical results for pain reduction predicted before the start of our pivotal trial are more likely. The assumptions for the statistical modeling and sample size of the trial were based on the successful, published two hundred patient trial."

Eric Strauss, MD, Professor of Orthopedic Surgery at NYU Langone Medical Center, and Co-Principal Investigator of the trial said, "The trial is progressing as expected with respect to patient safety and efficacy. We are encouraged by the favorable outcome of this interim analysis as one more step forward toward improving the management of knee osteoarthritis symptoms, especially for the most severe (KL4) patients, who are not adequately addressed with current non-surgical treatment modalities."

The fully enrolled 516 patient Phase 3 trial is a prospective, double-blind, multicenter, placebo-controlled, parallel group, randomized control trial (RCT) of ReNu, a cryopreserved amniotic suspension allograft (ASA), for the treatment of subjects with moderate to severe symptomatic knee osteoarthritis (OA). Patients were randomized to receive a single intra-articular (IA) injection of either saline control or ReNu. The primary endpoint is the reduction in knee pain assessed by the Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain scale performed on subjects treated with ReNu or saline.

OA is a degenerative joint disease that affects more than thirty million Americans and accounts for more than $185 billion in annual expenditures. Knee OA has been estimated to affect fourteen million Americans ages twenty-five and older, with nearly eight million under the age of sixty-five. The number of knee replacement surgeries is growing every year and expected to rise from approximately 680,000 Americans in 2014 to 1.28 million Americans in 2030.

Forward-Looking Statements
This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the likelihood that our Phase 3 trial of ReNu will meet its primary endpoints. These forward-looking statements relate to expectations or forecasts of future events. Forward-looking statements with respect to the Company's Phase 3 clinical trial 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 the risks and uncertainties inherent in clinical development; that interim results are not necessarily indicative of final results; 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, 2022. 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.

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.

Investor Inquiries: ICR Westwicke Mike Piccinino, CFA OrganoIR@westwicke.com Press and Media Inquiries: Organogenesis Ron O'Brien robrien@organo.com