FDA Clears TriCelX's Third IND: XytriX™ ALS Study May Proceed — Extending the Company's CTE Program into ALS

Phase 1/2 study will give XytriX™ by intravenous infusion and — for the first time — by needle-free intranasal delivery to people recently diagnosed with ALS

FRISCO, TX, UNITED STATES, September 28, 2026 /EINPresswire.com/ -- TriCelX, Inc. today announced that the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research has notified the company that its Phase 1/2 study of XytriX™ in amyotrophic lateral sclerosis (ALS) may proceed under IND 33245. It is TriCelX's third IND cleared to proceed in 2026, following knee osteoarthritis (IND 32759, April) and chronic traumatic encephalopathy, or CTE (IND 32912, June). All three programs run on the same product, XytriX™, made from the same cell banks to the same release standards.

From CTE to ALS

The ALS program is a direct extension of TriCelX's CTE work, and the link runs through the same people. Former NFL players die of ALS at more than four times the rate expected in the general population (Luster et al., eClinicalMedicine, 2026). Military veterans develop ALS at higher rates than civilians — a finding strong enough that the Department of Veterans Affairs treats ALS as presumptively service-connected. And in April 2026 the Boston University CTE Center reported that Pro Football Hall of Famer Steve McMichael, who died of ALS in 2025, had Stage 3 CTE. Whether the two diseases share a cause is not settled. What they share is a feature: chronic inflammation in the brain and spinal cord, which is central to CTE and a consistent part of ALS. That shared process — not either disease's signature protein — is what XytriX™ is designed to act on. The two programs are also linked in practice: the intravenous arms of the ALS study will not open until the independent safety board overseeing the CTE study has reviewed its first intravenous cohort and cleared that same dose.

The science

"ALS is not only a disease of dying motor neurons. It is a disease of the inflamed environment around them," said Abdul Baker, MD, FAANS, FACS, FCNS, Chief Medical and Scientific Officer of TriCelX and Principal Investigator of the study. "The immune cells of the brain and spinal cord that should protect those neurons turn against them, and the blood–brain barrier that should shield them starts to fail. XytriX™ is built to work in that environment. These are signaling cells — they don't need to become neurons, and we don't believe they need to cross the barrier to do their work. They read the inflammation and answer it: calming the immune response and

releasing the growth factors and vesicles that help surviving motor neurons hold on to their connections. Given into a vein, they act where the barrier is already breaking down. Given through the nose, they are designed to travel the olfactory and trigeminal nerve pathways and go around the barrier altogether. Two routes, one purpose — reach the fire, and protect what is still standing."

The protocol

Protocol TCX-ALS-001 is an open-label Phase 1/2 study of 20 adults with ALS, enrolled early — within 18 months of first symptoms and 12 months of diagnosis — while there are still motor neurons to protect. Participants are assigned to one of four arms of five: intravenous XytriX™; intranasal XytriX™ at two dose
levels; or intranasal and intravenous combined. Each receives three monthly treatment cycles over twelve weeks. XytriX™ is given on top of standard care, and participants stay on their existing ALS medicines. The primary objective is safety and tolerability, followed through 12 months with safety surveillance to 24 months. The secondary objective is a first look at efficacy: whether the rate of functional decline on the ALS Functional Rating Scale–Revised (ALSFRS-R), scored by independent raters blinded to treatment arm, changes after treatment. No one receives a placebo. Instead, each participant's decline is measured over a 12-week observation period before treatment and compared with their own rate afterward, and against a matched comparator drawn from the PRO-ACT database of completed ALS trials. Each arm begins with a single sentinel participant observed through a full cycle before others are dosed. Dr. Baker, a board-certified neurosurgeon who also leads the CTE study, will run the trial at the Baylor Scott & White Sports Therapy & Research Center in Frisco, Texas.

The intranasal route

The intranasal arm is a first for XytriX™. The cells are placed as small drops onto the lining of the nose over about 30 to 45 minutes — no needle, no lumbar puncture, no tissue penetrated. Nerve pathways running from the nose to the brain are surrounded by fluid spaces continuous with those around the brain, offering a route that bypasses the blood–brain barrier rather than crossing it. Because this is the first use of the route with XytriX™, the study approaches it at a lower dose before moving to the intended dose, and intranasal dosing begins only after the delivery device and supporting nonclinical data have been submitted to the FDA.

A devastating disease, and a platform built for it

"ALS takes everything — the ability to walk, to speak, to swallow, and finally to breathe — and it takes it fast. Most people have two to five years. Families are told there is nothing that will stop it, and since the first ALS drug was approved more than thirty years ago, that has remained true: the treatments we have slow the decline modestly, and none stops it," said Jakes Jordaan, Founder, President and CEO of TriCelX. "We will not accept that as the last word." "This is our third IND this year, and it runs on the same XytriX™ platform as our CTE and knee programs — one product, one manufacturing standard, one idea: calm the inflammation and protect what is left. The men who took the hits, on the field and in uniform, carry a higher risk of CTE and of ALS. We started with CTE for them. ALS is the next step on the same path."

About XytriX™
XytriX™ is TriCelX's proprietary investigational allogeneic biotherapeutic composed of human umbilical cord tissue-derived mesenchymal signaling cells (hUC-MSC), produced under TriCelX's manufacturing protocols at its FDA-registered facility in Frisco, Texas. The cells act by releasing signals that calm inflammation and support neurons, rather than by replacing tissue. XytriX™ is in clinical development for knee osteoarthritis (IND 32759), where dosing of trial participants is underway; chronic traumatic encephalopathy (IND 32912); and amyotrophic lateral sclerosis (IND 33245).

About TriCelX, Inc.
TriCelX, Inc. is a vertically integrated, clinical-stage allogeneic biotherapeutics company headquartered in Frisco, Texas. From a single donated umbilical cord, the company develops six birth-tissue products along separate regulatory paths. TriCelX has operations in Frisco, Texas; Utah; Florida; and Antigua. Learn more at www.tricelx.com.

XytriX™ is an investigational biotherapeutic that has not been approved by the U.S. Food and Drug Administration and has not been shown to be safe or effective. Orphan-drug designation for XytriX™ in ALS has been requested and has not been granted. Mesenchymal cell therapies have been studied in ALS before without demonstrated benefit. Statements about how XytriX™ works describe the company's scientific working model, not established fact. This release contains forward-looking statements that are subject to risks and uncertainties, and actual results may differ materially.

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