

TriCelX Takes On ALS — Its Third Clinical Program, and the Hardest

FRISCO, TX, UNITED STATES, August 25, 2026 /EINPresswire.com/ -- TriCelX Takes On ALS — Its Third Clinical Program, and the Hardest

With today's filing, TriCelX has three clinical programs running on one product — knee osteoarthritis, [CTE](#), and now ALS — and is among the few companies of any size working on treatments for either brain disease. Its idea is that long-term inflammation in the brain, and the damage that inflammation does to the brain's architecture, is part of what drives both diseases — and that calming it, while supporting the neurons and synapses that survive, may slow the damage.

TriCelX, Inc. today announced that it is testing [XytriX™](#), its experimental biotherapeutic made from signaling cells found in donated umbilical cord tissue, in amyotrophic lateral sclerosis, or ALS. The company today filed its application with the U.S. Food and Drug Administration — a single continuous study combining the three stages that drug development normally runs separately — and is asking the agency for two things: recognition of ALS as a rare disease, which brings extra support for developing treatments, and entry into an FDA program that speeds up work on drugs for life-threatening illnesses.

A disease with no cure and very little to offer

ALS destroys the motor neurons — and the synapses through which they work — that control movement, speech, swallowing and eventually breathing. Most people live two to five years after symptoms start. There is no cure. The handful of approved drugs slow the decline a little; none stops it or reverses it. About 30,000 Americans are living with ALS, which is few enough that the federal government classifies it as a rare disease.

How the brain works, and what ALS takes apart

The brain runs on about 86 billion neurons, connected by something on the order of a hundred trillion synapses — and it is that web of connections, more than the cells themselves, that does the work of thinking and moving. Neurons do not do this alone. Roughly an equal number of support cells work alongside them: astrocytes clear the chemical signals after each firing, oligodendrocytes insulate the long fibres, and microglia act as the brain's immune system. When those support cells turn hostile, they can destroy a neuron that was otherwise holding its own. The motor neurons ALS destroys are the extreme case — each carries twenty to fifty thousand synapses, and the longest run more than three feet from the spinal cord to the foot.

Two groups hit harder than most — and what the numbers actually show
Former NFL players. In a study of 19,824 retired players, ALS killed them at more than four times the rate of other American men, while their overall death rate ran below average — the extra deaths were specifically from brain disease. And a study published today in The BMJ by Mass General Brigham, Boston University and the Concussion & CTE Foundation put the first real number on CTE in the league: of the 878 former players who died between 2016 and 2021, at minimum one in four had the disease at death. Among the brain donors studied, roughly 60 percent met clinical criteria for dementia.

Military veterans. Veterans get ALS at higher rates than civilians. That has been found repeatedly over more than twenty years, and it is why the Department of Veterans Affairs automatically treats ALS as service-connected. One study followed about 9.2 million veterans over twenty-four years and counted 13,935 cases.

Why a company working on CTE is now working on ALS

In April 2026, the Boston University CTE Center reported that Steve McMichael — the Bears defensive tackle from the 1985 Super Bowl team, inducted into the Pro Football Hall of Fame in 2024, who died of ALS in 2025 at 67 — had Stage 3 CTE. He had pledged his brain to research years earlier, while still living with the disease. Announcing the finding, his wife of 25 years, Misty McMichael, said: “I donated Steve's brain to inspire new research into the link between them.” Several other former NFL players who died of ALS have been found, after death, to have had CTE as well.

TriCelX did not come to ALS from nowhere. It is already testing XytriX™ in CTE, in a study the FDA cleared to begin in June 2026. The link between the two diseases is biological, not a coincidence about who gets them: repeated head impacts cause long-term inflammation in the brain and spinal cord, that inflammation is central to CTE, and it is also part of what happens in ALS. It is that shared process — not any one group of people — that XytriX™ is built to act on.

The therapy works the same way in both. XytriX™ is designed to do two things at once: calm the inflammation around neurons already in distress, and help the neurons that are still alive — together with the synapses that connect them — hold on. That one-two is the same whether the disease is CTE or ALS, because it targets what the two share rather than what makes them different. Each disease has its own damaged protein building up — a different one in each — and XytriX™ does not go after either protein directly. It goes after the inflammation surrounding them — and, at the same time, tries to help the neurons and synapses that are still there hold on.

The two programs also use the identical product, made from the same cell banks to the same standards, given the same two ways. That is why the CTE study is the foundation for this one in a practical sense as well as a scientific one: no ALS patient will be treated until the independent safety board watching the CTE study has looked at real results and cleared that dose.

TriCelX calls this one neurological strategy rather than two programs.

With gratitude to the researchers

TriCelX would not have a case to make without work it did not do. The Company thanks the Concussion & CTE Foundation, Mass General Brigham and Boston University for the research that established this evidence base.

Why now

“Our neurological strategy is built on a chain of established science. Repeated trauma to the head sets off chronic inflammation in the brain and spinal cord. That inflammation does structural damage — to neurons, to the connections between them, and to the support cells that keep both alive. It is central to CTE and a recognised part of what happens in ALS. Every link in that chain is published, and it is the process itself — not any single protein — that we are going after,” said Jakes Jordaan, Founder, President and CEO of TriCelX.

“What gives us a reason to try is a connection, not a result — the connection between CTE and ALS, two different diseases that appear to share one underlying process: chronic inflammation in the brain and spinal cord, set off by repeated blows to the head. Former players and veterans both get ALS at higher rates, and both have a history of blows to the head.”

“A problem of that kind needs a solution of matching sophistication. The brain is roughly 86 billion neurons, on the order of a hundred trillion connections between them, and about as many support cells maintaining the whole arrangement. A drug built around a single molecule acting on a single target is the wrong shape of tool for a system like that. A mesenchymal signaling cell is itself highly complex — it reads the tissue it arrives in and releases a coordinated mixture of signals in response, calming inflammation and supporting the neurons and synapses that remain. We believe that is what this biology requires, and this trial is how we find out.”

“This is one neurological strategy rather than three separate programs. Where neuroinflammation sits at the core of the pathology, the same approach should apply. We are following the science and the numbers where they lead, and we will report what we find either way.”

The technology — XytriX™, TriCelX’s proprietary signaling cell technology

XytriX™ is TriCelX’s answer to that architecture. The signaling cells it is made from are themselves highly complex and sophisticated: not a single drug molecule aimed at a single target, but cells that each release a broad mixture of signals. That mixture is what allows the therapy to act on a network built out of neurons, synapses and glia rather than on any one part of it.

“XytriX is designed to work as a one-two,” said Dr. Abdul Baker, Chief Medical and Scientific Officer of TriCelX and lead investigator for the ALS study. “The first part calms the inflammation around the motor neurons that are under attack. The second, from those same cells, is meant to help the neurons that survive keep their synapses — because a motor neuron that holds on to its cell body but loses its connections has already stopped doing its job. What makes both

possible is the cell itself.”

What TriCelX is asking the FDA for

Because ALS affects fewer than 200,000 Americans, it qualifies as a rare disease under federal law, and the company is applying for that designation. TriCelX is also asking to be reviewed under an FDA program built for life-threatening illnesses, which lets the agency weigh risk and benefit differently when patients have no other options and little time.

Nobody in this study gets a placebo

Most trials give some patients a dummy treatment for comparison. In a disease that kills everyone who gets it, TriCelX does not think that is right — or workable. Instead, each patient in the study is compared against the records of thousands of people whose ALS progressed at a similar rate, drawn from a database of more than 13,700 anonymized patient records collected from completed ALS trials. That gives a real comparison without asking anyone with ALS to take a placebo, and it means useful answers can come from a small number of treated patients.

One study instead of three

Drug development normally runs in three separate stages, one after another, with gaps and delays between them. TriCelX has designed this as a single continuous study. It starts with ten patients, to confirm the treatment is safe and to look for a first sign that it is helping. If that sign appears, the study grows straight into its final, larger stage with no pause and no need to start over. The COVID-19 vaccine programs were run this way, and the approach is used routinely in cancer research. It is being used here because people with ALS cannot wait years between stages. Moving from one stage to the next depends on hitting targets set in advance, and requires FDA agreement.

The study will be run at one location, the Baylor Scott and White Sports Therapy and Research Center in Frisco, Texas, by Dr. Abdul Baker, a board-certified neurosurgeon who also leads the company’s CTE study.

Standing with the people affected

TriCelX is building relationships with former football players and with military and veteran organizations — the communities hit hardest by CTE and ALS.

“For the wives and families of retired players, brain health is not an abstract debate — it is the person we love, changing in front of us,” said Amber Staples, President of the National Football Wives Association. “We were reminded of the stakes again with Marshawn Kneeland — the Dallas Cowboys defensive end who died at just 24, whose brain, examined after his death, was found to carry CTE. Behind a diagnosis like his is a family left to carry the loss. That is why TriCelX’s work matters to our community: it treats these players, their husbands and their families as people worth fighting for. We are proud to stand with them.”

Behind every one of these numbers is a family. That is why TriCelX is doing this work.

About XytriX™

XytriX™ is TriCelX's experimental biotherapeutic made from signaling cells found in donated umbilical cord tissue, produced under the company's own manufacturing protocols at its FDA-registered facility in Frisco, Texas. The cells work by releasing chemical signals that calm inflammation and support neurons — an approach built on more than two decades of research into this cell type. XytriX™ is in early-stage development for chronic traumatic encephalopathy (cleared by the FDA to proceed in June 2026) and knee osteoarthritis, where dosing of trial participants is under way, and is now being advanced into ALS, with further conditions planned in neurology, immunology and orthopedics.

About TriCelX, Inc.

TriCelX, Inc. is a vertically integrated, clinical-stage allogeneic biotherapeutics company headquartered in Frisco, Texas. In its own FDA-registered facility, the company turns a single donated umbilical cord into six products developed along separate regulatory paths.

Signaling cells do not work the way a conventional drug works. They do not replace damaged tissue; they release a coordinated mixture of anti-inflammatory, immune-regulating and tissue-supporting signals that acts on the environment around it. The target is not a single receptor — it is the state the tissue is in.

TriCelX has operations in Frisco, Texas; Utah; Florida; and Antigua. Learn more at www.tricelx.com.

XytriX™ is an experimental biotherapeutic that has not been approved by the U.S. Food and Drug Administration. Rare-disease designation and expedited review have been requested and have not been granted. XytriX™ has not been shown to be safe or effective. Therapies of this kind have been tried in ALS before without demonstrated success. Statements about how XytriX™ works describe the company's scientific working model, not established fact.

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