FDA Clears First-in-Indication Cell Therapy Trial for Chronic Traumatic Encephalopathy — for the Warriors Who Carry CTE

FDA Authorizes TriCelX's XytriX™ to Enter the Clinic in CTE—the First Cell Therapy Ever Studied in a Disease That Has Devastated Navy SEALs & NFL Players Alike

FRISCO, TX, UNITED STATES, June 15, 2026 /EINPresswire.com/ -- TriCelX, Inc. today announced that the U.S. Food and Drug Administration has authorized a Phase 1/2 clinical trial of XytriX™ in Chronic Traumatic Encephalopathy (CTE) to proceed under IND 32912 — the first time a cell therapy will be studied in this disease. CTE is a progressive, currently untreatable tauopathy caused by repeated head impacts and blast exposure. Its toll is staggering and personal: in the largest study of its kind, researchers found CTE in 110 of 111 former NFL players whose brains were examined, and a Department of Defense laboratory found blast-related brain damage in every Navy SEAL brain it studied from operators who had died by suicide.

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>
> *Jakes Jordaan, Esq., Founder and Chief Executive Officer, TriCelX, Inc.*

Roughly 500,000 U.S. service members were diagnosed with traumatic brain injury between 2000 and 2023, the majority from blast exposure — much of it sustained not in combat but in training.

These are the same men, on two different fields. The Special Operations veteran carrying years of breaching-blast exposure and the former football player with a decade of subconcussive hits share one disease, one biology, and a need for options that do not yet exist. XytriX™ is designed to target the chronic neuroinflammation and tau pathology that drive CTE. With FDA clearance to proceed, that

scientific rationale now advances into a clinical trial.

The repetitive head impacts of contact sport — here, a tackle in an NFL game between the St. Louis Rams and New England Patriots — drive the same tauopathy seen in blast-exposed service members. (Getty Images)

One Disease, Two Battlefields

"For too long, the men who took these hits for us — in uniform and in pads — have been told there is nothing to be done. This trial says otherwise." said Jakes Jordaan, Chief Executive Officer of TriCelX. "XytriX™ is the first cell therapy ever cleared to be studied in CTE, and we built it for the SEAL who can no longer sleep and the lineman who can no longer remember." He continued: "This is the work that matters most to us." He added: "We owe them more than awareness. We owe them a shot at getting better — for our warriors from the gridiron and the battlefield."

The XytriX™ CTE Phase 1/2 Trial

The XytriX™ CTE trial is a Phase 1/2, open-label, three-cohort dose-escalation study (3+3 design) evaluating intravenously and intrathecally administered allogeneic human umbilical cord-derived mesenchymal stem cell (hUC-MSC) therapy in adults with probable CTE. Eligibility is established through a formal clinician diagnosis of Traumatic Encephalopathy Syndrome (TES) at the “probable” level, rendered by a qualified neurologist per the 2021 NINDS TES criteria (Katz et al., Neurology 2021). As a Phase 1/2 study, the trial evaluates both the safety and tolerability of XytriX™ — through treatment-emergent and serious adverse events and dose-limiting toxicities — and its preliminary efficacy, measured by change from baseline in validated neurocognitive, behavioral, and functional outcomes over 24 months. A panel of fluid biomarkers and advanced neuroimaging — including serum neurofilament light chain (NfL), GFAP, and plasma phosphorylated-tau species, alongside structural MRI, DTI, and functional MRI — is incorporated as exploratory measures to characterize biological activity and inform a subsequent controlled trial.

The trial will enroll adults with probable CTE across the two communities the disease has hit hardest: blast-exposed service members and veterans, and former contact-sport athletes.

A First-in-Indication Study

The XytriX™ CTE trial is the first in which a cell therapy will be investigated in Chronic Traumatic Encephalopathy; no cell therapy has previously been studied in this disease. That status is more than a milestone — it carries scientific and regulatory consequences. As the index study in a new indication, the XytriX™ CTE trial establishes the foundational safety, tolerability, and efficacy-assessment framework against which subsequent cell therapy programs in this disease will be evaluated. The dose-escalation design, the neurocognitive endpoint strategy, the exploratory biomarker and neuroimaging program, and the safety-monitoring schedule — including scheduled lumbar-spine MRI surveillance for the intrathecal cohort — are being defined here first.

The Federal Mandate Framework

The program is anchored in the federal framework for service-member brain health. The Blast Overpressure Safety Act of December 2024 codified federal responsibility for blast TBI and CTE, and DoD Instruction 6200.02 establishes the duty to provide the best available medical countermeasures and the Expanded Access mechanism for service-member access during clinical development. TriCelX is engaging counterparties across that architecture — including the U.S. Army Medical Materiel Development Activity, NIH/NINDS, and the National Intrepid Center of Excellence — to position XytriX™ as an operational pathway for the warfighter population the statute was enacted to protect.

A Surgeon's Perspective

"I have sat across from these families — the wife who has lost the husband she married, the son who no longer recognizes his father's temper." said Abdul Baker, MD, FAANS, FACS, FCNS, a board-certified neurosurgeon trained at Cleveland Clinic and Johns Hopkins, and Chief Medical Officer and Principal Investigator at TriCelX.

"Whether the hits came from an IED or an offensive line, the disease I see is the same, and for my entire career I have had nothing to offer but management of the decline." He continued: "XytriX™ is designed to go after the chronic neuroinflammation and tau pathology driving that decline." He added: "For the first time, I can tell a patient with CTE that there is a trial built for them."

About XytriX™

XytriX™ is TriCelX's proprietary investigational allogeneic human umbilical cord-derived mesenchymal stem cell (hUC-MSC) biotherapeutic, produced under proprietary cGMP protocols at the company's FDA-registered facility in Frisco, Texas. Its mechanism reflects more than two decades of MSC research into paracrine and extracellular-vesicle–mediated signaling, immunomodulation, and neurotrophic activity. XytriX™ is currently in Phase 1/2 development for Chronic Traumatic Encephalopathy (FDA-authorized to proceed under IND 32912, June 2026) and Knee Osteoarthritis (IND filed March 30, 2026), with additional indications planned across neurology, immunology, and orthopedics.

About TriCelX, Inc.

TriCelX, Inc. is a vertically integrated, clinical-stage allogeneic cell therapy company headquartered in Frisco, Texas. The company operates a five-product birth-tissue biotherapeutic platform — XytriX™, CB-NK™, LuMatriX™, OrthoMatriX™, and AlloCelX™ — converting a single umbilical cord donation event into differentiated products across the Phase 1/2 IND pathway and the Section 361 HCT/P commercial pathway. XytriX™ is in Phase 1/2 development for Chronic Traumatic Encephalopathy (authorized to proceed under IND 32912, June 2026) and Knee Osteoarthritis (IND filed March 30, 2026). The company maintains operations in Frisco, Texas; Utah; Florida; and Antigua. Learn more at www.tricelx.com.

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