# Organogenesis Announces FDA Acceptance of Biologics License Application for ReNu® for the Management of Symptomatic Knee Osteoarthritis

July 6, 2026

**PDUFA Target Action Date Set for April 24, 2027**

CANTON, Mass., July 06, 2026 (GLOBE NEWSWIRE) -- Organogenesis Holdings Inc. (Nasdaq: ORGO), a leading regenerative medicine company focused on product solutions for the Advanced Wound Care and Surgical and Sports Medicine markets, today announced that the U.S. Food and Drug Administration (FDA) has completed their filing determination and accepted for review the Company's Biologics License Application (BLA) for ReNu®, a cryopreserved, amniotic suspension allograft developed for the treatment of pain in symptomatic knee osteoarthritis (OA). The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of April 24, 2027.

"We are pleased to reach this important milestone and look forward to working with the FDA as they complete their review," said Patrick Bilbo, Chief Operating Officer of Organogenesis. "We are now one step closer to our goal of bringing the first non-surgical biologic therapy to the millions of Americans whose lives are impacted by knee OA pain."

Knee OA is a degenerative joint disease that is estimated to affect nearly 31 million Americans and projected to grow to more than 34 million Americans by 2027. It is ranked among the most common causes of disability and poor quality of life, generally characterized by pain and functional deficits. End stage management of the disease in these patients is typically a total knee replacement when all other treatment options have been exhausted.

**About ReNu®**

ReNu® is a cryopreserved, amniotic suspension allograft developed for the treatment of pain in symptomatic knee osteoarthritis. ReNu® consists of amniotic fluid cells and micronized amniotic membrane and contains cellular, growth factor, and extracellular matrix components. ReNu has been studied in three large RCTs consisting of more than 1,300 patients and received FDA RMAT designation for Knee OA in 2021.

The FDA has conditionally accepted Amnuvx (azimplacel) as the proprietary name, pending review and approval by the FDA.

**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 "planned," "goal," "projected," "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, including statements regarding the anticipated impact ReNu, if approved, will have on treatment options. These statements concern, and these risks and uncertainties include, among others: the risks and uncertainties inherent in clinical development; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to develop or commercialize ReNu; the likelihood and timing of possible regulatory approval and commercial launch of ReNu; the FDA may conclude the data we submit for ReNu is not sufficient for BLA approval; the FDA may require additional evidence for ReNu before we can get a BLA approved, which we may not be able to obtain; that other clinical trials of ReNu may produce different results; 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, 2025 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.

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