UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): **April 29, 2026**

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Connell Drive, Suite 3100, Berkeley Heights, New Jersey 07922
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(862) 799-8599**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**TNXP**	**The NASDAQ Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On April 29, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced program updates on its TNX-4800 (formerly known as mAb 2217LS) product candidate for protection against Lyme disease, and presented a poster on TNX-4800 Phase 1 data at the 4th Annual Ticks and Tickborne Diseases Symposium. A copy of the press release that discusses these matters is furnished hereto as Exhibit 99.01, and is incorporated herein by reference. A copy of the poster is furnished hereto as Exhibit 99.02, and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01 and 99.02 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On April 29, 2026, the Company announced program updates on its TNX-4800 product candidate for protection against Lyme disease, and presented TNX-4800 Phase 1 data at the 4th Annual Ticks and Tickborne Diseases Symposium.

The Company plans to initiate an adaptive Phase 2 field study of TNX-4800 in the first half of 2027, pending FDA agreement. The field study is intended to test a fixed subcutaneous ("SC") two-dose regimen of TNX-4800, with the first dose administered in the Spring and a second dose administered two months later. The primary endpoint is protection against Lyme disease for six months following the initial dose. The Company believes that the Phase 1 pharmacokinetic data support this study design. Each dose is expected to provide exposures comparable to the 5 mg/kg SC dose evaluated in the Phase 1 study. The Company has scheduled a Type C meeting with the U.S. Food and Drug Administration early in the third quarter of 2026 to discuss the Phase 2 field study design.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act and the Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines and approvals and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release of the Company, dated April 29, 2026
99.02	TNX-4800: A Monoclonal Antibody (mAb) to Protect Against Lyme Disease
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: April 29, 2026

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

EXHIBIT 99.01

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 a scheduled 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. 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.

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

TNX-4800: A Monoclonal Antibody (mAb) to Protect Against Lyme Disease

M.S. Klempner, MD[1]; Y. Wang, MD[1]; J. Sullivan-Bolyai, MD[1]; G. Sullivan, MD[2]; G. Chen-Phillips, MD[3]; Z. Rosenberg, MD[2]; S. Lederman, MD[2]

[1]UMass Chan Medical School, Worcester, MA; [2]Tonix Pharmaceuticals, Inc., Berkeley Heights, NJ; [3]Consultant to Tonix

Abstract

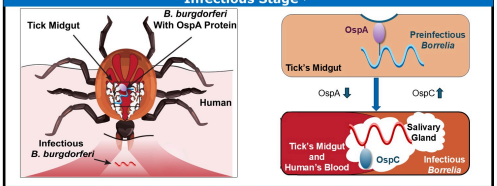
- *Borrelia burgdorferi* causes 99.9% of Lyme disease cases in the US
- There are currently no marketed US Food and Drug Administration (FDA)-approved vaccines or prophylactics to protect against Lyme disease
- TNX-4800 is a long-acting borreliacidal, human monoclonal antibody (mAb) with an engineered crystallizable fragment (Fc) domain for an extended half-life that targets outer surface protein A (OspA) of *Borrelia burgdorferi*
- TNX-4800 was studied in a phase 1, randomized, double-blind, sequential dose-escalation study (NCT04863287) that evaluated safety, tolerability, pharmacokinetics (PK), and immunogenicity of TNX-4800 in healthy adults
- The phase 1 data support a planned adaptive phase 2 field study, pending FDA agreement, to evaluate the safety and efficacy of TNX-4800 in preventing primary Lyme disease in volunteers from Lyme-endemic areas
- TNX-4800 is being developed as a prophylactic to be administered subcutaneously in the spring with a booster after 2 months, which is expected to provide protection within 2 days for at least 6 months to people in endemic areas during the US tick season

Introduction

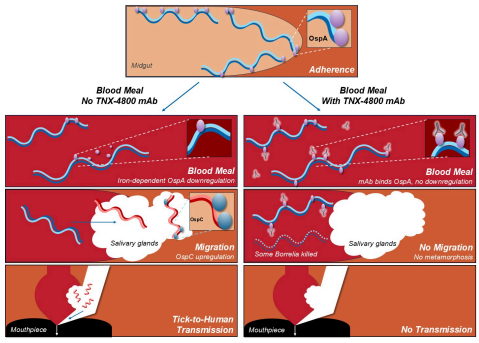
- TNX-4800 acts inside the tick to kill *Borrelia* and block the differentiation and transmission of *Borrelia*

OspA Is an Outer Membrane Protein on *Borrelia* That Facilitates Bacterial Adherence to the Tick Midgut[1-3]

Blood Induces Metamorphosis of *Borrelia* From the Preinfectious to Infectious Stage[4,5]

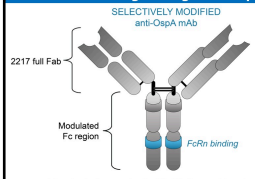


Anti-OspA mAb TNX-4800 Blocks Differentiation of *Borrelia* From the Preinfectious to Infectious Stage, Migration to Salivary Glands, and Transmission[6]



Methodology

TNX-4800 Long-Acting Anti-OspA Monoclonal Antibody Design



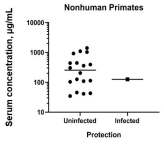
LS substitutions maintain C1q binding and function and augment FcRn binding for extended half-life

- TNX-4800 (formerly 2217LS) is a long-acting borreliacidal, human mAb with an engineered Fc domain for an extended half-life that targets OspA of *Borrelia burgdorferi*[7,8]

Multiple Approaches Informing Protective Exposure

Three methods:

- **Serum ~5 µg/mL – in vitro bactericidal activity**
  - TNX-4800 showed EC_{50} ≈ 0.56 µg/mL in vitro[7]
  - MEC ~ 10 times EC_{50}[8]
- **Serum <10 µg/mL – in vitro tick feeding experiment**
  - TNX-4800 showed killing ≥10 µg/mL[9]
- **Serum <21 µg/mL – in vivo primate challenge model (upper benchmark)**
  - TNX-4800 serum levels >21 µg/mL were 95% protective and represent an empirically observed upper correlate of protection (ceiling), not a minimum required concentration[7]



Derived from Schiller et al.[7]

- **Primate challenge model**
  - Tick-mediated transmission
  - Stringent test (prolonged exposure to 20 infected ticks over 6 days)

Results

Phase 1 Study Design

Primary Objective:
- Evaluate safety and tolerability of a SC injection of TNX-4800 when administered to healthy volunteers

Secondary Objective:
- Evaluate PK of a SC dose of TNX-4800 when administered to healthy volunteers

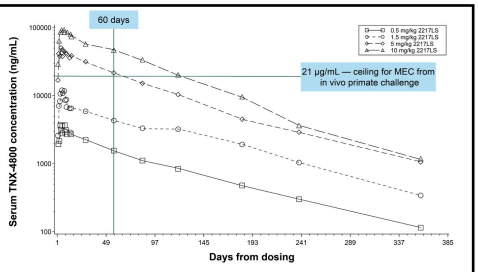
Study Population:
- Healthy male and female subjects, aged 19 to 65 years, inclusive. 44 volunteers enrolled; 41 completed

Cohort	No. of participants	TX-4800 dose (mg/kg)
1	10 TNX-4800 2 placebo	0.5
2	8 TNX-4800 2 placebo	1.5
3	8 TNX-4800 2 placebo	5
4	8 TNX-4800 2 placebo	10

Participants received either placebo or TNX-4800 by subcutaneous (SC) injection

Observed Phase 1 Pharmacodynamics

- 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 2 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 (ie, ≥1.5 mg/kg)
- Mean half-life ranged from 62 to 69 days across groups. Serum concentrations remained quantifiable for up to 12 months in most volunteers. Mean exposure for the 10 mg/kg cohort was less than 17% of the highest exposures in a rat toxicology study
- Transient low levels of antidrug antibodies were detected in <10% of treated volunteers, with no impact on PK
- All drug-related adverse events (AEs) were mild or moderate: injection site AEs 14%, headache 12%, COVID-19 and fatigue 9%, with rest reported in 2 of fewer cases (≤6%)



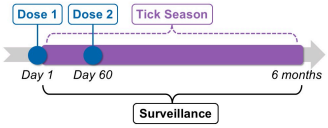
Each point represents a mean for the cohort at the time point and dose

Summary

- TNX-4800 acts inside the tick to kill *Borrelia* and block the differentiation and transmission of *Borrelia*
- Estimates of MEC indicate that serum levels of 21 µg/mL in nonhuman primates are a ceiling but that lower serum levels can be protective
- Phase 1 study of TNX-4800, a long-acting, human mAb, showed no significant clinical or laboratory safety signals
- Serum TNX-4800 was measurable at the earliest sampling time of 48 hours, indicating rapid absorption
- TNX-4800 was found to be safe when administered to healthy volunteers
- The PK of TNX-4800 were typical of a human IgG1 with an Fc domain mutation that extends half-life

Design of Planned Phase 2 Study

2027 Planned TNX-4800 Adaptive Phase 2 Field Study Design



Study participants randomized 1:1 to receive TNX-4800 or placebo

- An adaptive phase 2 field study of TNX-4800 is planned for 2027
- Dosing regimen: day 1 initial dose (fixed dose with ~5 mg/kg exposure) will be followed by a booster at 2 months
- Primary endpoint will be decrease in Lyme disease at 6 months in TNX-4800 arm

Conclusions

- TNX-4800 is being developed as a prophylactic to be administered subcutaneously in the spring with a booster after 2 months, which is expected to provide protection within 2 days for at least 6 months to people in endemic areas during the US tick season
- TNX-4800 avoids the onerous immunization regimens of over 6 to 12 months for protection required by OspA vaccines in development
- TNX-4800 is a mAb measured by µg/mL in serum, which is different from the polyclonal antibody responses to vaccines that are measured in "titers"
- TNX-4800 serum concentration enables direct PK-driven exposure targeting

References

1. de Silva AM, et al. *J Exp Med.* 1996;183(1):271-275. **2.** Radolf JD, et al. *Nat Rev Microbiol.* 2012;10(2):87-99. **3.** Anderson C, et al. *Pathogens.* 2021;10(3):281. **4.** Dattwyler RJ, et al. *NPJ Vaccines.* 2022;7(1):10. **5.** de Silva AM, et al. *Infect Immun.* 1999;67(1):30-35. **6.** Woodman ME, et al. *FEMS Immunol Med Microbiol.* 2008;54(2):277-282. **7.** Schiller ZA, et al. *J Clin Invest.* 2021;131(11):e144843. **8.** Wang Y, et al. *J Infect Dis.* 2016;214(2):205-211. **9.** Regoes RR, et al. *Antimicrob Agents Chemother.* 2004;48(10):3670-3676.