TriCelX Files FDA IND for XytriX™ in Chronic Traumatic Encephalopathy (CTE)

XytriX™ Becomes First CTE Biotherapeutic to Reach FDA
Under the Blast Overpressure Safety Act


Neurological Activity

FRISCO, TX, UNITED STATES, May 18, 2026 /EINPresswire.com/ -- TriCelX, Inc. ("TriCelX"), a translational leader in evidence-based biotherapeutics, has submitted a Phase 1/2 Investigational New Drug (IND) application to the U.S. Food and Drug Administration for XytriX™ — its proprietary allogeneic UC-MSC biotherapeutic, ethically sourced from donated human birth tissue — for adults with confirmed or probable Chronic Traumatic Encephalopathy (CTE). The submission was made to FDA's Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT), and includes concurrent requests for Regenerative Medicine Advanced Therapy (RMAT) Designation and Breakthrough Therapy Designation (BTD).

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

This is the first IND filing for a CTE-directed biotherapeutic since the enactment of the Blast Overpressure Safety Act (BOSA) in December 2024. XytriX™ is positioned to answer BOSA's care access mandate — the first federal statute requiring neurological monitoring, blast exposure tracking, and expanded access to care for service members with blast-related brain injury.

The CTE submission follows TriCelX's prior IND for XytriX™ in Knee Osteoarthritis (KOA, IND 32759), which received a "Study May Proceed" determination on April 22, 2026. The XytriX™

drug substance is identical to that previously reviewed under the KOA program, with divergence only at fill/finish to support intravenous and intrathecal administration.

CTE: A National Public Health Crisis

CTE is a progressive, fatal tauopathy caused by cumulative repetitive head impacts and blast overpressure exposure. It advances through cognitive decline, behavioral dysregulation, psychiatric collapse, and dementia, typically in the fourth through seventh decades of life. There
is no FDA-approved treatment, no disease-modifying therapy, and no accepted means of slowing progression. Postmortem evidence from the Boston University CTE Center (Alosco et al., 2026; n=614) formally identifies CTE as a cause of dementia.

The Military Epidemic

Between 2000 and 2023, approximately 500,000 U.S. military personnel were diagnosed with traumatic brain injury, the vast majority mild TBI from explosive blast exposure. A 2024 New York Times investigation revealed that a Defense Department laboratory found distinctive blast-

related brain damage in all eight Navy SEAL brains it examined — SEALs who had died by suicide, with damage originating from their own training, not enemy fire. CNN reporting has confirmed that troops deployed to Afghanistan experienced roughly 70% of their blast exposure
during training.

Congress responded in December 2024 with BOSA, which mandates baseline and career-long neurocognitive monitoring of all service members, individual longitudinal blast exposure logs, weapons acquisition reform, retaliation protections for those who seek care, the Special Operations Comprehensive Brain Health and Trauma program, and elevation of the National Intrepid Center of Excellence (NICoE) to a program of record. BOSA establishes the federal policy and institutional infrastructure within which a biotherapeutic such as XytriX™ can be systematically deployed.

The Sports Epidemic

In the most comprehensive neuropathological study of its kind, the Boston University CTE Center confirmed CTE in 110 of 111 former NFL brains examined — a 99% prevalence rate (Mez et al., JAMA, 2017). CTE has since been confirmed in former boxers, wrestlers, soccer, hockey, MMA, and rugby players. The at-risk population extends to an estimated four million active high school and college football players, plus amateur boxers, ice hockey players, soccer players, and military reserve and ROTC programs — tens of millions of Americans.

XytriX™: A Potential Disease-Modifying Biotherapeutic

XytriX™ is an off-the-shelf allogeneic biotherapeutic of ethically sourced UC-MSCs. Unlike conventional neurological pharmaceuticals — more than 98% of which cannot cross the blood-brain barrier in therapeutic concentrations — XytriX™ cells cross the BBB via a documented,

biologically active SDF-1α/CXCR4 homing mechanism, migrate to the most severely damaged regions of CTE pathology, and deploy a therapeutic secretome including BDNF, GDNF, NGF, VEGF, IGF-1, IL-10, and TGF-β.

Mechanisms of action include:

• Immunomodulation and suppression of chronic neuroinflammation

• Polarization of microglia from the neurotoxic M1 to the neuroprotective M2 phenotype

• Neurotrophic support for hippocampal neurogenesis and synaptic plasticity

• Repair of disrupted BBB tight junctions via VEGF and angiopoietin-1

• Reduction of tau hyperphosphorylation through GSK-3β suppression

• Oligodendrocyte support and remyelination of blast-damaged white matter

Because SDF-1α/CXCR4 homing is amplified by neuroinflammation, more severe blast- or impact-related CTE pathology produces stronger recruitment to affected brain regions. XytriX™ is, in effect, a self-directing therapy.

XytriX™ is manufactured at TriCelX's FDA-registered cGMP/cGTP-compliant facility in Frisco, Texas. Each batch is tested for sterility, endotoxin, identity, and viability, and cryopreserved in a serum-free, animal-component-free medium. As an off-the-shelf allogeneic product, it requires no HLA matching, no autologous harvest, and no specialized neurosurgical infrastructure for intravenous administration — supporting large-scale deployment across the populations identified by BOSA monitoring.

Concurrent RMAT and Breakthrough Therapy Designation Requests
TriCelX has submitted concurrent requests for RMAT under 21 U.S.C. § 356(g) and BTD under 21 U.S.C. § 356(b)(1). Both remain under FDA review. The requests are grounded in published clinical evidence supporting MSC therapy for TBI, including the Wang et al. (2013, Brain Research) Phase 1/2 trial of IV UC-MSCs in adult TBI sequelae; the STEMTRA Phase 2 RCT (Kawabori et al., Neurology, 2021) providing Class I evidence that allogeneic MSC therapy in chronic TBI produces statistically significant motor improvement versus surgical sham; the Saboori et al. (2024) systematic review identifying stem cell therapy as "perhaps the most promising treatment modality for traumatic brain injury to date"; and the December 2024 approval of Ryoncil®, the first FDA-approved allogeneic MSC product, which establishes the regulatory and safety benchmark for the class. If granted, the designations would enable accelerated FDA engagement, rolling BLA review, priority review, senior FDA guidance, and eligibility for accelerated approval pathways.

BOSA Alignment and Federal Partnership Pathways

BOSA establishes the detection and monitoring infrastructure; XytriX™ provides the therapeutic response.

TriCelX intends to engage with:

• USAMMDA and SOCOM — regarding eligibility for protocol expansion to Special Operations Forces, the cohort that sustains the highest cumulative blast exposures in the U.S. military.

• CDMRP — the Psychological Health and TBI Research Program (PHTBI) and the Defense Medical Research and Development Program (DMRDP), which funds TBI therapeutic development directly. BOSA significantly strengthens the policy justification for a CDMRP application.

• BARDA Other Transaction Authority — given XytriX™'s alignment with BARDA's PHEMCE mandate to develop scalable medical countermeasures for warfighter health threats.

• Defense Health Agency CRADA — enabling access to BOSA-mandated blast exposure databases and neurocognitive monitoring data for enrollment, plus DoD scientific collaboration.

• NICoE and the VA Cooperative Studies Program — providing the institutional infrastructure for future Phase 2 and Phase 3 pivotal studies in blast-related CTE.

Phase 1/2 Clinical Trial Design

The Phase 1/2 trial — "A Phase 1/2, Open-Label, Dose-Escalation Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of Intravenous and Intrathecal Administration of XytriX™ in Adults with Confirmed or Probable CTE" — is a prospective, open-label, dose-escalation, single-center study enrolling approximately 24 base subjects across three dose cohorts, with an optional 12-subject expansion at the recommended Phase 2 dose for total enrollment up to 36. Subjects receive three treatment cycles at Months 0, 3, and 6, with longitudinal follow-up through Month 24.

Cognitive efficacy is measured by the Neuropsychological Assessment Battery (NAB), which covers all three cognitive domains specified in BOSA's mandatory neurocognitive monitoring program: delayed verbal memory, visual-spatial memory, and executive function. Secondary endpoints include MoCA, the CTE Core Assessment Protocol (CAP), PCL-5, NPI, C-SSRS, SF-36, and longitudinal plasma biomarkers (NfL, GFAP, p-tau181, total tau) on the Quanterix Simoa HD-X platform. An independent DSMB provides safety oversight.

The Principal Investigator is Abdul Baker, MD, FAANS, FACS, FCNS, Chief Medical Officer of TriCelX and a board-certified neurosurgeon. The trial will be conducted at Baylor Scott & White

Sports Therapy & Research Center in Frisco, Texas.

Acknowledging NIH Investment in CTE Biomarker Science

CTE today can only be definitively diagnosed post-mortem, and validated in vivo biomarkers remain one of the most consequential open problems in neurology. TriCelX commends the National Institutes of Health for its sustained investment in CTE biomarker science, including NINDS funding of the DIAGNOSE CTE Research Project and the November 2025 launch of DIAGNOSE CTE Research Project II — a $15 million next-generation biomarker initiative led by Dr. Michael L. Alosco at Boston University. The diagnostic and response-assessment paradigm in the XytriX™ IND is grounded in DIAGNOSE CTE plasma (Alosco et al., 2024) and CSF (Jansson et al., 2026) biomarker findings, and in the NINDS Consensus Traumatic Encephalopathy Syndrome (TES) Criteria (Katz et al., Neurology, 2021).

Leadership Statements

“We have known about this disease for decades — from the autopsies of NFL players, from the brains of Navy SEALs — and until today we have had no treatment to offer. What we are filing is more than an IND for a single indication. It is the foundation of a new treatment paradigm for two of America’s most under-served populations: warriors who carry blast-related brain injury home from training and combat, and athletes whose careers have left them with progressive neurodegenerative disease. The MSC platform underlying XytriX™ has shown clinical signals across a broader neurological landscape — multiple sclerosis, ALS, Parkinson’s, ischemic stroke. With the Knee Osteoarthritis program already cleared by FDA to proceed, XytriX™ becomes a two-IND platform spanning orthopedic and neurological indications. We look forward to engagement with FDA, with USAMMDA and SOCOM under BOSA, with CDMRP, BARDA, DHA, the VA, NICoE, and NIH.” — Jakes Jordaan, Esq., Founder and Chief Executive Officer, TriCelX, Inc.

“Every neurosurgeon who has cared for a service member or former athlete with CTE has had to give that family the same answer: we have no treatment. CTE is a tauopathy. Its defining lesion is the pathological accumulation of hyperphosphorylated tau as neurofibrillary tangles, placing it in the same biological family as Alzheimer’s disease, frontotemporal dementia, progressive supranuclear palsy, and corticobasal degeneration. The GSK-3β and CDK5 kinase cascades that drive tau hyperphosphorylation in CTE activate downstream of chronic microglial neuroinflammation — substantially the same pathways that drive Alzheimer’s tau pathology. That convergence is what makes XytriX™ a tauopathy platform candidate, not a single-indication therapy. We owe this work to the men and women who sustained these injuries serving their country and entertaining the rest of us on Sunday afternoons.”
-Abdul Baker, MD, FAANS, FACS, FCNS, Chief Medical Officer and Principal Investigator, TriCelX, Inc.

About TriCelX, Inc.
TriCelX is a global translational biotherapeutics company advancing evidence-based, personalized regenerative medicine. With operations in Texas, Utah, and Antigua, TriCelX harnesses the regenerative power of Mesenchymal Signaling Cells (MSCs) ethically sourced from donated human birth tissue. The company's proprietary platform enables MSCs to differentiate into connective tissue, regenerate neurons, reduce neuroinflammation, and modulate the immune system. In addition to the XytriX™ CTE program, TriCelX holds IND 32759 for XytriX™ in Knee Osteoarthritis (FDA "Study May Proceed," April 22, 2026), and is developing novel biological medical countermeasures for U.S. military battlefield challenges. For
more information, visit www.tricelx.com.

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