March 23, 2026

# Tonix Pharmaceuticals Announces Presentations at World Vaccine Congress Washington 2026

*Monday, March 30: Phase 1 data on TNX-4800 (long-acting anti-Borrelia OspA human monoclonal antibody) for the seasonal prevention of Lyme disease*

*Wednesday, April 1: Animal and in vitro studies on TNX-801 (horsepox, live virus vaccine) for the prevention of smallpox and mpox*

*Wednesday, April 1: Horsepox as a modular antigen-delivery system for broad and sustained immunity in novel vaccines to protect against other pathogens*

BERKELEY HEIGHTS, N.J., March 23, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial biotechnology company, today announced an oral presentation of Phase 1 data on TNX-4800 (formerly known as mAb 2217LS)[1,2], a long-acting human monoclonal antibody (mAb) that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the causative agent of Lyme disease in humans in the U.S., at the World Vaccine Congress Washington 2026 held in Washington, D.C., March 30-April 2, 2026.

The Company's Farooq Nasar, PhD, Director, Virology will present data on TNX-801, the Company's attenuated, live orthopoxvirus (horsepox) vaccine candidate with the potential capability to protect against smallpox and mpox. Finally, Christopher Cooper, PhD, Director, Immunology at Tonix will serve as moderator on a panel discussing modular antigen-delivery systems in novel pox-based vaccines.

**TNX-4800 Presentation Details**

**Title:** A Long-Acting Monoclonal Antibody for Seasonal Prevention of Lyme Disease
**Location:** Room 202B
**Date and Time:** March 30, 2026, 10:10 a.m. ET
**Session Category:** Measuring Breadth & Emerging Targets
**Presenters:** Mark S. Klempner, MD, Professor of Medicine at UMass Chan Medical School, inventor of TNX-4800, and Principal Investigator of the study

**Other Session Details**

**Title:** A Live Attenuated, Minimally Replicative MPOX Vaccine
**Location:** Room 202A, Level 2
**Date and Time:** April 1, 2026, 10:10 am ET
**Session Category:** Emerging & Re-Emerging Diseases

**Presenter:** Farooq Nasar, PhD, Director, Virology, Research and Development Center (RDC), Tonix Pharmaceuticals

**Title:** Poxvirus as a Modular Antigen-Delivery System for Broad and Sustained Immunity
**Location:** Room 20A, Level 2
**Date and Time:** April 1, 2026, 3:25 p.m. ET
**Session Category:** Emerging & Re-Emerging Diseases
**Moderator:** Christopher Cooper, PhD, Director, Immunology, RDC, Tonix Pharmaceuticals

**About TNX-4800**
TNX-4800 (formerly known as mAb 2217LS) is a human monoclonal antibody with an engineered extended half-life that targets the outer-surface protein A (OspA) on Lyme-causing *Borrelia* bacteria. When TNX-4800-containing blood is ingested by the tick, TNX-4800 kills and blocks the maturation of *Borrelia burgdorferi* in the mid-gut of infected deer ticks. The Company in-licensed TNX-4800 from UMass Chan Medical School in 2025. Published work in animals showed that TNX-4800 was 95% effective in preventing infection after a six-day challenge with ticks infected with *Borrelia burgdorferi*.[1] TNX-4800 was derived from mAb 2217 by amino acid substitutions in its crystallizable fragment (Fc) domain which serve to prolong the serum half-life. A single administration in the Spring is designed to potentially provide immunity within two days and maintain protective antibody titers for the entire tick season, providing pre-exposure prophylaxis against Lyme disease without relying on the recipient's immune system to generate antibodies. By delivering a well-characterized antibody directly, TNX-4800 has been shown to block transmission of *Borrelia burgdorferi* from ticks to animals. TNX-4800 also sidesteps the multidose schedules required for OspA vaccines in development[3] and the FDA-approved vaccine that was withdrawn from the market.[4] The Company expects to have GMP investigational product available for clinical testing in early 2027. Pending FDA clearances, a field study is expected to initiate enrollment in the first half of 2027, and a controlled human infection model (CHIM) study in 2028.

**About the TNX-4800 Phase 1 Study**
TNX-4800 was studied in a randomized, double-blind, sequential dose-escalation study (NCT04863287) that evaluated safety, tolerability, pharmacokinetics (PK), and immunogenicity of TNX-4800 in healthy adults. 44 subjects were randomized, and 41 completed the study. Subjects received a single subcutaneous (SC) administration of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg. Safety was assessed via clinical and lab evaluations. Drug exposure increased by approximately 25 times for a 20 times increase in dose. Serum TNX-4800 was measurable at the earliest sampling time of 24 hours, indicating rapid systemic absorption. TNX-4800 concentrations remained quantifiable for >200 days in 80% of volunteers at the lowest dose and for up to 350 days in the majority of volunteers at higher doses (i.e., ≥ 1.5 mg/kg). Mean half-life ranged from 62-69 days across groups. Serum concentrations remained quantifiable for up to 12 months in most subjects. Mean exposure for the 10 mg/kg cohort was less than 20% of the highest exposures in a rat toxicology study. Anti-drug antibodies (ADA) were detected in <10% of treated subjects, with no impact on PK. Most adverse events were mild or moderate. TNX-4800 was determined to be generally safe and well tolerated.

**About Lyme Disease**
In the United States, Lyme disease is caused by the bacterium*Borrelia burgdorferi*. Lyme disease remains the most common vector-borne infection in the United States, and its

incidence is climbing each year, due in part to global changes in climate expanding the habitat range for ticks.[5] It occurs most commonly in the Northeast, mid-Atlantic, and upper-Midwest regions. Lyme disease bacteria are transmitted through the bite of infected *Ixodes* ticks. Typical symptoms include fever, headache, fatigue, and a characteristic skin rash called erythema migrans. If left untreated, infection can spread to joints, heart, and nervous system. Laboratory testing is helpful if used correctly and performed with FDA-cleared tests. Although many cases of Lyme disease can be treated successfully with antibiotics, diagnosis and treatment are often delayed or missed. Chronic Lyme is considered an Infection Associated Chronic Illness (IACI), and is a chronic, debilitating disease state characterized by joint and muscle pain, fatigue, and other symptoms.[6]

**About TNX-801**

TNX-801 (recombinant horsepox virus) is an attenuated, minimally replicative, live virus vaccine based on horsepox in pre-clinical development to prevent mpox and smallpox. TNX-801 is expected to enter a Phase 1 study in 2027 pending FDA clearance. TNX-801 is in the pre-IND stages of development.

**Citations**

[1]Schiller ZA, et al. *J Clin Invest.* 2021 131(11):e144843.

[2]Wang Y, et al. *J Infect Dis*. 2016. 214(2):205-11.

[3]Comstedt P, et al. *Vaccine*. 2015 33(44):5982-8.

[4]Connaught's (ImuLyme™) and SmithKline Beecham's (LYMErix™) Lyme disease vaccines were withdrawn. Nigrovic LE, et al. *Epidemiol Infect.* 2007 135(1):1-8. doi: 10.1017/S0950268806007096. Epub 2006 Aug 8. PMID: 16893489; PMCID: PMC2870557.

[5]Gomes-Solecki M, et. al. *Clin Infect Dis.* 2020 70(8):1768-1773. doi: 10.1093/cid/ciz872. PMID: 31620776; PMCID: PMC7155782.

[6]National Academies of Sciences, Engineering, and Medicine. 2025. *Charting a Path Toward New Treatments for Lyme Infection-Associated Chronic Illnesses*. Washington, DC: The National Academies Press. https://doi.org/10.17226/28578.

**Tonix Pharmaceuticals Holding Corp.**

Tonix Pharmaceuticals* is a fully-integrated, commercial-stage biotechnology company focused on central nervous system (CNS) and immunology treatments in areas of high unmet medical need. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8 mg), is the first new treatment for fibromyalgia in adults in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® SymTouch® (sumatriptan injection 3 mg) and Tosymra® (sumatriptan nasal spray 10 mg). Tonix is investigating TONMYA in Phase 2 clinical trials to evaluate its potential in major depressive disorder and acute stress disorder/acute stress reaction. In addition, the Company's CNS portfolio includes TNX-2900 (intranasal oxytocin), which is Phase 2 ready for the treatment of Prader-Willi syndrome, a rare disease. Tonix is also advancing a pipeline of immunology programs, including long-acting human monoclonal antibody TNX-4800 for Lyme disease prophylaxis, and TNX-1500, a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. To learn more, visit www.tonixpharma.com and follow the Company on LinkedIn and X.

*Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.



**Forward Looking Statements**

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statements that are predictive in nature. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially as a result of a number of factors, including the ability of the Company to satisfy the conditions to the closing of the offering and the timing thereof, as well as those described in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. Tonix does not undertake an obligation to update or revise any forward-looking statement. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

**Investor Contacts**
Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 799-8599

Brian Korb
astr partners
(917) 653-5122
brian.korb@astrpartners.com

**Media Contacts**
Deborah Elson
Tonix Pharmaceuticals
deborah.elson@tonixpharma.com

Ray Jordan
Putnam Insights
ray@putnaminsights.com


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