Organogenesis Enrolls First Patient in Pivotal Phase 3 Clinical Trial of RMAT-Designated ReNu® for Knee Osteoarthritis

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CANTON, Mass., Jan. 14, 2021 (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 & Sports Medicine markets, today announced that the first patient has been enrolled in its pivotal Phase 3 clinical trial evaluating the safety and efficacy of ReNu®, a cryopreserved amniotic suspension allograft (ASA), for the management of symptoms associated with knee osteoarthritis (OA).

"We are very pleased to have initiated our ReNu pivotal Phase 3 trial," said Patrick Bilbo, Chief Operating Officer for Organogenesis. "This significant milestone comes on the heels of the FDA's RMAT designation underscoring the strength of our existing ReNu clinical evidence and its potential to address a largely unmet medical need. We look forward to leveraging our RMAT designation to work closely with the FDA to expedite the review of ReNu as the study progresses."

The Phase 3 study is a prospective, double-blind, multicenter, placebo-controlled, parallel group, randomized control trial (RCT) of ReNu in 474 subjects with moderate to severe symptomatic knee osteoarthritis. Patients will be randomized to either a single intra-articular (IA) injection of saline (placebo control) or a single injection of ReNu. The primary efficacy endpoint is the difference in pain from baseline to 6 months as assessed by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

OA is a degenerative joint disease that affects more than 30 million Americans and accounts for more than $185 billion in annual expenditures. Knee OA has been estimated to affect approximately 14 million Americans ages 25 and older, with nearly 8 million under the age of 65. 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.

About ReNu®

ReNu® is a cryopreserved, amniotic suspension allograft (ASA) for the treatment of symptomatic knee osteoarthritis. ReNu consists of amniotic fluid cells and micronized amniotic membrane and contains cellular, growth factor, and extracellular matrix components.

Learn more at https://organogenesis.com/surgical-sports-medicine/renu/

About Organogenesis Holdings Inc.

Organogenesis Holdings Inc. is a leading regenerative medicine company offering a portfolio of bioactive and acellular biomaterials products in advanced wound care and surgical biologics, including orthopedics and spine. Organogenesis's comprehensive portfolio is designed to treat a variety of patients with repair and regenerative needs.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about the potential benefits of an RMAT designation. These forward-looking statements relate to expectations or forecasts for future events. Forward-looking statements may be identified by the use of words such as "will," "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "outlook," "extend," "continue" and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements 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 risks related to the Company's ability to maintain and benefit from RMAT designation, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities, in addition to 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, 2019. 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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