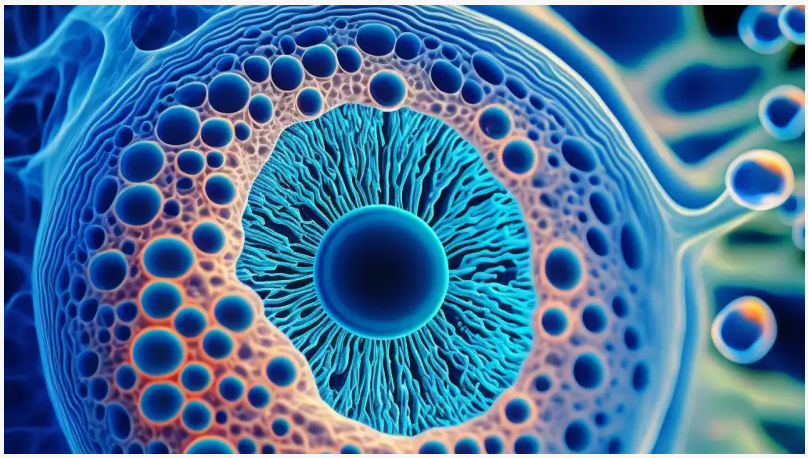
TriCelX Receives FDA Study May Proceed Letter for XytriX™

The FDA has issued a Study May Proceed letter for TriCelX's Phase 1/2 IND application for XytriX™, authorizing the commencement of the clinical trial.


Mesenchymal Signaling Cells (MSCs)

FRISCO, TX, UNITED STATES, April 23, 2026 /EINPresswire.com/ -- TriCelX, Inc. ("TriCelX"), a global translational leader in evidence-based biologics, today announced that the U.S. Food and Drug Administration (FDA) has issued a Study May Proceed letter in connection with TriCelX's Phase 1/2 Investigational New Drug (IND) application for XytriX™, its proprietary allogeneic umbilical cord tissue-derived mesenchymal stem cell (hUC-MSC) biotherapeutic for the treatment of adult patients with Grade I–IV Knee Osteoarthritis (KOA). The FDA's Study May Proceed letter clears TriCelX to initiate the clinical trial as designed. Concurrent with the IND, TriCelX has submitted a formal request for Regenerative Medicine Advanced Therapy (RMAT) designation — one of the FDA's highest-priority development pathways. The FDA has not yet issued a decision on the RMAT designation request, which remains pending.

A Disease in Desperate Need of a Better Answer

Osteoarthritis (OA) is the world's most prevalent joint disease, affecting more than 500 million people globally and one in seven American adults. The knee is the most commonly affected joint. OA imposes a staggering economic burden exceeding $137 billion in the United States alone and is a leading cause of disability, chronic pain, and diminished quality of life. Today's standard-of-care interventions — including corticosteroid injections — manage symptoms at best, and carry serious risks including cartilage degradation, tendon rupture, hyperglycemia, and rapid joint destruction. No disease-modifying therapy is currently approved.

XytriX™: A Potential Disease-Modifying Biotherapeutic

XytriX™ is a next-generation, off-the-shelf allogeneic cell therapy derived from Wharton's jelly of donated human umbilical cords. Unlike existing symptomatic treatments, XytriX™ is designed to address the underlying biology of knee OA through multiple complementary mechanisms —

including immunomodulation, anti-inflammatory signaling, stimulation of endogenous progenitor cells, promotion of cartilage formation and collagen deposition, and cytoprotection against cell death. More than two decades of published evidence on hUC-MSCs support a favorable safety profile, with a landmark 2026 systematic review and meta-analysis reporting no serious adverse events attributable to MSC therapy across randomized controlled trials and a favorable short-to-medium-term safety profile.

XytriX™ is manufactured to exacting standards at TriCelX's FDA-registered cGMP/cGTP-compliant facility in Frisco, Texas. Each batch is rigorously tested for sterility, endotoxin levels, and MSC identity marker profiles, and cryopreserved in a serum-free, animal-component-free medium — ensuring consistency, purity, and readiness for clinical use.

RMAT Designation Request: Pending FDA Decision
Concurrent with the IND filing, TriCelX submitted a formal request for FDA RMAT designation. The FDA has not yet issued a decision on the RMAT request, which remains under review. RMAT designation is granted by the FDA to regenerative medicine therapies that show preliminary clinical evidence supporting the potential to address serious or life-threatening conditions. If granted, RMAT designation would provide TriCelX with a suite of accelerated development advantages:

- Accelerated FDA Engagement: Early and frequent interactions with the FDA's Center for Biologics Evaluation and Research (CBER)/Office of Tissues and Advanced Therapies (OTAT)
- Rolling BLA Review: The ability to submit and receive review of sections of the Biologics License Application (BLA) on a rolling basis, compressing the path to approval
- Priority Review: An expedited BLA review timeline, consistent with the FDA's Priority Review designation framework
- Additional Development Tools: Use of accelerated approval and breakthrough therapy designation tools to further streamline development

TriCelX's RMAT request is grounded in the extensive published body of clinical evidence demonstrating MSC efficacy and safety in knee OA, including multiple randomized controlled trials, systematic reviews, and meta-analyses — culminating in the 2026 Wang et al. systematic review confirming favorable outcomes with intra-articular MSC therapy.

Phase 1/2 Clinical Trial Design
The Phase 1/2 trial — formally titled "A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Intra-Articular (IA) Injection of XytriX™ in Adult Subjects with Grade I–IV Knee Osteoarthritis (KOA)" — is a prospective, single-center study enrolling approximately 50 adult subjects at TriCelX's Frisco, Texas clinical site. Enrolled subjects will receive a single intra-articular injection of 30 million hUC-MSCs (~3 mL) — a dose selected based on published evidence demonstrating optimal efficacy with an acceptable safety margin.

Participants will be monitored over a 180-day follow-up period with assessments at 1, 3, and 6

months using validated, clinically rigorous outcome measures including the Knee Injury and Osteoarthritis Outcome Score (KOOS), WOMAC Index, 100-mm Visual Analog Scale (VAS) for pain, SF-36 Quality of Life survey, and the Timed Up and Go (TUG) functional test. A Data Safety Monitoring Board (DSMB) will provide independent safety oversight throughout the trial.

“The FDA’s Study May Proceed letter is a critical validation of the scientific rigor and clinical rationale embedded in our XytriX™ IND submission. We are now cleared to initiate what we believe will be a landmark clinical trial for the hundreds of millions of patients worldwide who are suffering from osteoarthritis and have run out of options. XytriX™ is not simply another symptomatic treatment — it is designed to harness the body’s own regenerative biology to address the root cause of joint destruction. We remain optimistic about our pending RMAT designation request and look forward to a productive, ongoing collaboration with the FDA as we advance this promising therapy toward patients.”
— Jakes Jordaan, Founder and Chief Executive Officer, TriCelX, Inc.

About TriCelX, Inc.
Led by world-class scientists and surgeons, TriCelX is a global translational biologics company dedicated to advancing evidence-based, personalized regenerative medicine therapies. With operations in Texas, Utah, and Antigua, TriCelX offers globally harmonized cell therapy solutions designed to harness the regenerative power of afterbirth-derived Mesenchymal Signaling Cells (MSCs). TriCelX’s proprietary platform enables MSCs to differentiate into connective tissue, regenerate neurons, reduce neuroinflammation, and modulate the immune system. In addition to its XytriX™ program, TriCelX is developing novel biological medical countermeasures to address the unique battlefield challenges faced by the U.S. military. For more information, visit www.tricelx.com

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