Organogenesis Shares ReNu® Program Update

August 8, 2024

- On track to submit ReNu BLA by the end of 2025
- Enrollment in second Phase 3 complete; significantly ahead of expectations
- Subgroup analysis demonstrated most severe (KL4) subjects responded comparably to moderate (KL3)

CANTON, Mass., Aug. 08, 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 a development program update for ReNu®, a cryopreserved amniotic suspension allograft (ASA), for the management of symptoms associated with knee osteoarthritis (OA).

Organogenesis completed a Type-B meeting with the Food and Drug Administration (FDA) on July 25th. The FDA typically requires two well-controlled Phase 3 clinical trials to support regulatory approval. The FDA indicated that a second Phase 3 study would be needed to support BLA submission. Organogenesis recently completed enrollment in the second Phase 3 multi-center RCT evaluating the safety and efficacy of ReNu with 594 patients, significantly outperforming enrollment expectations. Based on the success of the first Phase 3 study and the completion of enrollment of the second study, Organogenesis expects to submit the BLA by the end of 2025.

“We are pleased with the progress we have made in the ReNu development program as the feedback we have received from our investigators along with the quick pace of enrollment suggests that clinicians and patients are eager for a non-surgical option for knee OA pain,” said Patrick Bilbo, Chief Operating Officer of Organogenesis. “The addition of our second clinical trial strengthens our position as the combined Phase 3 studies will increase the number of patients evaluated to more than 1,100, significantly enhancing the robustness of the evidence package for the BLA program and the evidence available to clinicians.”

Additionally, subgroup data analysis revealed that the most severe patients (Kellgren-Lawrence [KL] grade 4) treated with ReNu responded with similar reductions in pain to those patients with moderate disease (KL 3), supporting the top line results. As previously announced, the first Phase 3 randomized clinical trial (RCT) achieved the pre-defined requirements for study success - statistically significant reduction in knee pain ($p=0.0177$) and statistically significant maintenance of function ($p<0.0001$), at six months. Additional sensitivity analysis showed that subjects in the saline group took substantially more (30%) acetaminophen for break through pain during the study.

“We are pleased with the response of the most severe knee OA patients, who are unlikely to respond to non-surgical treatment,” continued Mr. Bilbo. “If approved, ReNu will have the unique opportunity to address a critical unmet medical need for all knee OA patients, including the most severe cases for whom non-surgical treatment options are very limited and which represent approximately 15% of Americans with knee OA.”

About Knee OA
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. Up to 15 percent of knee OA patients are classified as severe (Kellgren-Lawrence grade 4). 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 (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.

Forward-Looking Statements
This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our ReNu product. 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,” “if approved,” “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. These statements concern, and these risks and uncertainties include, among others: the risks and uncertainties inherent in clinical development; that interim results are not necessarily indicative of final results; 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 our filings with the Securities and Exchange Commission, including Item 1A (Risk Factors) of our Form 10-K for the year ended December 31, 2023 and our 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 we may voluntarily do so from time to time, we undertake 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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