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): **March 30, 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, 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 Capital 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 March 31, 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. A copy of the press release that discusses these matters is furnished hereto as Exhibit 99.01, and is incorporated herein by reference. Copies of presentations that discuss these matters are furnished hereto as Exhibits 99.02 and 99.03, and are incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01, 99.02 and 99.03 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.

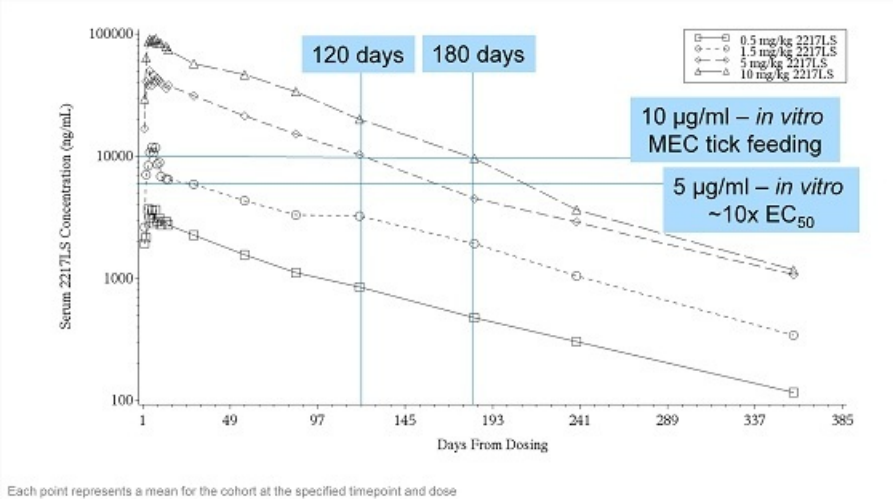
On March 31, 2026, the Company announced program updates on its TNX-4800 product candidate for protection against Lyme disease, including the announcement that Phase 1 data of TNX-4800 was presented by Mark S. Klempner, MD, professor of medicine at UMass Chan Medical School, an inventor of TNX-4800 and principal investigator of the study, on March 30, 2026, at the World Vaccine Congress Washington 2026.

The Company also announced its strategy for a Phase 2 field study of TNX-4800, expected to initiate in the first half of 2027, pending U.S. Food and Drug Administration ("FDA") clearance. The Company intends to study TNX-4800 in a randomized, double-blind, placebo-controlled, adaptive Phase 2 field study to evaluate the efficacy of a single subcutaneous 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). A fixed dose of 350 mg was selected for the Phase 2 field study based on Phase 1 pharmacokinetic data, which dose (i) is expected to provide exposures comparable to the 5 mg/kg dose evaluated in the Phase 1 study and (ii) resulted in mean blood levels of 10 µg/ml at four months. 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). The key secondary endpoint will be the prevention of Lyme disease at six months (comparison of TNX-4800 vs. placebo).

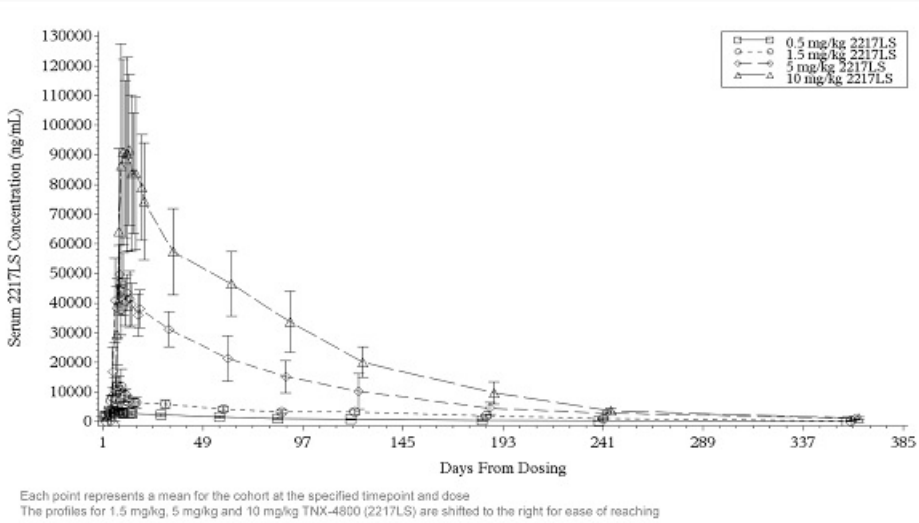
The Company expects to have GMP investigational product available for clinical testing in early 2027. Additionally, if necessary and pending FDA clearance, the Company plans to initiate a controlled human infection model study in 2028.

The charts below set forth certain data from the Phase 1 trial for TNX-4800.

Observed Phase 1 Pharmacokinetics



TNX-4800 Phase 1: Variability of Serum Concentrations at Sampling Time Points Among Subjects in Each Dosing Cohort



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, March 31, 2026
99.02	Corporate Presentation, March 31, 2026
99.03	Presentation, March 30, 2026
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: March 31, 2026

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

Exhibit 99.01

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.

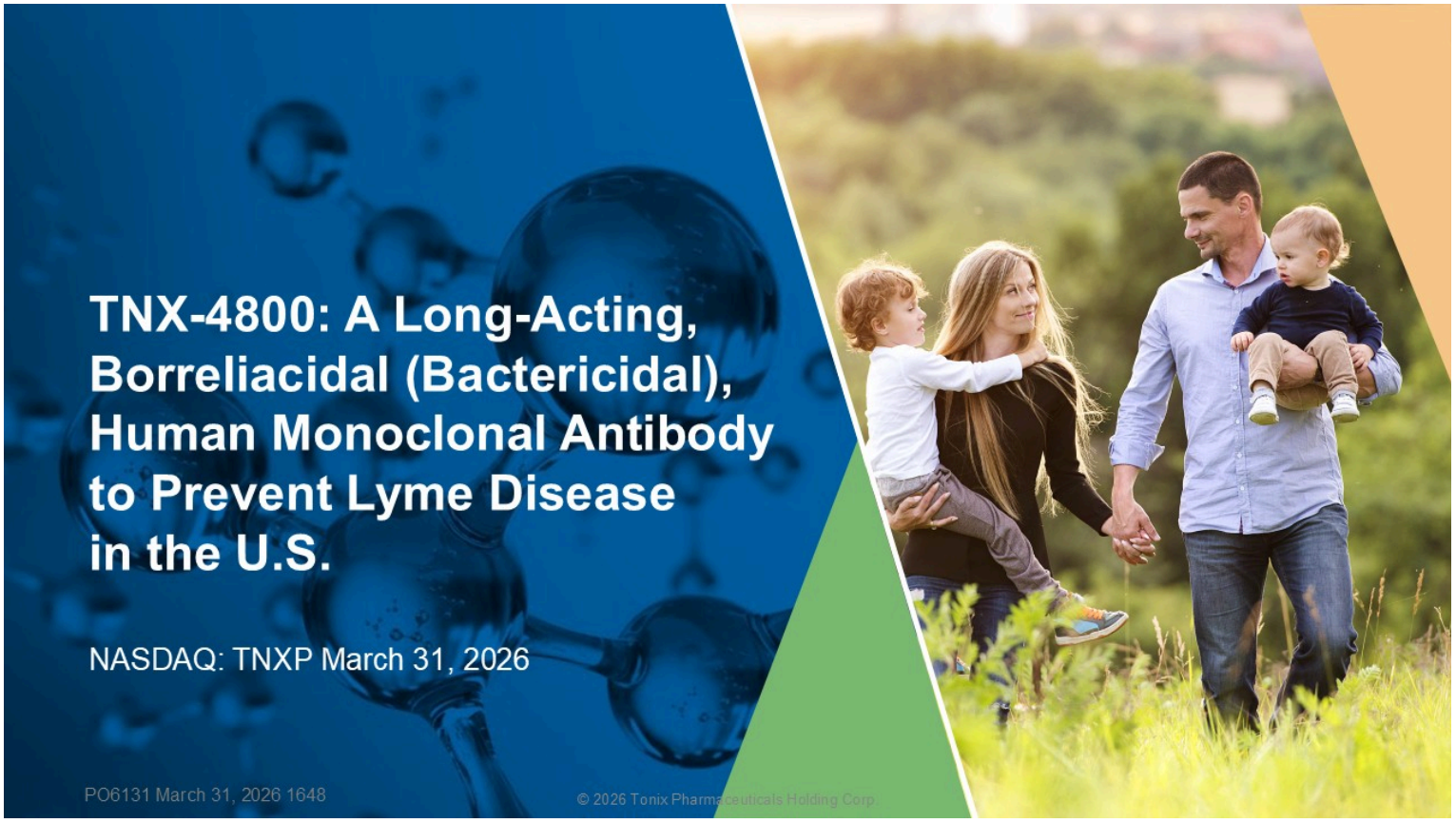
Investor Contacts
Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 799-8599

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

EXHIBIT 99.02



Cautionary Note on Forward-Looking Statements

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. 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. 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 forth in the Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission (the “SEC”) on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. 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.

Addressing the Significant Public Health Challenge of Lyme Disease in the U.S.

- ✓ Phase 1 study complete, showing favorable safety, tolerability, immunogenicity, and pharmacokinetics

Manufacturing GMP Material for Human Studies Currently on Track for Early 2027

Plan to Initiate Adaptive Phase 2 Field Study, Pending FDA Clearance

Plan to Initiate CHIM (Controlled Human Infection Model) Study, If Necessary

Lyme Disease: Epidemiology in the U.S.

The range of Lyme disease is expanding[1]

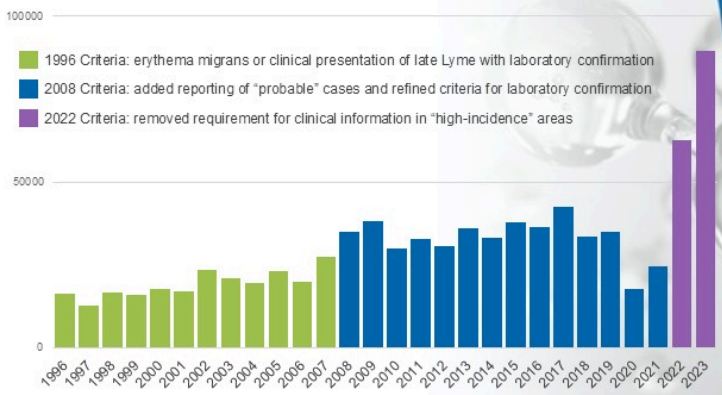
1995

2023

Images from CDC NNDSS

Lyme disease is reported most often in the Northeast and Midwest, with 95% of cases coming from "high-incidence" areas[1]

Lyme disease is an increasing problem[2]



The actual prevalence of Lyme disease is estimated to be 8 to 12 times higher than reported.[3] In 2022, more sensitive surveillance criteria resulted in a 67% increase in reported cases[2]

1. U.S. Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System; maps. February 11, 2025. Accessed July 18, 2025. https://www.cdc.gov/lyme/data-research/facts-stats/surveillance-data-1.html.
2. U.S. Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System; graphs: annual cases. February 11, 2025. Accessed July 18, 2025. https://www.cdc.gov/lyme/data-research/facts-stats/surveillance-data-1.html.
3. Rodino KG, et al. *J Clin Microbiol*. 2025:e0080723.

CDC=Centers for Disease Control and Prevention; NNDSS=National Notifiable Diseases Surveillance System.

TONIX PHARMACEUTICALS

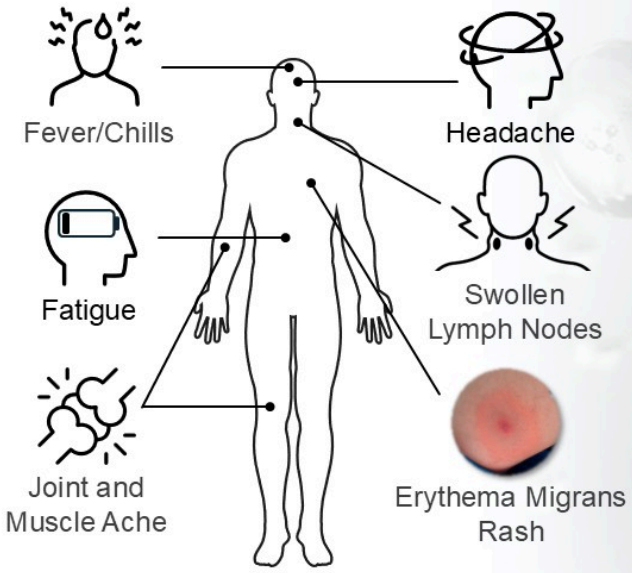
Clinical Presentation: Acute Lyme Disease

There are 3 stages of Lyme disease: early, early disseminated, and late[1]

Early, or acute, Lyme disease has many signs or symptoms[1,2]

Erythema migrans rash is a hallmark symptom of early Lyme disease, occurring in 70% to 80% of people[1,2]

- Begins at site of tick bite and expands up to 12 inches in diameter
- Development is delayed, with an average of 7 days after bite
- Sometimes has a "bull's-eye" appearance



1. Cleveland Clinic. Updated August 16, 2022. Accessed July 18, 2025. https://my.clevelandclinic.org/health/diseases/11586-lyme-disease.
2. U.S. Centers for Disease Control and Prevention. May 15, 2024. Accessed July 18, 2025. https://www.cdc.gov/lyme/signs-symptoms/index.html.

TONIX PHARMACEUTICALS

Current Landscape for Lyme Disease Prophylaxis and Treatment

U.S. population where Lyme disease is endemic is estimated to be 87 million[1]

Recommendations for pre-exposure prevention focus on tick bite avoidance. No vaccine is currently on the market[2-5]

Presently available post-exposure prophylaxis is limited to antibiotic regimens, typically doxycycline.[6] Extended use of antibiotics has recognized side effects[5]

Approximately 10-20% of Lyme disease patients experience long-term sequelae including Post-Treatment Lyme Disease Syndrome (PTLDS)[6,7]

1. Kugeler KJ, et al. *Emerg Infect Dis.* 2021;27(2):616-619.
2. U.S. Centers for Disease Control and Prevention. May 15, 2024. Accessed July 18, 2025. https://www.cdc.gov/lyme/signs-symptoms/index.html.
3. https://www.idsociety.org/practice-guideline/lyme-disease/o.
4. Chan PA, et al.. *Sex Transm Dis.* 2023 50(11):701-712.
5. Lantos PM et al, *Clinical Infectious Diseases*, 72,(1) 2021, Pages e1–e48.
6. Zafar K, et al. *Front Microbiol.* 2024;15:1459202.
7. Melia M.T.*N Engl J Med.* 2016;374:1277–1278.

TONIX PHARMACEUTICALS

Lyme Disease in the U.S. and Europe are Caused by Different *Borrelia*

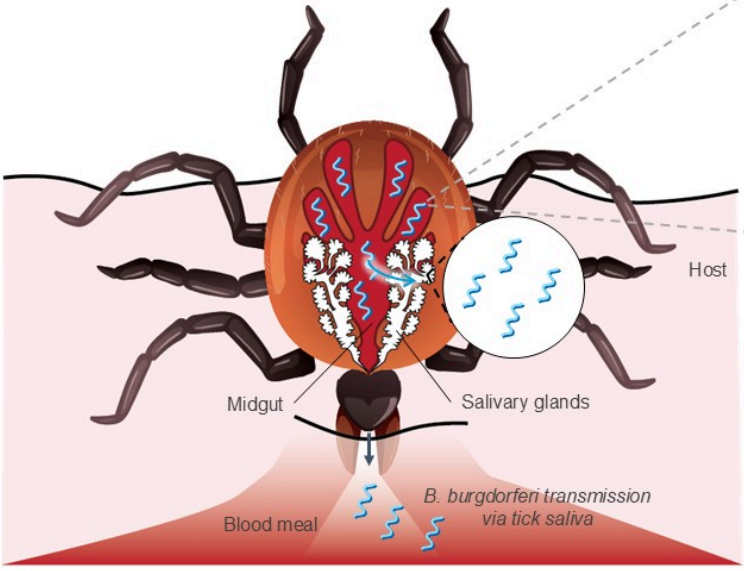
- **>99.9% caused by *B. burgdorferi* sensu stricto (s.s.)[1,2]**
  - U.S. *B. burgdorferi* minimal genetic variability[3]
  - Incidence is seasonal in summer months[3]

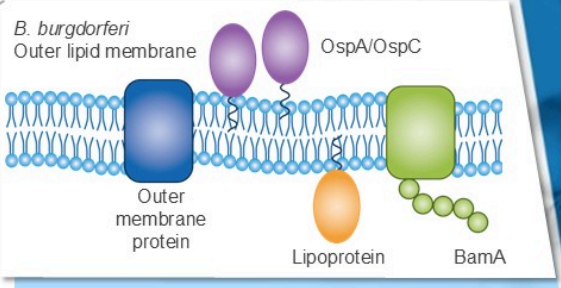
- **Caused by a diverse group of serotyptes[1]**
  - Serotypes are (*B. afzelii, B. garinii, B. bavariensis*, etc.)
  - Lyme disease "Season" varies, based on country and climate

- **The only approved U.S. vaccine was directed to *B. burgdorferi* OspA**
  - SmithKline Beecham's LYMErix vaccine had ~70-80% protection, but was withdrawn from the market[4]

1. Marques AR, et al. *Emerg Infect Dis.* 2021. 27(8):2017-2024.
2. Pritt BS, et al. *Lancet Infect Dis.* 2016. 6(5):556-564.
3. Lemieux JE, et al. *PLoS Pathog.* 2023.19(8):e1011243.
4. Nigrovic LE, et al. *Epidemiol* Infect. 2006. Aug 8;135(1):1-8.

B. burgdorferi Bacteria Are Transmitted to Humans *via* Tick Salivary Glands[1]





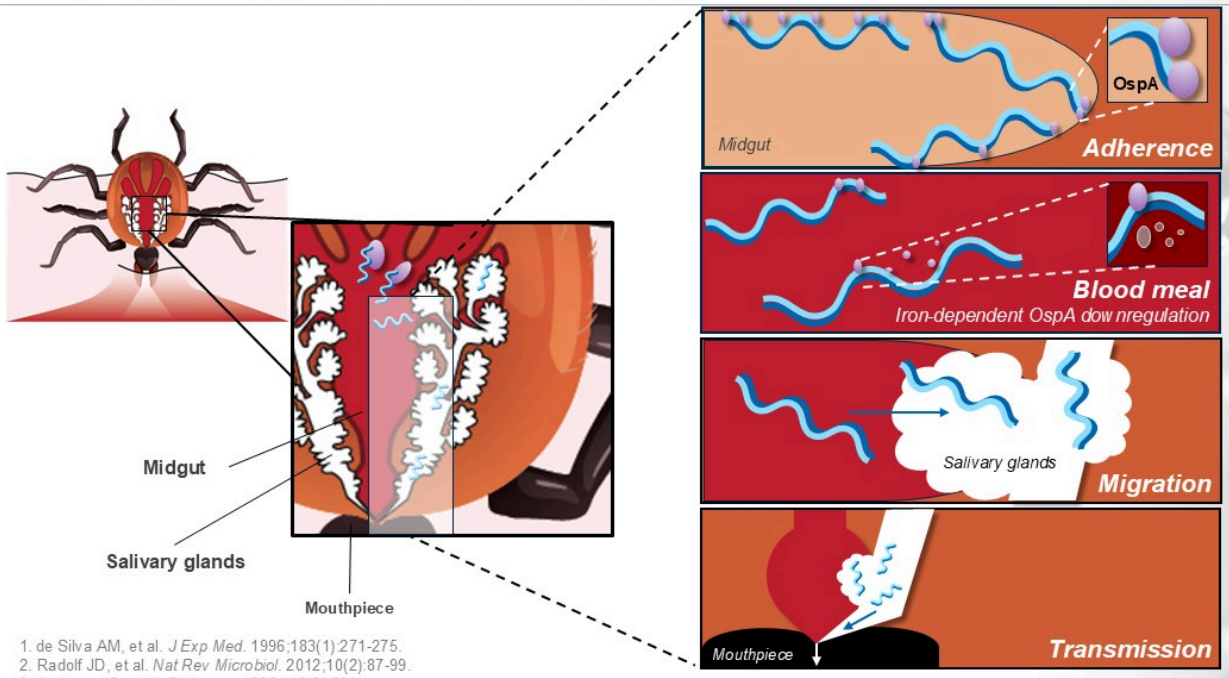
- The outer membrane protein OspA supports *B. burgdorferi* survival in the tick midgut via adherence[1-3]
- Once the tick bites a host, the iron in a blood meal downregulates OspA, and bacteria migrate from the midgut to the salivary glands for transmission[1-3]
- While OspA is essential for transmission, it is only expressed within infected ticks, and levels seen in the human host are insufficient for seroconversion (antibody production)[4]

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. Woodman ME, et al. *FEMS Immunol Med Microbiol*. 2008;54(2):277-282.

Bam=β-barrel assembly machinery; Osp=outer surface lipoprotein.

TONIX PHARMACEUTICALS

OspA Facilitates Bacterial Adherence to the Tick Midgut, and Downregulation Promotes Migration to Salivary Glands for Transmission[1-3]

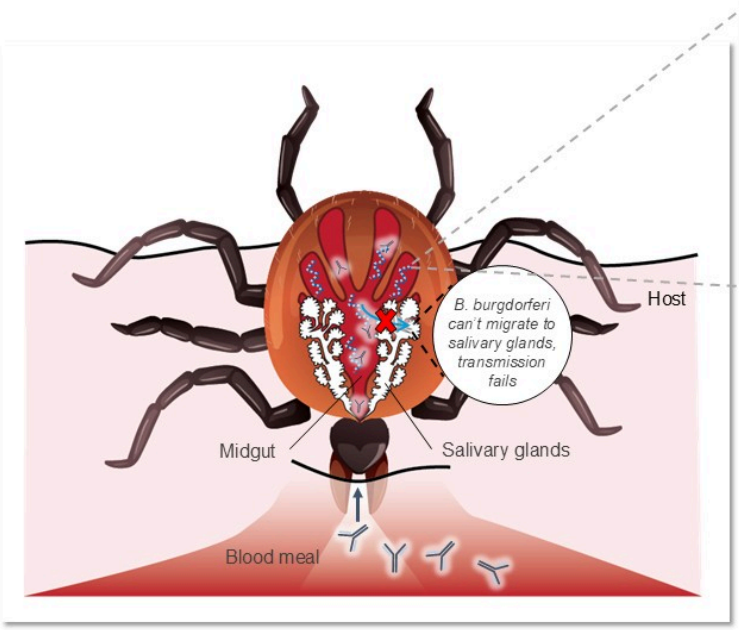


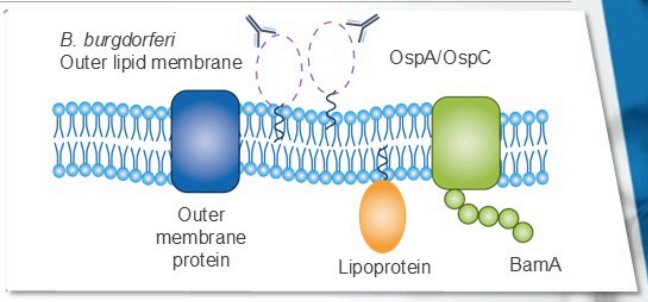
1. de Silva AM, et al. *J Exp Med*. 1996;183(1):271-275.
2. Radolf JD, et al. *Nat Rev Microbiol*. 2012;10(2):87-99.
3. Anderson C, et al. *Pathogens*. 2021;10(3):281.

Osp=outer surface lipoprotein.

TONIX PHARMACEUTICALS

Circulating Anti-OspA Monoclonal Antibody (TNX-4800) Ingested by Tick Blocks *B. burgdorferi* Transmission From Tick to Human[1]





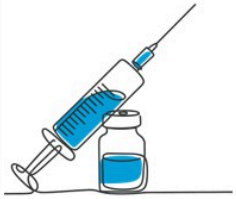
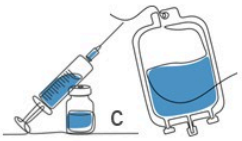
- TNX-4800 is a human monoclonal antibody against OspA[1]
- An Fc region mutation in TNX-4800 extends its half-life: a single administration provides protection during the months of high infection risk
- If a tick bites a human immunized with TNX-4800, anti-OspA antibodies enter the tick midgut and bind to OspA on *B. burgdorferi* spirochetes[2,3]
- After TNX-4800:OspA binding, bacteria are killed or fail to migrate from the midgut to salivary glands, preventing transmission to the human host[2]

1 Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.
2. de Silva AM, et al. *J Exp Med*. 1996;183(1):271-275.
3. Radolf JD, et al. *Nat Rev Microbiol*. 2012;10(2):87-99.

Bam=β-barrel assembly machinery; Fc=fragment crystallizable; Osp=outer surface lipoprotein.

TONIX PHARMACEUTICALS

Antibodies Can Be Created Endogenously or Received From Exogenous Sources

Active		Passive	
Natural	Engineered	Natural	Engineered
Pathogen Exposure	Vaccines	Maternal Antibodies	Monoclonal Antibodies
			
Infection with a pathogen stimulates the immune system to create antibodies	Injection of weakened pathogens or pathogen components stimulates the immune system to create antibodies	Breast milk contains maternal antibodies that support underdeveloped infant immune systems	Monoclonal antibodies may be infused or delivered subcutaneously including in patients who require additional immune support

Active immunity necessitates the creation of endogenous antibodies, while passive immunity entails the transfer of external antibodies

U.S. Centers for Disease Control and Prevention. July 30, 2024. Accessed July 15, 2025. https://www.cdc.gov/vaccines/basics/immunity-types.html

Introducing TNX-4800

TNX-4800[1] is a human anti-OspA monoclonal antibody with engineered Fc domain for extended half-life, licensed from UMass Chan Medical School in 2025

Expected Mechanism of Action

TNX-4800 provides passive immunity by directly supplying neutralizing antibodies, bypassing the need for a patient's immune system to generate its own antibodies

1. TNX-4800 is an investigational biologic and is not approved for any indication.

Clinical and Market Acceptance of Monoclonal Antibody Preventive Treatments

Monoclonal antibody prophylaxis has been approved for respiratory syncytial virus (RSV) and COVID-19, including ENFLONSIA™,[1] BEYFORTUS®,[2] and PEMGARDA™[3]

1. Enflonsia. Prescribing information. Merck Sharp & Dohme LLC; 2025.
2. Beyfortus. Prescribing information. Sanofi; 2024.
3. Pemgarda. Prescribing information. Invivyd, Inc.; 2025.

Not All anti-OspA mAbs are Bactericidal

Name		OspA Epitope[1,2]				Bactericidal
Antibody	Vaccine	*N*-terminus	Central Domain		*C*-terminus	
				~aa 165–173		
184.1		+				-
TNX-4800			+			+
LA-2					+	+
	LYMErix	+	+	+	+	+
	VLA15	+	+	-	+	+

- **Monoclonal anti-OspA antibodies can be bactericidal**
  - In a series of mAbs, only those directed towards the *C*-terminal and central domains manifested bactericidal activity *in vitro*, and prevention of transmission *in vivo*[1]
  - For example, mAbs TNX-4800 (2217) (central domain)[2] and LA-2 (*C*-terminal) are bactericidal
- ***N*-terminal anti-OspA antibodies can be inactive**
  - 184.1 is an example of a non-bactericidal mAb that binds the *N*-terminal region

1. Embers ME, et al. *Vaccine*. 2026 75:128231. doi: 10.1016/j.vaccine.2026.128231.
2. Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.
3. LYMErix was full length OspA aa 20-273 from *B. burgdorferi* strain B31produced in *E. Coli*
4. VLA15 modifies the B31 OspA sequence to remove the putative arthritogenic/LFA-1–mimicking epitope (~aa 165–173)

TONIX PHARMACEUTICALS

Comparison of TNX-4800 with VAL15, mRNA-1975, and mRNA1982

	TNX-4800	VLA15	mRNA-1975	mRNA-1982
Sponsor	Tonix	Pfizer/Valneva	Moderna	Moderna
Status	Phase 2-ready	Phase 3	Phase 1/2	Phase 1/2
Type	Monoclonal Antibody	Vaccine – alum adjuvant	mRNA	mRNA
Immunity	Passive	Active	Active	Active
Target Market	U.S.	EU + U.S.	U.S.	EU + Asia
Borrelia targeted[1-4]	*B. burgdorferi* (U.S.)	*B. burgdorferi* (U.S.) *B. afzelii* (Europe) *B. garinii** (Europe) *B. Bavariensis* (Europe)	*B. burgdorferi* (U.S.)	*B. burgdorferi* (U.S.) *B. afzelii* (Europe) *B. garinii* (Europe) *B. bavariensis* (OspA type 4)(Europe) *B. garinii* (OspA type 5 and 6 variants)(Asia) *B. spielmanii*

1. Marques AR, et al. *Emerg Infect Dis*. 2021. 27(8):2017-2024. doi: 10.3201/eid2708.204763.
2. Pritt BS, et al. *Lancet Infect Dis*. 2016. 6(5):556-564. doi: 10.1016/S1473-3099(15)00464-8.
3. Lemieux JE, et al. *PLoS Pathog*. 2023.19(8):e1011243. doi: 10.1371/journal.ppat.1011243.
4. Comstedt P, et al. *PLoS One*. 2014 9(11):e113294. doi: 10.1371/journal.pone.0113294.
*VLA15 contains 3 OspA's from different garinii genospecies.

Comparison of TNX-4800 with Alum-Adjuvanted Subunit Vaccines LYMErix (Withdrawn) and VLA15 (in Development) in Terms of OspA Targeting

	TNX-4800	LYMErix[1-4]	VLA15[1-4]
Sponsor	Tonix	SmithKline (GSK)	Pfizer/Valneva
Status	In Development	Withdrawn	In Development
Type	Monoclonal Antibody	Vaccine	Vaccine
Immunity	Passive	Active	Active
Target Market	U.S.	U.S.	EU + U.S.
Clinical Trials	U.S.	U.S.	EU + U.S.
Borrelia targeted	*B. burgdorferi* (U.S.)	*B. burgdorferi* (U.S.)	*B. burgdorferi* (U.S.) *B. afzelii* (Europe) *B. garinii** (Europe) *B. Bavariensis* (Europe)

1. Marques AR, et al. *Emerg Infect Dis.* 2021. 27(8):2017-2024. doi: 10.3201/eid2708.204763.
2. Pritt BS, et al. *Lancet Infect Dis.* 2016. 6(5):556-564. doi: 10.1016/S1473-3099(15)00464-8.
3. Lemieux JE, et al. *PLoS Pathog.* 2023.19(8):e1011243. doi: 10.1371/journal.ppat.1011243.
4. Comstedt P, et al. PLoS One. 2014 9(11):e113294. doi: 10.1371/journal.pone.0113294.
*VLA15 contains 3 OspA's from different garinii genospecies.

Comparison of TNX-4800 with Alum-Adjuvanted LYMErix and VAL15 Administration Protocol and Intended Timing (Onset and Duration) of Protection

	TNX-4800	LYMErix (Withdrawn)	VLA15[1]
Sponsor	Tonix	SmithKline (now GSK)	Pfizer/Valneva
1st dose	Day 1	Day 1	Day 1
2nd dose	-	1 month	2 months
3rd dose	-	12 months	5-9 months
4th dose	-	-	12 months
Protection duration	At least ~four months	Seasonal	Seasonal
Protection onset	Within 2 days	After 3rd shot	After 4th shot[2]

- **TNX-4800 is expected to be protective within 2 days**
  - Based on human pharmacokinetics and animal models
- **Lyme vaccines typically take >6 months to be protective**
  - Depend on high-titer antibodies
  - Require annual boosters
  - Complex immunization schedule may have contributed to poor LYMErix uptake

1. Comstedt P, et al. *PLoS One*. 2014 9(11):e113294. doi: 10.1371/journal.pone.0113294
2. VALOR study missed primary endpoint – Pfizer press release March 23, 2026

Comparison of TNX-4800 (Monoclonal Antibody) and VLA15 (Vaccine): Administration Protocol and Intended Timing (Onset and Duration) of Protection

Criteria	TNX-4800 (mAb)[1,2]	VLA15[4,5]
Treatment mode	Pre-exposure single-dose mAb	Pre-exposure 4-dose vaccination regimen
Onset of maximal protection	Within 2 days following subcutaneous (SC) dose	> 1 year post 4th intramuscular (IM) dose[3]
Target patient population	General population Populations with short-term trips/summer vacations/deployments to endemic areas	General populations who do not need immediate protection
Activity	Designed to cover *B. burgdorferi*	The VLA15 vaccine reportedly covers 6 serotypes prevalent in North America and Europe
Dosing regimen	Single dose expected to provide approximately four months protection	Multiple doses needed to obtain initial protection with seasonal durability
Dosing route	SC	IM
Risks	*Anticipated low safety risk like other fully human mAbs for which there is considerable experience* Does not recognize the putative arthritogenic T-cell epitope	OspA-targeted vaccines induce immune responses (associated with side effects), and include polyclonal antibody responses (that may have off-target effects)

1. Wang Y, et al. *J Infect Dis*. 2016. 214(2):205-11.
2. Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.
3. VALOR study missed primary endpoint – Pfizer press release March 23, 2026.
4. Proposed attributes – not yet finalized or validated
5. https://valneva.com/research-development/lyme-disease.

Data on file.
Proposed attributes – not yet finalized or validated
IM=intramuscular; mAb=monoclonal antibody; Osp=outer surface protein

Comparison of TNX-4800 and VLA15 Lyme Preventatives in Development

- **TNX-4800 is a long-acting humanA mAb (in development) against *B. burgdorferi* OspA**
  - Bactericidal monoclonal antibody
    - TNX-4800 showed EC_{50} ≈ 0.56 µg/mL *in vitro*[1]
  - Planned testing exclusively targets U.S. serotype (*Borrelia burgdorferi*)
  - Safety studies, field testing, and marketing approval, if any, planned for U.S. only

- **Pfizer/Valneva's VLA15 (in development) is a vaccine that elicits antibodies against 6 different *Borrelia* OspAs**[2]
  - Vaccine that elicits polyclonal antibodies to six OspA-derived peptide antigens
  - Field tests in EU and the U.S.
  - 5 of 6 OspA antigens in VLA15 are European serotypes:
    - *B. afzelii* (one serotype), *B. garinii* (3 serotypes), *B. bavariensis* (one serotype)
  - 1 of 6 OspA antigens in VLA15 is US: *Borrelia burgdorferi* sensu stricto (s.s.)

1. Schiller ZA, et al. *J Clin Invest.* 2021;131(11):e144843.(TNX-4800 has EC_{50} = 3.71 ± 2.81 nM)
2. Comstedt P, et al. *PLoS One.* 2014 9(11):e113294. doi: 10.1371/journal.pone.0113294.

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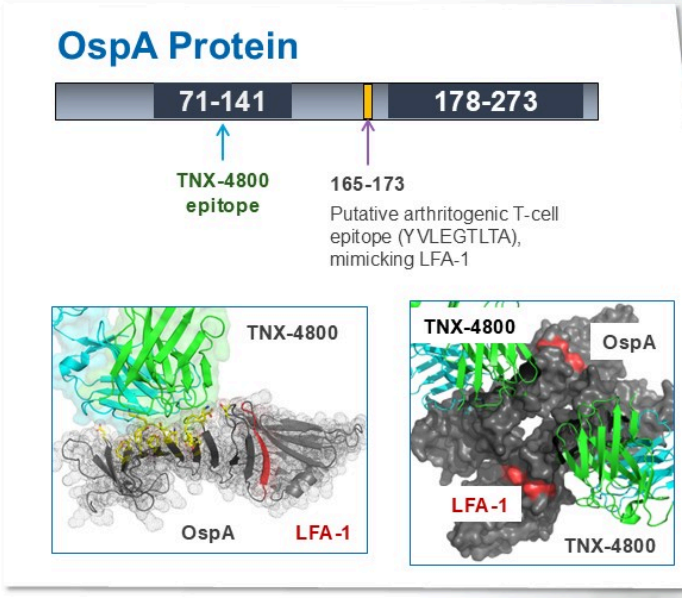
TNX-4800 Binds to a Specific Epitope on OspA to Avoid Off-Target Effects

- An epitope in the OspA protein mimics human leukocyte function–associated antigen 1 (hLFA-1 or LFA-1)[1]
- Antibodies to the LFA-1-like epitope can trigger an arthritogenic autoimmune condition[1,2]
- LYMErix™ was withdrawn from the market in part over unsubstantiated claims of this concern[2]
- TNX-4800 does not bind to this epitope and instead binds to the 71-141 region, which has no human homologue and does not carry the same risk[3]
- This advantage of TNX-4800 may extend to individuals who have experienced previous infections and/or carry allelic genotype predispositions (*HLA-DRB1*0401*) to autoimmune arthritis[1]



1. Steere AC, et al. *Arthritis Rheum*. 2003;48(2):534-540.
2. Nigrovic LE, Thompson KM. *Epidemiol Infect*. 2007 135(1):1-8.
3. Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.

Osp=outer surface lipoprotein.

TNX-4800 Target Product Profile (TPP)*

Variable	Target
Primary Indication	Pre-exposure prophylactic against Lyme disease
Clinical Pharmacology	Blood levels sufficient to provide protection within 2-3 days and maintained efficacy for ≥ four months Consistent with bacterial-targeted, fully human mAbs
Nonclinical Toxicology	Consistent with bacterial-targeted, fully human mAbs
Patient Population	Adolescents and adults 16-65 initially, then ≥6 months old Persons at risk living in or traveling to endemic areas
Limitations of Use in Specific Populations	None
Duration of protection	Single dose Expected to provide approximately four months protection
Delivery Mode	SC injection
Efficacy	Protection against the transmission of Lyme disease from an infected tick ≥80% efficacy*
Storage Requirements	2°C to 8°C
Drug Interactions	None
Target Jurisdictions	United States
Safety Profile Risks/Side Effects Warnings and Precautions Adverse Reactions	Consistent with fully human mAbs directed against bacterial antigen with no human homologue
Contraindications	None currently

*Subject to change and to FDA approval
mAb=monoclonal antibody; mg=milligrams; SC=subcutaneous.

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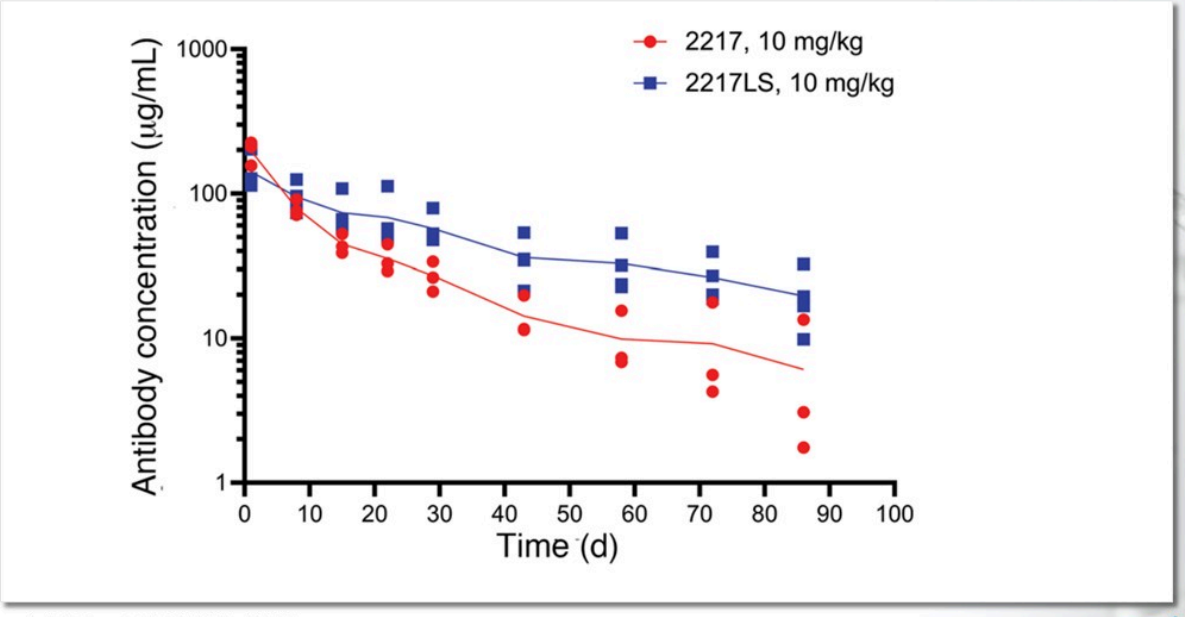
Engineered Fc Mutations Extend Half-Life of TNX-4800 (2217LS) in Nonhuman Primates Relative to mAb 2217[1]



[1]Schiller ZA, et al. *J Clin Invest.* 2021;131(11):e144843.
N=4 for each group and each dot represents one monkey. Half-lives are reported in days and hours as mean ± SD (line)
Fc=fragment crystallizable.

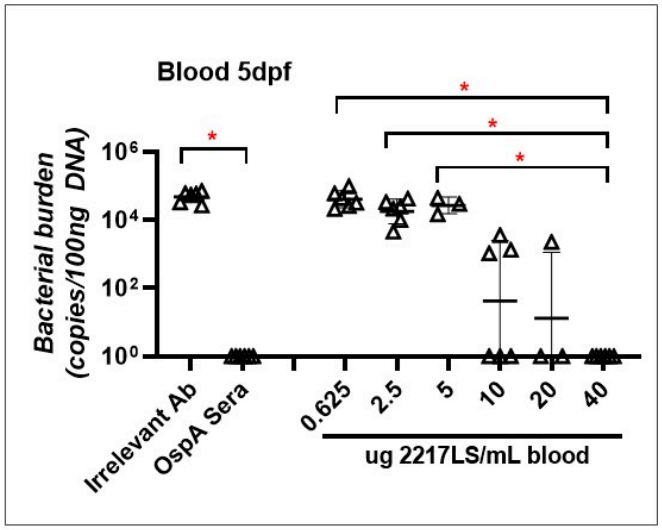
Analysis of Minimum Effective Concentration (MEC) #1 – *in vitro* Bactericidal Activity

- **TNX-4800 showed EC_{50} ≈ 0.56 µg/mL *in vitro*[1]**
  - MEC ~ 10X EC_{50}[2]
- **Conclusion: MEC ~5 µg/mL – based on *in vitro* bactericidal activity**

1. Wang Y, et al. *J Infect Dis*. 2016. 214(2):205-11.
2. Rogers RR et al , *Antimicrobial Agents and Chemotherapy*, Oct. 2004, p. 3670–3676

Analysis of Minimum Effective Concentration (MEC) #2
Tick Feeding Method

The monoclonal anti-OspA antibody TNX-4800 (2217LS) inhibits tick-to-blood transmission of *B. burgdorferi* B31-5A4 in a dose-dependent manner in an artificial membrane feeding system



Data on file.
N=5
Asterisk * = statistically significant
Methods described in: Kröber T, Guerin PM. *Trends Parasitol.* 2007 23(9):445-9.

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Analysis of Minimum Effective Concentration (MEC) #3 – *in vivo* Primate Challenge Model

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Blocking *Borrelia burgdorferi* transmission from infected ticks to non-human primates with a human monoclonal antibody

Zachary A. Schiller, … , Mark S. Klempner, Yang Wang

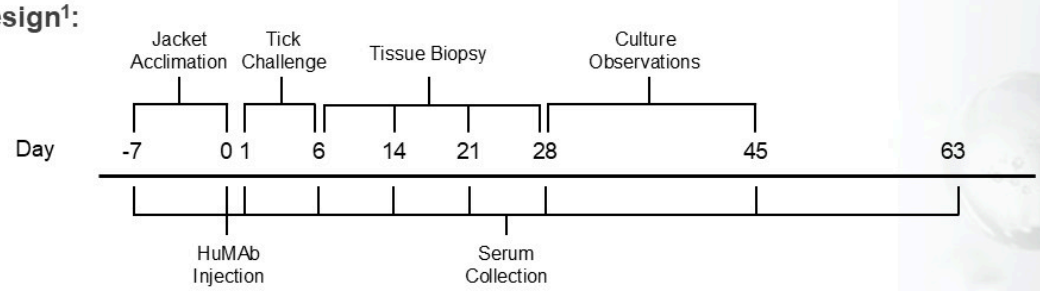
Published April 29, 2021

Citation Information: *J Clin Invest.* 2021. https://doi.org/10.1172/JCI144843.

View: Text | PDF

Nonhuman Primate Challenge Model: Protocol and Protection by Dosage Level

Study Design[1]:



- 4 dosing cohorts, 1 irrelevant IgG control
- 4 to 6 animals per cohort
- Seroconversion for IgG antibodies against *B. burgdorferi* was measured as an indicator of efficacy

Results:

Cohort	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Irrelevant IgG
Dose (mg/kg)	3	10	30	90	10
Protection (%)	100	83	100	100	0
P value	<0.001	<0.001	<0.001	<0.001	N/A

1. Schiller ZA, et al. *J Clin Invest.* 2021;131(11):e1144843.
HuMAb=human monoclonal antibody; IgG=immunoglobulin G.

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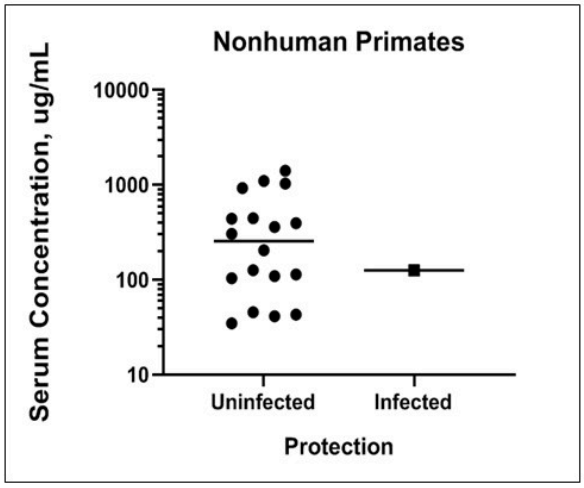
Primate Challenge Model

- Infected ticks were placed on each non-human primate administered TNX-4800 (N=20) for 6 days[1]
- Only 1 in 20 became infected (95% protection)



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

Analysis of Minimum Effective Concentration (MEC)

Three methods:

- **Serum ~5 µg/mL – *in vitro* bactericidal activity**
  - TNX-4800 showed EC_{50} ≈ 0.56 µg/mL *in vitro*[1]
  - MEC ~ 10X EC_{50}[2]
- **Serum <10 µg/mL – *in vitro* tick feeding experiment**
  - TNX-4800 showed killing ≥ 10 µg/ml[3]
- **Serum <21 µg/mL – *in vivo* primate challenge model**
  - TNX-4800 serum levels >21 µg/ml were 95% protective[1,3]

[1] Wang Y, et al. *J Infect Dis*. 2016. 214(2):205-11.
[2] Rogers RR et al , Antimicrobial Agents and Chemotherapy, Oct. 2004, p. 3670–3676
[3] Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.

TNX-4800: Nonclinical Safety Data

- **cGLP Tissue Cross Reactivity study in rat and human tissues**
  - No significant cross-reactivity
- **Non-GLP pharmacokinetic and tick challenge studies in monkeys**
  - Did not reveal a safety signal
- **cGLP 5-week multiple dose study with 4-week recovery in rats and a cGLP single dose local tolerance study in rats**
  - Observed abnormalities were mild to moderate and all findings were judged non aversive (hematologic and ALT, AST ALP and APTT increases (notably without bilirubin changes), injection site inflammation, liver and spleen organ weight increases, liver histopathology, primarily in males. All findings were reversible)
- **Exposure in Phase 1 study was multiples relative to NOAEL in rats**
  - Starting dose: 63- to 242-fold lower
  - Highest dose: 3- to 12-fold lower

cGLP = clinical good laboratory practice, ALT = alanine transaminase, AST = aspartate aminotransferase, AP = alkaline phosphatase, APTT = activated partial thromboplastin time, NOAEL = No-observed-adverse-effect level
Once weekly administration of TNX-4800 (intravenous or subcutaneous) for 4 weeks followed by a 35-day recovery period in male and female Sprague Dawley rats was tolerated at doses of up to 500 mg/kg/week intravenous or 300 mg/kg/week SC with no adverse findings. Therefore, under the conditions of this study, 500 mg/kg/week intravenous or 300 mg/kg/week SC was considered to be the NOAEL.

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TNX-4800 Phase 1 Study Overview

Primary Objective:

- Evaluate safety and tolerability of a SC injection of TNX-4800 (2217LS) when administered to healthy subjects

Secondary Objective:

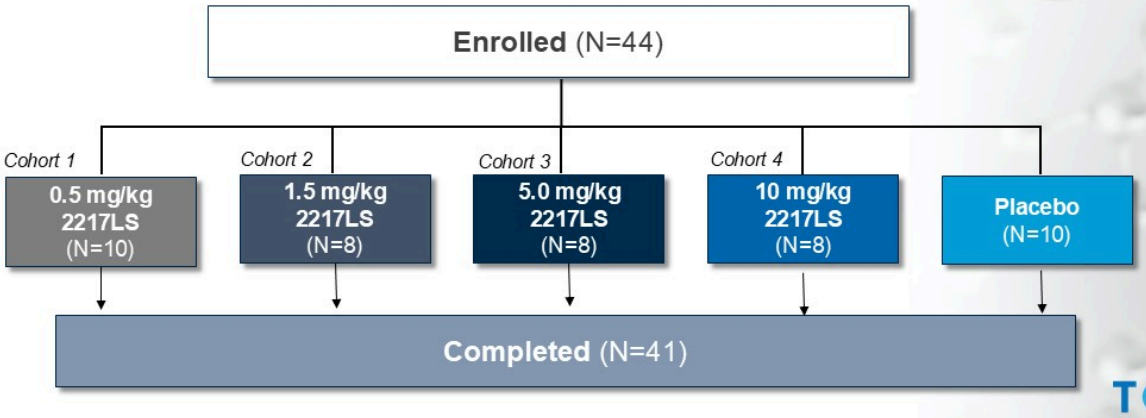
- Evaluate pharmacokinetics of a SC dose of TNX-4800 (2217LS) when administered to healthy subjects

Study Population:

- Healthy male and female subjects, age 19 to 65 years, inclusive

Human Phase 1 Study: Safety, Tolerability and Immunogenicity: Design

- First-in-human, randomized, double-blind, sequential dose-escalation study (N=44)
- Healthy male and female subjects aged 19 to 65 years, serum negative for anti–*B. burgdorferi* antibodies, by an FDA-approved modified 2-tier ELISA test, were recruited
- Safety was assessed via clinical and lab evaluations
- Serum TNX-4800 concentrations were measured by ELISA, with pharmacokinetic analysis
- Antidrug antibodies were detected using an electrochemiluminescence immunoassay



Sullivan-Bólyai JZ, et al. Manuscript in progress. 2025.

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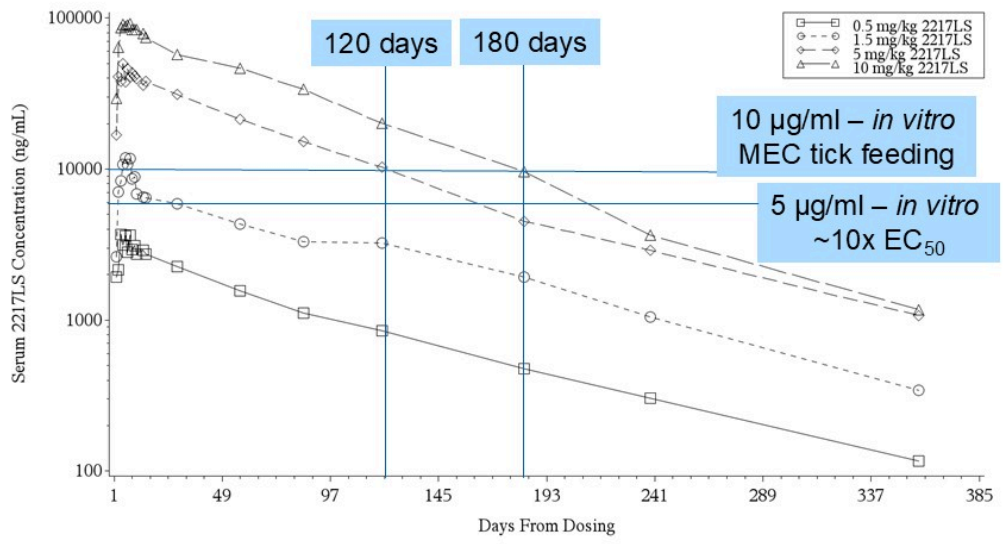
TNX-4800 Phase 1 Study Results

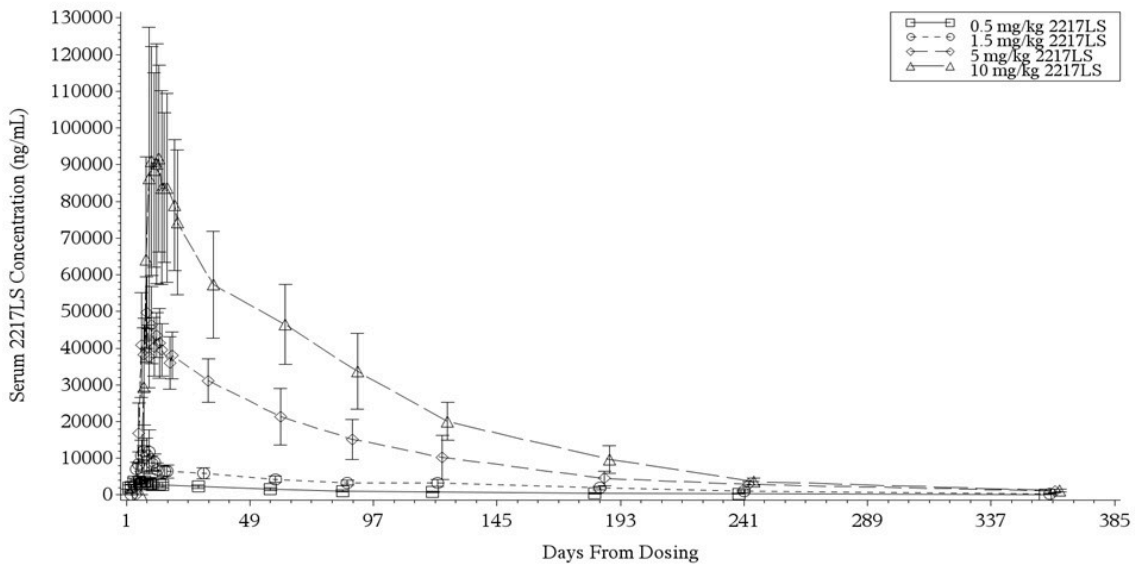
- **No significant clinical or laboratory safety signals**
- **The mean exposure, based on AUC-inf and C_{max} for Cohort 4 (10mg/kg), was less than 17% of the highest exposures in the rat toxicology study**
- **Serum TNX-4800 (2217LS) was measurable at the earliest sampling time of 2 days indicating rapid absorption**
- **For all cohorts C_{max} was observed at 10-13 days followed by a prolonged elimination phase**
- **Apparent terminal $T_{½}$ after 10 mg/kg dose was 64 days**
- **Max $T_{½}$ ranged from 81-104 days:**
  - 10mg/kg - 97 days, 5mg/kg - 87 days, 1.5mg/kg - 104 days, 0.5mg/kg - 81 days
- **Cohort 3 (5mg/kg) serum concentrations:**
  - 10 µg/ml at 4 months (~ *in vitro* tick-feeding MEC and > ~ *in vitro* MEC)

Observed Phase 1 Pharmacokinetics



Each point represents a mean for the cohort at the specified timepoint and dose

TNX-4800 Phase 1: Variability of Serum Concentrations at Sampling Time Points Among Subjects in Each Dosing Cohort



Each point represents a mean for the cohort at the specified timepoint and dose
The profiles for 1.5 mg/kg, 5 mg/kg and 10 mg/kg TNX-4800 (2217LS) are shifted to the right for ease of reaching

TNX-4800 Phase 1 Pharmacokinetics Parameters

Pharmacokinetic Parameters	0.5 mg/kg 2217LS	1.5 mg/kg 2217LS	5 mg/kg 2217LS	10 mg/kg 2217LS
AUC0-t (ng*hr/mL)	6271000 (26.0) [n=10]	20610000 (23.7) [n=8]	79760000 (36.5) [n=8]	165500000 (26.0) [n=8]
AUC0-inf (ng*hr/mL)	6812000 (25.3) [n=10]	21490000 (23.5) [n=8]	82070000 (37.2) [n=8]	168100000 (25.9) [n=8]
AUC% ext (%)	7.832 ± 4.8735 [n=10]	4.103 ± 1.6271 [n=8]	2.805 ± 1.3920 [n=8]	1.494 ± 0.49258 [n=8]
Cmax (ng/mL)	3397 (31.4) [n=10]	10880 (41.3) [n=8]	45650 (22.0) [n=8]	84560 (37.5) [n=8]
Tmax (hr)	96.075 (72.00, 335.91) [n=10]	144.019 (95.95, 215.95) [n=8]	108.319 (71.98, 216.06) [n=8]	108.050 (48.00, 167.78) [n=8]
Kel (1/hr)	0.0004984 ± 0.00025308 [n=10]	0.0004258 ± 0.000060386 [n=8]	0.0005851 ± 0.00037231 [n=8]	0.0004751 ± 0.000072023 [n=8]
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0.5 mg/kg 2217LS: A single subcutaneous injection of 0.5 mg/kg 2217LS, Cohort 1
1.5 mg/kg 2217LS: A single subcutaneous injection of 1.5 mg/kg 2217LS, Cohort 2
5 mg/kg 2217LS: A single subcutaneous injection of 5 mg/kg 2217LS, Cohort 3
10 mg/kg 2217LS: A single subcutaneous injection of 10 mg/kg 2217LS, Cohort 4
AUCs and Cmax are presented as geometric mean (geometric CV%).
Tmax values are presented as median (min, max).
Other parameters are presented as arithmetic mean ± SD.
Source: Tables 14.2.1.5 through 14.2.1.8
Program: /CA29655/sas_prg/pksas/adam_intext_pkparam.sas 13FEB2023 9:20

Each point represents a mean for the cohort at the specified timepoint and dose

Phase 1 Clinical Trial Summary Results

- TNX-4800 studied in randomized, double-blind, sequential dose-escalation study (NCT04863287) to evaluate its safety, tolerability, pharmacokinetics and immunogenicity
- 44 healthy adult subjects randomized and 41 completed study; subjects received a single subcutaneous (SC) administration of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg
- Peak serum concentration (C_{max}) increased by ~25-fold for a 20-times increase in dose
- Serum TNX-4800 measurable at earliest sampling time of 2 days, indicating rapid systemic absorption
- TNX-4800 levels remained quantifiable for >200 days in 80% of subjects at lowest dose and for up to 350 days in majority of participants at higher doses (i.e., ≥ 1.5 mg/kg)
- Mean half-life ranged from 62–69 days across TNX-4800 groups; serum concentrations quantifiable for up to 12 months in most subjects; mean exposure for 10 mg/kg group <17% of the highest exposures in a nonclinical toxicology study
- Anti-drug antibodies (ADA) detected in <10% of treated subjects, with no impact on pharmacokinetics
- Most adverse events were mild or moderate[1]
- TNX-4800 determined to be generally safe and well tolerated

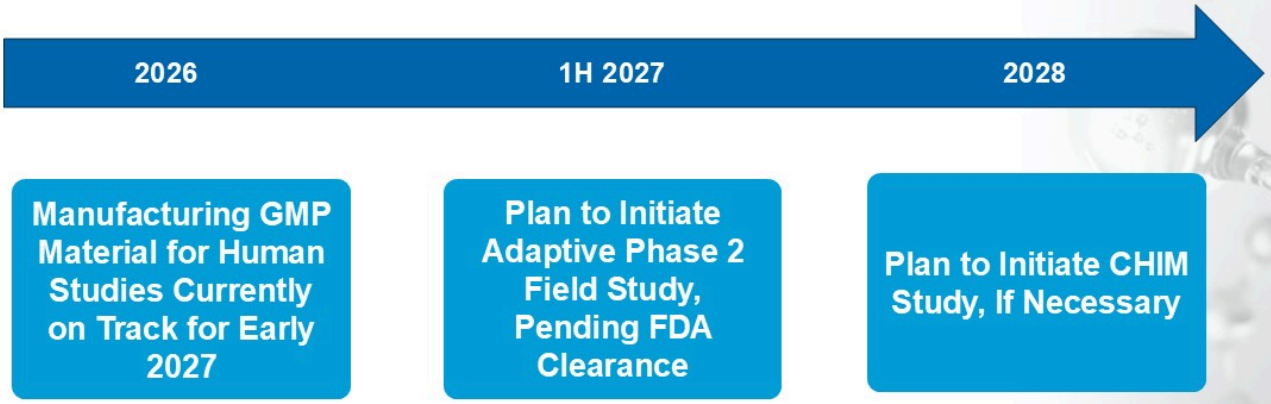
1. One serious adverse event deemed unrelated to study drug.

Planned Phase 2 Field Trial

- **TNX-4800 intended to be studied in an adaptive randomized, double-blind, placebo-controlled study, pending FDA clearance**
- **Goal:** To evaluate the efficacy and safety of TNX-4800 in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period (Day 3 through Month 4 following administration)
- **Inclusion:** Adolescents and adults 16 to 65 years of age from Lyme-endemic areas in the U.S.
- **Primary endpoint:** Prevention of Lyme disease at four months (comparison of TNX-4800 group and placebo group)
- **Key secondary endpoint:** Prevention of Lyme disease at six months (comparison of TNX-4800 vs. placebo)
- **Dose:** A single SC dose of placebo or TNX-4800 350 mg
  - Rationale: TNX-4800 5 mg/kg dose resulted in mean blood levels of 10 µg/ml at four months[1]

1. Average patient is assumed to be approximately 70kg.

Phase 2 Ready: Clinical Development Plans for TNX-4800 Pending FDA Clearance



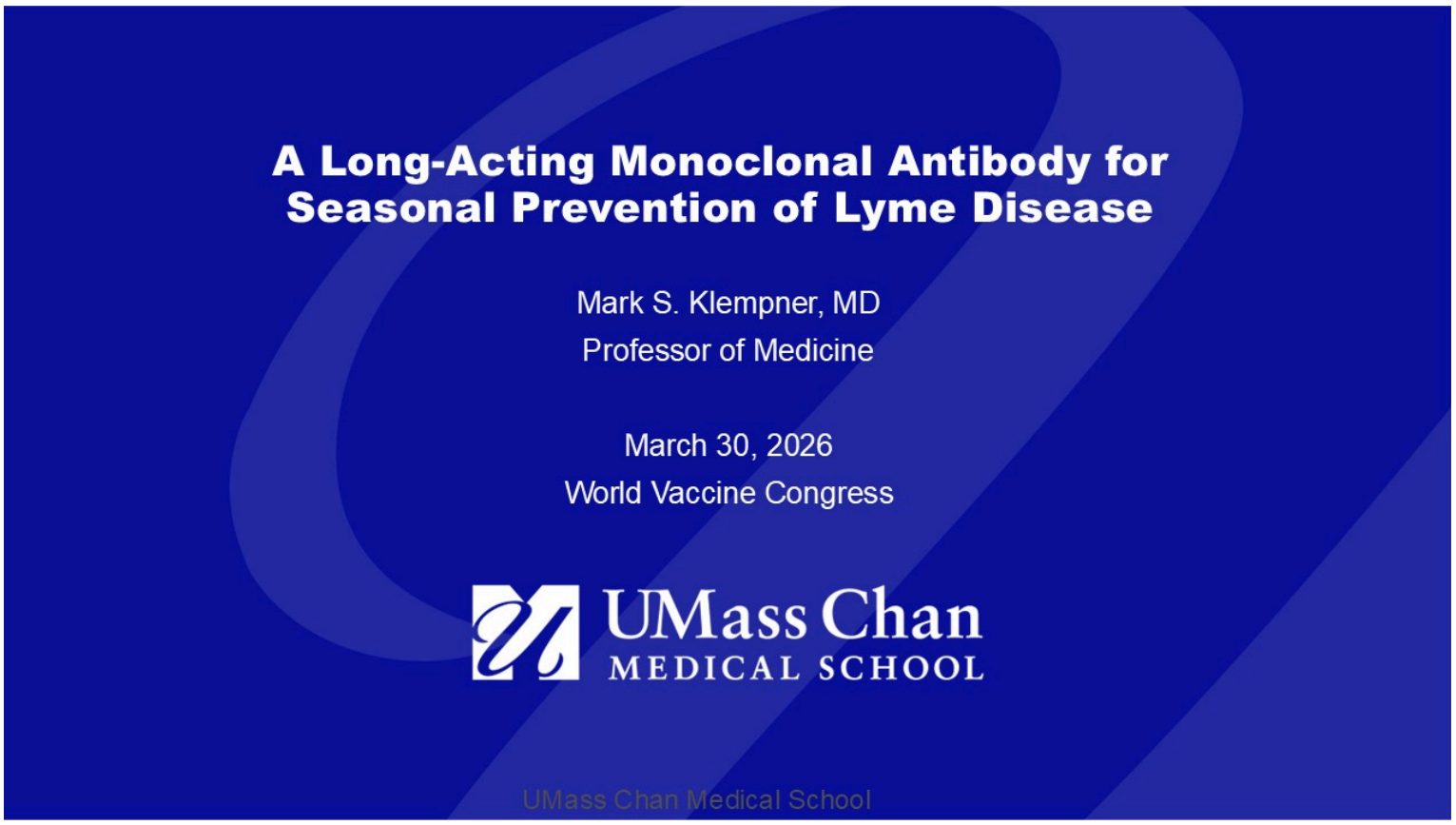
Manufacturing GMP Material for Human Studies Currently on Track for Early 2027

Plan to Initiate Adaptive Phase 2 Field Study, Pending FDA Clearance

Plan to Initiate CHIM Study, If Necessary

THANK YOU

EXHIBIT 99.03



Disclosures

Co-Inventor US Patent 10,457,721

Consultant Tonix Pharmaceuticals, Inc

Support from National Center for Advancing Translational Sciences (NCATS) NIH, DARPA, DOD Tick Borne Disease Research Program, and NIAID

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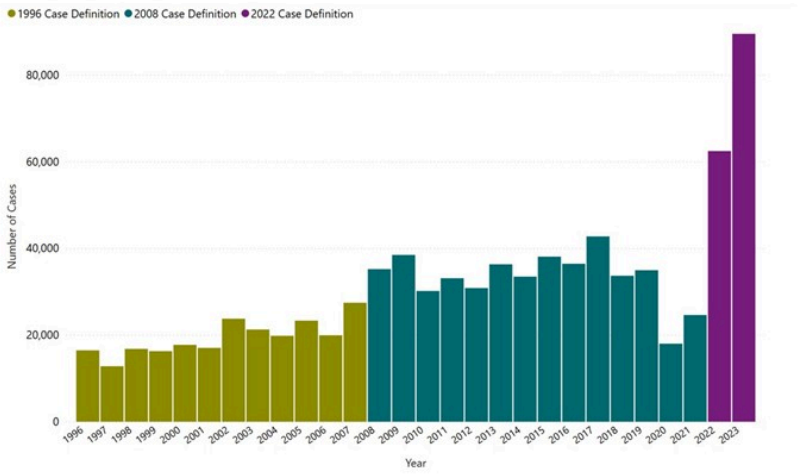
Growing Unmet Need:
Prevention of Lyme Disease

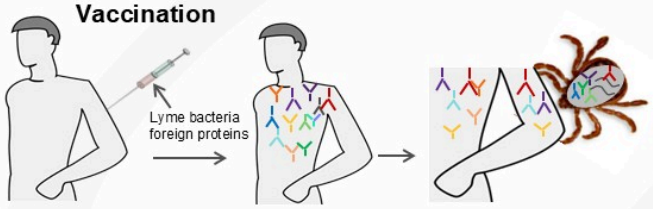
- Lyme disease is the most common tick-borne illness (80% of all tick-borne diseases) in the Northern hemisphere. The CDC estimates over 450,000 cases annually.
- Global changes in climate is a factor in the expanding habitat range for ticks and other vectors, indicating the problem is likely to worsen in the coming years.
- LYMErix (GSK Vaccine) was FDA approved in 1998 but **withdrawn** due to low sales amid overhyped fears of vaccine-induced side effects including arthritis. LYMErix elicited active immunity (antibody responses) against outer surface protein A (OspA) and demonstrated an efficacy of 78%.
- Vaccine hesitancy, now driven mostly by online misinformation, continues to be a headwind for the uptake of new vaccines.

We are developing a monoclonal antibody treatment (not a vaccine) for Lyme Disease prevention. A single shot potentially provides protection 2 days after dosing and lasts approximately 4 months



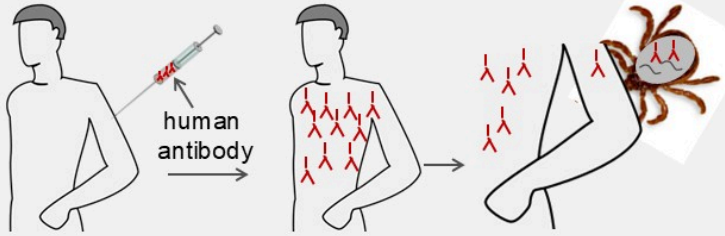
Preventing Lyme Disease
Vaccine Compared to Antibody Pre-Exposure Prophylaxis

Vaccination



Person receives 3 injections over 6 months of Lyme bacteria proteins and develops many different antibodies. Tick carrying the Lyme disease bacteria bites the vaccinated person, takes in blood containing multiple antibodies including one (red) that prevents transmission.

Pre-exposure prophylaxis



Person receives 1 injection of a single protective antibody (red) at beginning of tick season. Tick carrying the Lyme disease bacteria bites the person and takes in blood containing the protective antibody preventing transmission.

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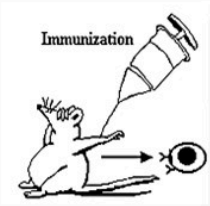
Discovery of mAB 221-7 with Potent Bactericidal Activity and Coverage of Three OspA Serotypes

The Target

Outer surface protein A (OspA) of the Spirochete

- Essential for survival while in tick midgut
- Anti-OspA immunity is effective in both animals and humans

Approach



Immunize mice (HuMab Mice, BMS/Mederex) with recombinant OspA

Immunized transgenic mice with OspA → Fused 12 spleens → Identified hybridomas producing human IgG → Determined whether recognized OspA

589 OspA reactive HuMabs were identified
93 HuMabs had unique CDR3 sequence

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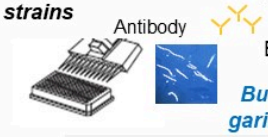
Discovery of mAb 221-7 with Strong Potency and Coverage

In vitro Potency and Coverage

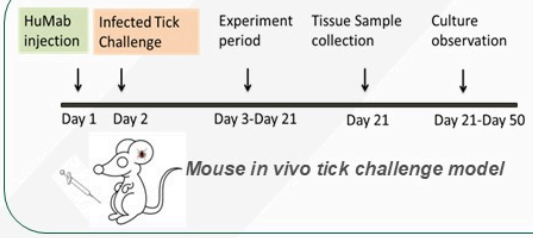
In vitro Borreliacidal assay against three Borrelia strains



Burgdorferi, afzelii, and garinii

4 leads were selected for animal study
319-44, 221-7, 857-2 and 221-55

In vivo Potency



Mouse in vivo tick challenge model

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Identified Four Lead anti-OspA *Borrelia* Antibodies

Criteria:	319-44	221-7	212-55	857-2
Burgdorferi borreliacidal	YES (<0.4 nM)	**YES (<0.4 nM)**	YES (1.4 nM)	YES (2.0 nM)
Afzelii borreliacidal	YES (4.0 nM)	**YES (0.9 nM)**	NO	YES (2.0 nM)
Garinii borreliacidal	NO	**YES (6.6 nM)**	NO	YES (41.6 nM)
Epitope map (a.a.)	178-273	**71-141**	142-177	106-141
OspA Affinity	328 nM	**0.66 nM (Az 7.8; Gn 1.3)**	0.43 nM	0.65 nM
Protection (10 mg/kg)	100%	**100%**	YES	YES
Protection (5 mg/kg)	100%	**100%**	NA	NA
Protection (1 mg/kg)	40%	**60%**	NA	NA
Half-life in vivo (FcRn mice)	26.9	**23.5**	39	16.2

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mAb 221-7 Epitope Resolved by Crystallization


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Blocking *Borrelia burgdorferi* transmission from infected ticks to non-human primates with a human monoclonal antibody

Zachary A. Schiller, ... , Mark S. Klempner, Yang Wang

Published April 29, 2021

Citation Information: *J Clin Invest*. 2021. https://doi.org/10.1172/JCI144843.

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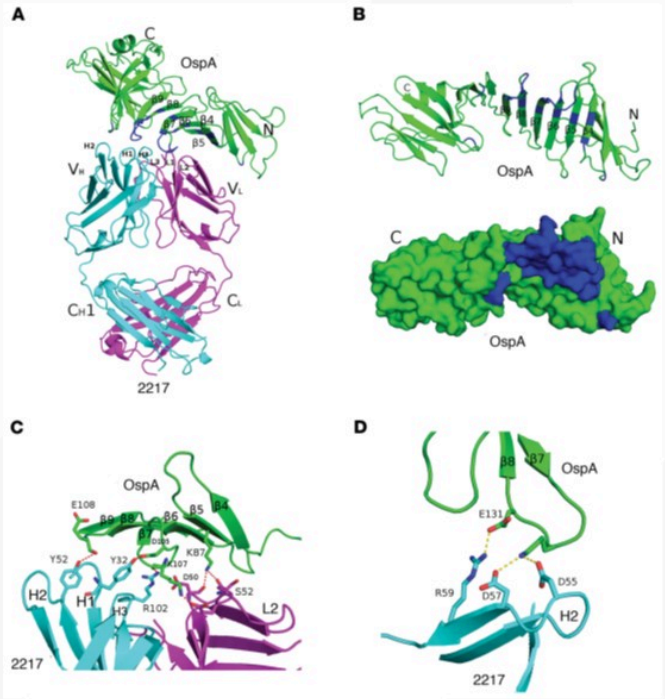

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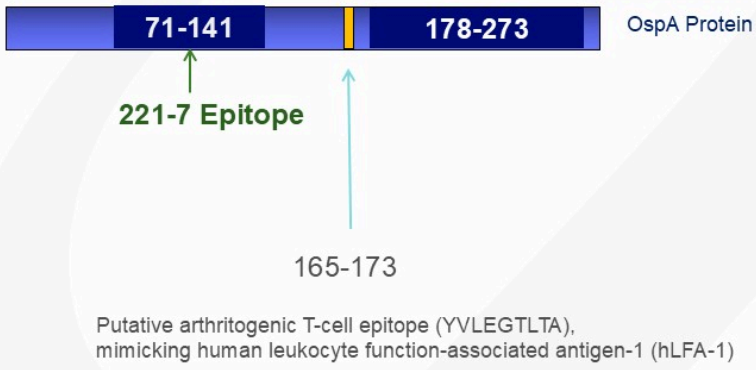
mAb 221-7 Does not Recognize the Putative Arthritogenic T-cell Epitope



Putative arthritogenic T-cell epitope (YVLEGTLTA),
mimicking human leukocyte function-associated antigen-1 (hLFA-1)

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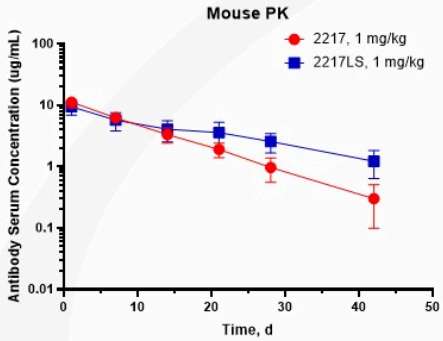
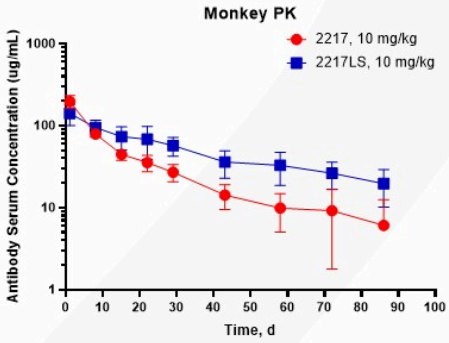
Half-Life Extension in FcRn Mice and NHP: TNX-4800 (2217LS)





Species	Average Human Ab half-life	2217WT	2217LS	Fold Change to WT
FcRN Mice	6-8 days	8.0 ± 0.4 days	16.0 ± 1.1 days	2.0
Nonhuman Primates	10.2 ± 3.3 days	15.41 ± 7.5 days	31.8 ± 2.5 days	2.1

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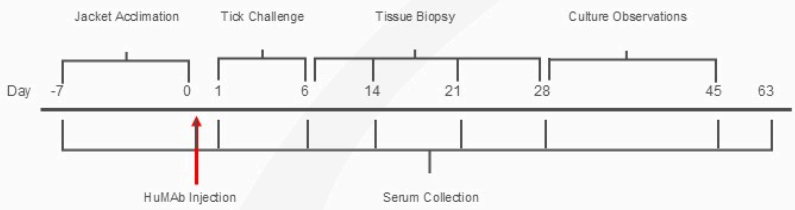
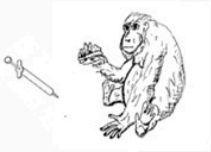
NHP= non-human primate

Blocking *Borrelia burgdorferi* Transmission from Infected Ticks to Non-Human Primates with TNX-4800 (2217-LS)





4-6 animals each dose group

Monoclonal Antibody	Dose (mg/kg)	Protection (%)	P value
2217LS	90	100%	<0.001
2217LS	30	100%	<0.001
2217LS	10	83%	<0.001
2217LS	3	100%	<0.001
Irrelevant IgG	10	0%	N/A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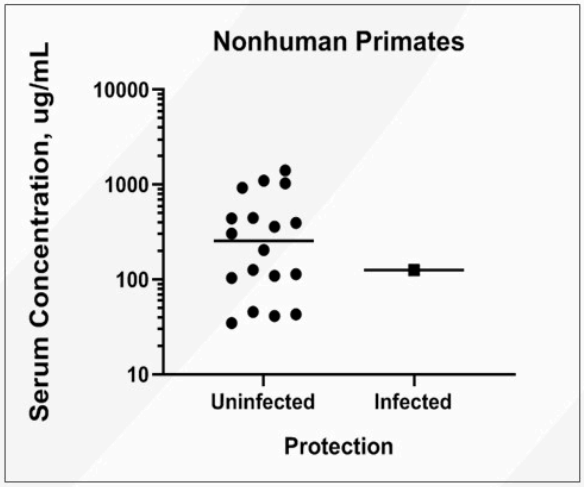
Estimating Minimum Effective Concentration of TNX-4800 (2217-LS) in Non-Human Primates

Serum levels above 21 µg/mL were ~95% protective.



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Minimum Effective Concentration (MEC) TNX-4800 (2217-LS)

- **~5 µg/mL – *in vitro* bactericidal activity**
  - TNX-4800 showed EC_{50} ≈ 0.56 µg/mL *in vitro*[1]
  - MEC ~ 10X EC_{50}
- **<10 µg/mL – *in vitro* tick feeding experiment**
  - TNX-4800 showed bactericidal activity ≥10 µg/ml
- **<21 µg/mL – *in vivo* primate challenge models**[1,2]
  - TNX-4800 serum levels >21 µg/ml were 95% protective

[1]Wang Y, et al. J Infect Dis. 2016 Jul 15;214(2):205-11.
[2]Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.

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Nonclinical Safety Data
TNX-4800

- cGLP Tissue Cross Reactivity study in rat and human tissues
  - No significant cross-reactivity
- Non-GLP pharmacokinetic and tick challenge studies in monkeys
  - Did not reveal a safety signal
- cGLP 5 week multiple dose study with 4 week recovery in rats and a cGLP single dose local tolerance study in rats
  - Observed abnormalities were mild to moderate and all findings were judged non aversive (hematologic and ALT, AST ALP and APTT increases (notably without bilirubin changes), injection site inflammation, liver and spleen organ weight increases, liver histopathology, primarily in males. All findings were reversible).
- Exposure in Phase 1 was multiples relative to NOAEL in rats
  - Starting dose: 63 to 242 –fold lower
  - Highest dose: 3 to 12 –fold lower

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NOAEL = No-observed-adverse-effect level


Celerion
&
MassBiologics
February
2021
DOCUMENT RECORDING EVERY
DETAIL OF LIFE OBSERVATIONS
WHO WHAT WHEN WHERE WHY
HOW ALL ABOUT IT TRUE STORY

TNX-4800 Phase 1 Study Overview

Primary Objective:

- Evaluate safety and tolerability of a SC injection of TNX-4800 (2217LS) when administered to healthy subjects

Secondary Objective:

- Evaluate pharmacokinetics (PK) of a SC dose of TNX-4800 (2217LS) when administered to healthy subjects

Study Population:

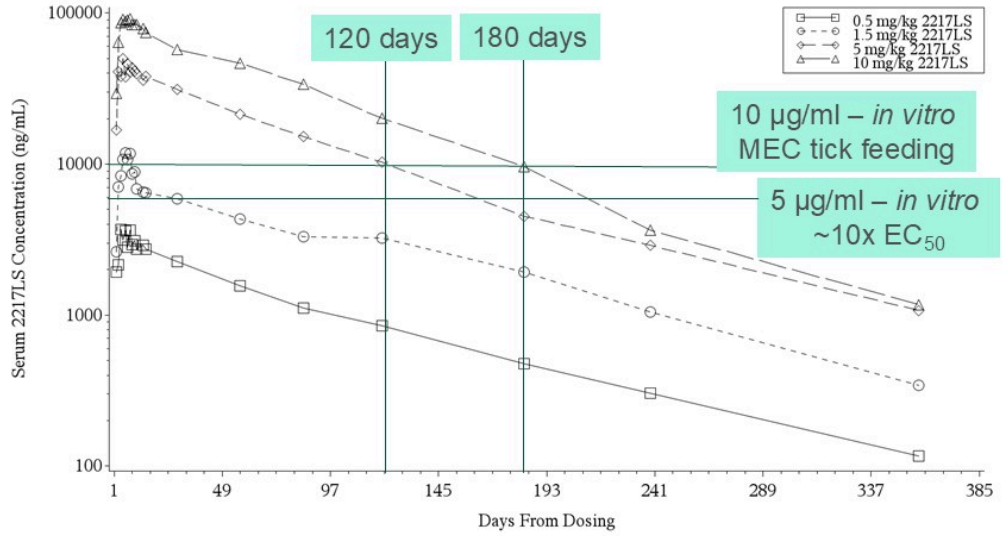
- Healthy male and female subjects, age 19 to 65 years, inclusive. 44 volunteers enrolled, 41 completed.

Cohort	N[1]	Treatment	2217LS Dose (mg/kg)	Route
1	12	2 subjects: placebo 10 subjects: 2217LS	0.5	SC
2	10	2 subjects: placebo 8 subjects: 2217LS	1.5	SC
3	10	2 subjects: placebo 8 subjects: 2217LS	5	SC
4	10	2 subjects: placebo 8 subjects: 2217LS	10	SC

TNX-4800 Phase 1 Study Results

- No significant clinical or laboratory safety signals
- The mean exposure, based on AUC-inf and C_{max} for Cohort 4 (10mg/kg), was less than 17% of the highest exposures in the rat toxicology study
- Serum TNX-4800 (2217LS) was measurable at the earliest sampling time of 24 hours indicating rapid absorption.
- For all cohorts C_{max} was observed at 10-13 days followed by a prolonged elimination phase.
- Apparent terminal $T_{½}$ after 10 mg/kg dose was 64 days
- Max $T_{½}$ ranged from 81-104 days: (**10mg/kg - 97 days, 5mg/kg - 87 days, 1.5mg/kg - 104 days, 0.5mg/kg - 81 days)**
- **Cohort 3 (5mg/kg) serum concentrations:**
  - **10 µg/ml at 4 months (~ *in vitro* tick-feeding MEC and >*in vitro* MEC or ~10x EC_{50})**

Observed Phase 1 Pharmacokinetics



Each point represents a mean for the cohort at that timepoint and dose

Next Steps: Phase 2 Field Study

- Licensed to Tonix Pharmaceuticals - 2025 now TNX-4800
- Proposed Phase 2 field study – 2027 pending FDA clearance

A Long-Acting Monoclonal Antibody for Seasonal Prevention of Lyme Disease

Mark S. Klempner, MD
Professor of Medicine

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Supplemental Slides

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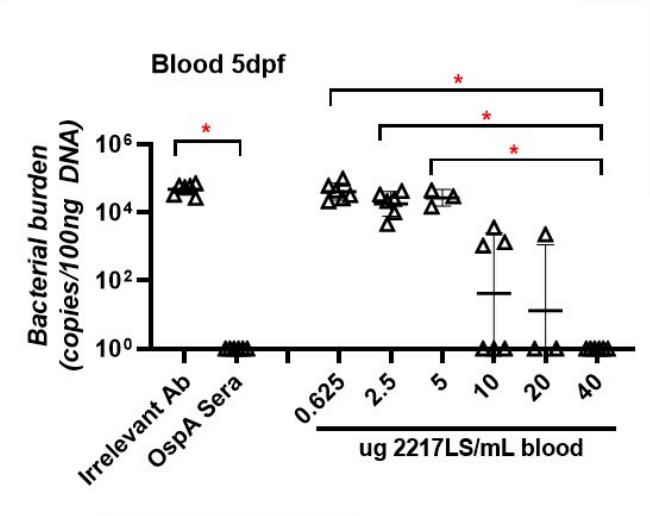
Minimum Effective Concentration of TNX-4800 is < 10µg/ml in the Infected Tick

The monoclonal OspA antibody TNX-4800 (2217LS) inhibits tick-to-blood transmission of *B. burgdorferi* B31-5A4 in a dose-dependent manner in an artificial membrane feeding system.



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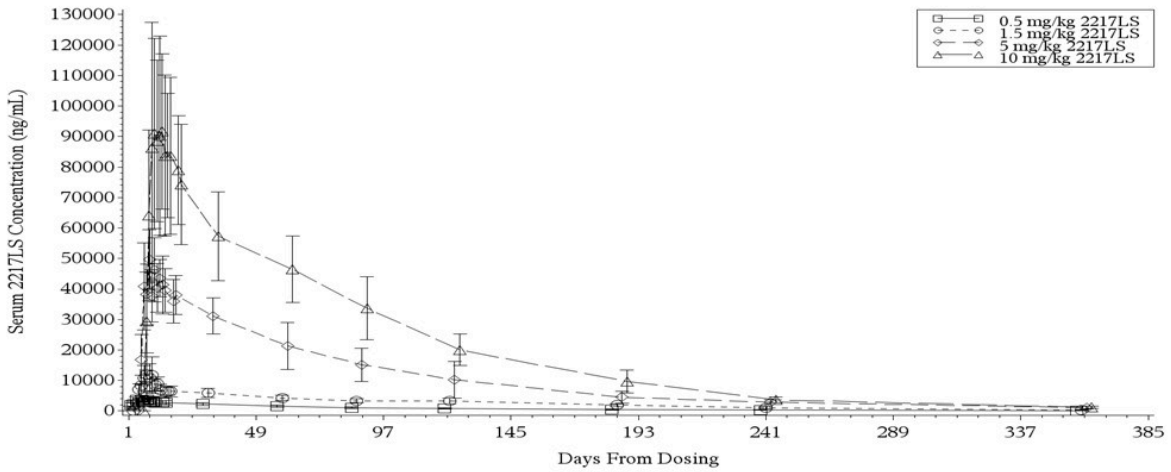
Variability of serum concentrations at sampling time points among subjects in each dosing cohort



The profiles for 1.5 mg/kg 2217LS, 5 mg/kg 2217LS, and 10 mg/kg 2217LS are shifted to the right for ease of reading.
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5 mg/kg 2217LS: A single subcutaneous injection of 5 mg/kg 2217LS, Cohort 3
10 mg/kg 2217LS: A single subcutaneous injection of 10 mg/kg 2217LS, Cohort 4
AUCs and Cmax are presented as geometric mean (geometric CV%).
Tmax values are presented as median (min, max).
Other parameters are presented as arithmetic mean ± SD.
Source: Tables 14.2.1.5 through 14.2.1.8
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CDC Study Makes a Strong case for Antibody vs Vaccine

Lyme Disease Vaccine Intentions Among Parents of 5–18 Year Olds in U.S. States with High or Emerging Incidence

(CDC-sponsored study presented at 2023 Pediatric Academic Societies (PAS) Conference)

Methods

- Conducted online survey (N=1,351) of parents of children aged 5–18 years in states with high or emerging Lyme Disease (LD) incidence.
- Primary outcome was willingness (definitely / probably would vs unsure or definitely / probably would not) for their child to receive an LD vaccine.
- Secondary outcome was preference for annual monoclonal antibody injections vs. a 3-dose vaccine series with boosters every few years.

Outcome

- Two-thirds of parents were willing to vaccinate their child against LD (68.0% definitely/probably would, 18.4% unsure, 13.7% definitely/probably would not)
- Parental willingness to be vaccinated against LD was highly correlated with willingness for their child in.
- Vaccine safety concerns were among the top reasons for LD vaccine hesitancy
- More parents preferred pre-formed antibody (42.4%) over 3-dose vaccine series (36.2%)
- Significant predictors of preference for monoclonal antibody included prior awareness of LD, living in a rural area, and positive attitude towards vaccines

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CDC = U.S. Centers for Disease Control