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Tonix Pharmaceuticals Announces Presentation of Phase 1 Data and Plans for an Adaptive Phase 2 Field Study of TNX-4800 (anti-Borrelia OspA monoclonal antibody) for the Prevention of Lyme Disease at the 4th Annual Ticks and Tickborne Diseases Symposium at Johns Hopkins University

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

Phase 2 field study expected to test a two-dose regimen of TNX-4800 subcutaneous with an initial Spring dose followed by a Summer booster two months later; the primary endpoint is Lyme disease prevention for six months

TNX-4800 is expected to provide protection against Lyme disease within two days of the first dose for the peak of the U.S. Lyme season

BERKELEY HEIGHTS, N.J., April 29, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial biotechnology company, announced presentation of Phase 1 data and plans for an adaptive Phase 2 field study of TNX-4800 (formerly known as mAb 2217LS)[1,2] for the prevention of Lyme disease in the U.S., at the 4th Annual Ticks and Tickborne Diseases Symposium. The Phase 2 study is expected to initiate in the first half of 2027, pending FDA agreement.

The Phase 1 study was conducted by a team at UMass Chan Medical School led by Mark S. Klempner, MD, Professor of Medicine at UMass Chan and an inventor of TNX-4800. The adaptive Phase 2 field study is being planned by Tonix, which licensed TNX-4800 from UMass Chan Medical School in 2025.

TNX-4800 is a long-acting bactericidal (or borreliacidal), human monoclonal antibody (mAb) that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the spirochete bacteria that causes 99.9% of Lyme disease cases in the U.S.[3,4] TNX-4800 was engineered to include a crystallizable fragment (Fc) domain that provides an extended half-life. Tonix is developing TNX-4800 for the prevention of Lyme disease 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.

“We plan to initiate an adaptive Phase 2 field study in the first half of 2027 pending FDA agreement,” said Seth Lederman, MD, Chief Executive Officer of Tonix Pharmaceuticals. “We intend to test a two-dose regimen of TNX-4800, with the first dose administered in the Spring and a second dose administered two months later, for protection against Lyme disease for six months following the initial dose as the primary endpoint. We believe the Phase 1 pharmacokinetic (PK) data support this study design. Each fixed subcutaneous (SC) dose is expected to provide exposures comparable to the 5 mg/kg SC dose evaluated in Phase 1. We have scheduled a meeting with the FDA early in the third quarter of 2026. We look forward to advancing the clinical investigation of TNX-4800 as we strive to overcome the major public health challenges posed by Lyme disease.”

Dr. Lederman continued, “As a long-acting monoclonal antibody that offers passive immunity against the Lyme-causing bacteria within two days, we believe TNX-4800 offers significant advantages over the alum-based combination multi-OspA subunit vaccine in late-stage clinical development. Lyme disease vaccines that elicit antibodies to OspA take more than six months to offer protection and require complex immunization schedules which are obstacles to adherence. A previously approved alum-based OspA subunit vaccine was withdrawn due to poor uptake,[6] potentially relating to its complex immunization schedule. We believe TNX-4800’s differentiating characteristics could offer meaningful improvements for people seeking protection from Lyme disease.”

A copy of the poster is available under the Scientific Presentations tab on the Tonix website at www.tonixpharma.com.

Adaptive Phase 2 Field Study Plans
Pending FDA agreement, the Company plans to initiate an adaptive field study in the first half of 2027. The Company plans to study TNX-4800 in a randomized, double-blind, placebo-controlled, adaptive Phase 2 field study to evaluate the efficacy of a two-dose regimen of TNX-4800 SC, in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period (Day 3 through Month 6 following administration). The two-dose regimen of TNX-4800 was selected for the Phase 2 field study based on the pharmacokinetic results of the Phase 1 study. Each fixed dose is expected to provide exposures comparable to the 5 mg/kg dose evaluated in Phase 1. The first dose will be administered in the Spring and the second booster dose will be administered two months later. Participants will include adolescents and adults 16 years of age and older in Lyme-endemic areas in the U.S. The primary endpoint will be the prevention of Lyme disease for six months (comparison of TNX-4800 group and placebo group) following the initial dose. The Company has scheduled a Type C meeting with the FDA early in the third quarter of 2026 to discuss the planned adaptive Phase 2 field study design.

The Company expects to have Good Manufacturing Practice (GMP) investigational product available for clinical testing in early 2027.

About TNX-4800
TNX-4800 (formerly known as mAb 2217LS) is a long-acting 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 either kills or 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 serum levels of at least 21 µg/ml, were approximately 95% effective at preventing infection of non-human primates after six days of exposure to ticks infected with *Borrelia burgdorferi*.[1,2] TNX-4800 was derived from mAb 2217 by amino acid substitutions in its Fc domain, which serve to prolong the serum half-life. As a monoclonal antibody, TNX-4800 is designed to provide passive immunity against Lyme disease within two days without relying on the recipient's immune system to generate antibodies. TNX-4800 also avoids the complex immunization schedules required for an alum-based combination multi-OspA subunit vaccine in development[7] and the FDA-approved alum-based OspA subunit vaccine that was withdrawn from the market.[8] TNX-4800 is protected by Issued US Patent US 10,457,721, which is licensed from UMass Chan with expiry in January 2036, excluding any possible Patent Term Extension based on the duration of the clinical trials and the FDA approval process.

TNX-4800 Phase 1 Study Results

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 dose of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg. Safety was assessed via clinical and lab evaluations. Results showed no significant clinical or laboratory safety signals. All drug-related adverse events were mild or moderate, except for a single severe adverse event that was deemed not drug-related. 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 up to 12 months in the majority of participants. At the highest dose of TNX-4800 tested in rats with 1.5-fold higher exposure compared to 10 mg/kg cohort, no adverse toxicity was observed, thus the highest dose tested was considered No Observed Adverse Effect Level (NOAEL). Confirmed anti-drug antibodies (ADSs) were observed transiently in <10% of treated participants, with no impact on PK. TNX-4800 was determined to be generally safe and well tolerated.

About Lyme Disease

In the U.S., Lyme disease is caused by the spirochete bacteria *Borrelia burgdorferi*. Lyme disease remains the most common vector-borne infection in the United States, and its incidence is climbing each year, due to the expanding the habitat range for ticks.[8] Approximately 87 million people in the United States live, work, or vacation in a tick-endemic area placing them at risk of contracting the disease.[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] Nigrovic LE, et al. *Epidemiol* Infect. 2006. Aug 8;135(1):1-8.

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

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

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

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

[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. 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 CD154/CD40 ligand (CD40L) inhibitor for the prevention of kidney transplant rejection. In addition, Tonix is progressing TNX-2900 (intranasal potentiated oxytocin), which is Phase 2 ready for the treatment of Prader-Willi syndrome, a rare disease. To learn more, visit www.tonixpharma.com.

*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. 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.

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