Organogenesis ReNu® Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation For Osteoarthritis of the Knee

January 11, 2021

FDA Determines ReNu Preliminary Clinical Evidence Indicates Potential to Address Unmet Medical Needs for the Management of Symptoms Associated with Knee Osteoarthritis

RMAT Designation Enables Closer FDA Interactions to Support Accelerated Approval

CANTON, Mass., Jan. 11, 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 U.S. Food and Drug Administration (FDA) has granted ReNu®, a cryopreserved amniotic suspension allograft for the management of symptoms associated with knee osteoarthritis (OA), Regenerative Medicine Advanced Therapy (RMAT) designation.

The FDA created the RMAT designation program to expedite development and review of regenerative medicine therapies intended to treat, modify, reverse or cure a serious or life-threatening disease or condition. To qualify for RMAT designation, a therapy must also be supported by preliminary clinical evidence indicating the potential to address unmet medical needs related to the serious condition.

“Securing RMAT designation is a significant milestone for ReNu that underscores the potential impact of this therapy for knee osteoarthritis,” said Gary S. Gilheeney, Sr., President and CEO of Organogenesis. “We are very pleased that the FDA has provided us with these key regulatory advantages and a pathway for expedited approval of ReNu for this degenerative and life-altering disease.”

RMAT designation includes all of the benefits of the *Fast Track* and *Breakthrough Therapy* designation programs. It also provides the advantage of early interactions and intensive guidance from the FDA on development of the therapy, including potential priority review of the biologics license application (BLA) and potential ways to support accelerated approval and satisfy post-approval requirements.

The FDA granted RMAT designation for ReNu based on clinical evidence from a 200 patient multicenter single-blinded randomized controlled trial demonstrating at 6 months that patients with knee OA treated with ReNu experienced a statistically significant reduction in pain and improvement in function compared with hyaluronic acid, a commercially available therapy commonly used to treat knee OA, and saline.

OA is a degenerative joint disease affecting 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 management of symptomatic knee osteoarthritis. ReNu® consists of amniotic fluid cells and micronized amniotic membrane and contains cellular, growth factor, and extracellular matrix components.

To learn more about ReNu, visit https://organogenesis.com/surgical-sports-medicine/renu/.

About Organogenesis
Organogenesis 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. For more information, visit www.organogenesis.com.

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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