March 31, 2026

Tonix Pharmaceuticals Announces Presentation of Phase 1 Data and Outlines Planned Adaptive Phase 2 Field Study of TNX-4800 for the Prevention of Lyme Disease, at the World Vaccine Congress Washington 2026

TNX-4800 is a long-acting anti-Borrelia burgdorferi OspA human monoclonal antibody in development as a single-dose Lyme prophylactic

Phase 1 study of TNX-4800 demonstrated safety, tolerability, and pharmacokinetics supportive of approximately four months protection

Company expects to initiate a randomized, double-blind, placebo-controlled, adaptive Phase 2 field study in the first half of 2027, pending FDA clearance

BERKELEY HEIGHTS, N.J., March 31, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial biotechnology company, announced Phase 1 data of TNX-4800 (formerly known as mAb 2217LS)[1,2] was presented by Mark S. Klempner, MD, professor of medicine at UMass Chan Medical School, an inventor of TNX-4800 and principal investigator of the study, on March 30, 2026, at the World Vaccine Congress Washington 2026. Tonix also announced its planned strategy for an adaptive Phase 2 field study expected to initiate in the first half of 2027, pending FDA clearance.

TNX-4800 is a long-acting borreliacidal (or bactericidal), human monoclonal antibody (mAb) with an engineered crystallizable fragment (Fc) domain for an extended half-life that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, which causes 99.9% of Lyme disease cases in the U.S.[3,4] Tonix is developing TNX-4800, which the Company in-licensed from UMass Chan Medical School in 2025, as a prophylactic that is administered in a single subcutaneous (SC) dose expected to provide approximately four months protection to people in endemic areas during the U.S. tick season. There are currently no marketed U.S. Food and Drug Administration (FDA)-approved vaccines or prophylactics to protect against Lyme disease.

"TNX-4800 is expected to provide a preventative option to the 87 million[5] people in the

United States who are at high risk of contracting the disease because they live, work, or vacation in a tick-endemic area," said Seth Lederman, MD, Chief Executive Officer of Tonix Pharmaceuticals. "As a monoclonal antibody, we believe TNX-4800 offers significant advantages over vaccines in development. Lyme disease vaccines that elicit antibodies to OspA currently in development take more than six months to offer protection and require complex immunization schedules. A previously approved anti-OspA vaccine was withdrawn due to poor uptake,[6] potentially relating to its complex immunization schedule."

Dr. Lederman continued, "TNX-4800, targeting *Borrelia burgdorferi*, the serotype that causes 99.9% of Lyme disease in the U.S., is a single dose subcutaneous administration that potentially offers immunity within two days for a duration of approximately four months. We believe TNX-4800's differentiating characteristics could offer meaningful improvements for people seeking protection from Lyme disease. We believe the Phase 1 pharmacokinetic (PK) data support our plan to conduct an adaptive field study in the first half of 2027, pending FDA clearance, in which protection at four months is the primary endpoint, and protection at six months is a key secondary endpoint."

Phase 1 Results

"Our study demonstrated potentially protective blood levels of TNX-4800 at two days, with protective blood levels sustained for at least four months due to its extended half-life design," said Dr. Klempner. "Additionally, with its differentiated mechanism of action, TNX-4800 has the potential to provide passive immunity by directly supplying neutralizing antibodies, bypassing the need for a vaccine to induce a patient's immune system to generate its own antibodies, which can be associated with other issues. We look forward to further clinical investigation of TNX-4800 as we strive to overcome this major public health challenge."

The primary objective of the Phase 1 study was to evaluate the safety and tolerability of a SC injection of TNX-4800 when administered to healthy male and female subjects ages 19-65 years old. The secondary objective was to evaluate the PK of a SC dose of TNX-4800 when administered to healthy subjects. 44 subjects were enrolled, with 41 subjects completing the study. Subjects received a single SC administration of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg.

Results showed no significant clinical or laboratory safety signals, with most adverse events mild or moderate. Peak serum concentration (Cmax) increased by ~25-fold for a 20-times increase in dose. Serum TNX-4800 was measurable at earliest sampling time of two days, indicating rapid systemic absorption. TNX-4800 levels remained quantifiable for >200 days in 80% of subjects at the lowest dose, and for up to 350 days in the majority of subjects at higher doses (i.e., ≥ 1.5 mg/kg). The mean half-life ranged from 62-69 days across TNX-4800 cohorts. Serum concentrations were quantifiable for up to 12 months in most subjects.

- Mean exposure for the 10 mg/kg cohort had <17% of the highest exposures in a nonclinical toxicology study.
- The maximum half-life ranged from 81-104 days, with the 10mg/kg cohort at 97 days and 5mg/kg cohort at 87 days.
- In the 5mg/kg dose cohort, mean serum TNX-4800 concentration was approximately 10 µg/ml at four months, which was approximately twice the minimum effective concentration, or MEC, calculated from *in vitro* bactericidal activity, and approximately the MEC from *in vitro* tick-feeding experiments. These data support Tonix's planned

evaluation of protection at four months as the proposed primary endpoint.

Adaptive Phase 2 Field Study Plans

Pending FDA clearance, the Company plans to initiate an adaptive field study in the first half of 2027. TNX-4800 will be studied in a randomized, double-blind, placebo-controlled, adaptive Phase 2 field study to evaluate the efficacy of a single SC dose of TNX-4800, 350 mg, in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period (Day 3 through Month 4 following administration). Based on the Phase 1 PK data, a fixed dose of 350 mg was selected for the Phase 2 field study, which is expected to provide exposures comparable to the 5 mg/kg dose evaluated in Phase 1. Participants will include adolescents and adults 16 to 65 years of age in Lyme-endemic areas in the U.S. The primary endpoint will be the prevention of Lyme disease at four months (comparison of TNX-4800 group and placebo group). A key secondary endpoint will be the prevention of Lyme disease at six months (comparison of TNX-4800 and placebo).

The Company expects to have GMP investigational product available for clinical testing in early 2027. Additionally, if necessary and pending FDA clearance, the Company plans to initiate a controlled human infection model (CHIM) study in 2028.

A copy of Dr. Klempner's World Vaccine Congress Washington 2026 presentation is available under the Scientific Presentations tab on the Tonix website at https://www.tonixpharma.com/scientific-presentations. The Company's TNX-4800 specific presentation can be found under the Presentations tab on the Investors section of the Tonix website at https://ir.tonixpharma.com/presentations.

About TNX-4800

TNX-4800 (formerly known as mAb 2217LS) is a long-acting borreliacidal (or bactericidal), 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 at preventing infection of non-human primates after six days of exposure to ticks infected with *Borrelia burgdorferi*.[1] TNX-4800 was derived from mAb 2217 by amino acid substitutions in its Fc domain, which serve to prolong the serum half-life. A single administration is designed to potentially provide immunity against Lyme disease within two days and maintain protective antibody levels for approximately four months, without relying on the recipient's immune system to generate antibodies. TNX-4800 also avoids the multidose priming schedules required for OspA vaccines in development[7] and the FDA-approved vaccine that was withdrawn from the market.[8]

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, PK, and immunogenicity of TNX-4800 in healthy adults. 44 subjects were randomized, and 41 completed the study. Subjects received a single 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 two days, 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 17% of the highest exposures in a rat toxicology study. Anti-drug antibodies 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.[9] 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.[10]

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]Marques AR, et al. *Emerg Infect Dis.* 2021. 27(8):2017-2024.

[4]Pritt BS, et al. *Lancet Infect Dis.* 2016. 6(5):556-564.

[5]Kugeler KJ, et al. *Emerg Infect Dis.* 2021. 27(2):616-619.

[6] Nigrovic LE, et al. *Epidemiol* Infect. 2006. Aug 8;135(1):1-8.

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

[8]Connaught's (ImuLyme™) and SmithKline Beecham's (LYMErix™) Lyme disease vaccines were withdrawn. Nigrovic LE, et al. *Epidemiol Infect.* 2007 135(1):1-8.

[9]Gomes-Solecki M, et. al. *Clin Infect Dis.* 2020 70(8):1768-1773.

[10]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 TNX-4800, a Phase 2 ready long-acting human anti-*Borrelia* OspA monoclonal antibody (mAb) for the prevention of Lyme disease in the U.S., and TNX-1500, a Phase 2 ready 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.

About UMass Chan Medical School

UMass Chan Medical School, one of five campuses of the University of Massachusetts system, comprises the T.H. Chan School of Medicine, the Morningside Graduate School of Biomedical Sciences, the Tan Chingfen Graduate School of Nursing, ForHealth Consulting at UMass Chan Medical School, MassBiologics, and a thriving Nobel-Prize-winning biomedical research enterprise. UMass Chan is advancing together to improve the health and wellness of our diverse communities throughout Massachusetts and across the world by leading and innovating in education, research, health care delivery and public service. It is ranked among the best medical schools in the nation for primary care education and biomedical research by U.S. News & World Report. Learn more at www.umassmed.edu.

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. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to successfully launch and commercialize TONMYA® and any of our approved products; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set 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@tonixpharmaceuticals.com

Ray Jordan
Putnam Insights
ray@putnaminsights.com

Source: Tonix Pharmaceuticals Holding Corp.