TNX-4800: A Long-Acting, Bactericidal, Human Monoclonal Antibody to Prevent Lyme Disease in the U.S.

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Tonix Pharmaceuticals

Global Lyme Alliance

PO6143 May 15, 2026 1660

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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.

Tonix Pharmaceuticals – Transforming Medicine for the Future

3 FDA Approved Products

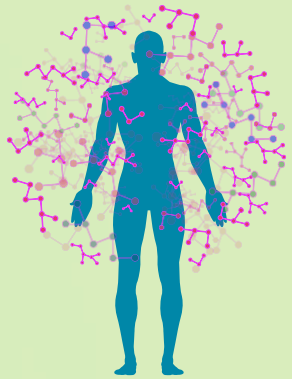
Tonmya®
(cyclobenzaprine HCl) sublingual tablets 2.8mg

tosymra®
(sumatriptan nasal spray) 10 mg

Zembrace® SYMTOUCH®
(sumatriptan injection) 3 mg

Therapeutic Areas of Focus:

- CNS
- Infectious Disease
- Immunology
- Rare Disease



Fully Integrated

- Research
- Development
- Manufacturing
- Commercial

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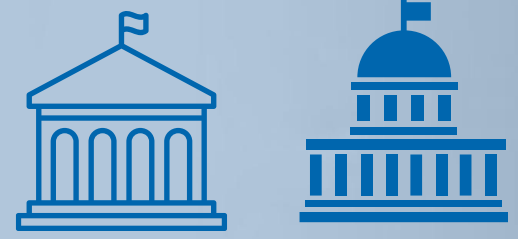
Nasdaq TNXP

- ~$185.5 M cash as of March 31, 2026
- No debt

Partnerships

with major Universities and the U.S. Federal Government



First FDA-Approved Treatment for Fibromyalgia in Over 15 Years

Tonmya®
(cyclobenzaprine HCl)
sublingual tablets 2.8mg

First-in-class, First-line Medicine
Unique, Sublingual, Proprietary Formulation Supports:
Efficacy, Absorption, and Tolerability

Current Treatments

- Limited approved and effective options
- High rate of patient and HCP dissatisfaction
- Off-label opioids often used

TONMYA

- Distinct mechanism of action versus current therapies
- Robust efficacy
- Generally well-tolerated

TONMYA (cyclobenzaprine HCl sublingual tablets) is indicated for the treatment of fibromyalgia in adults

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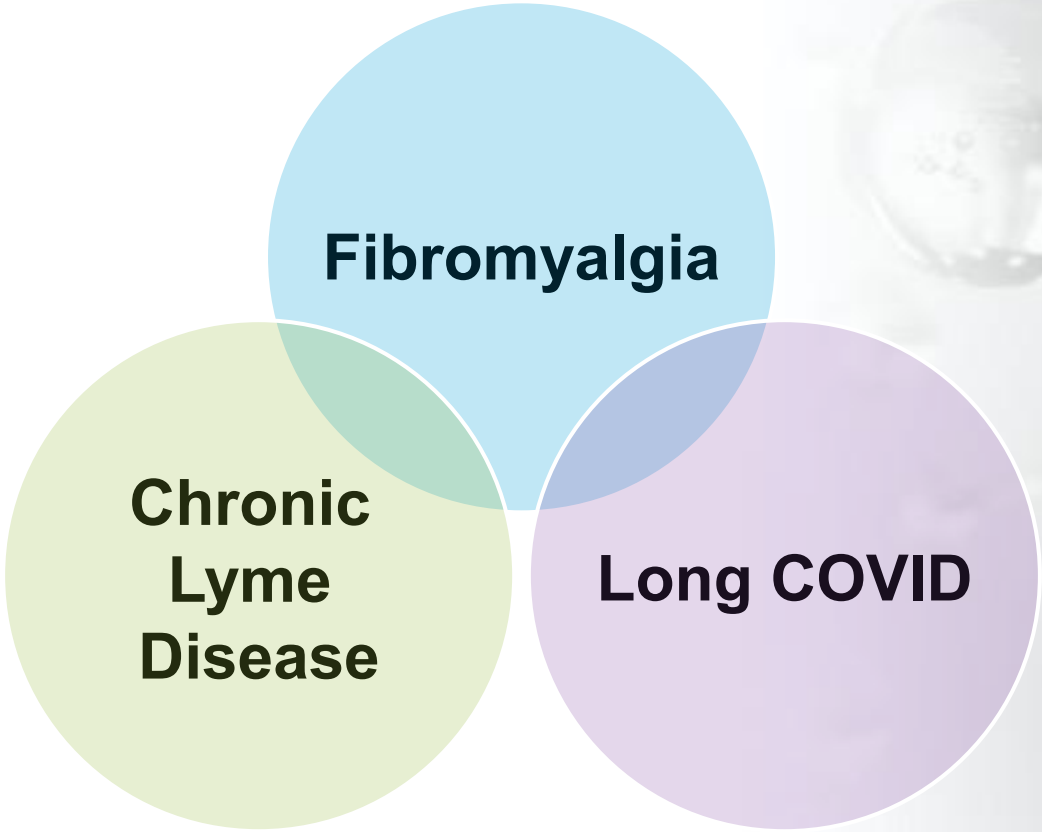
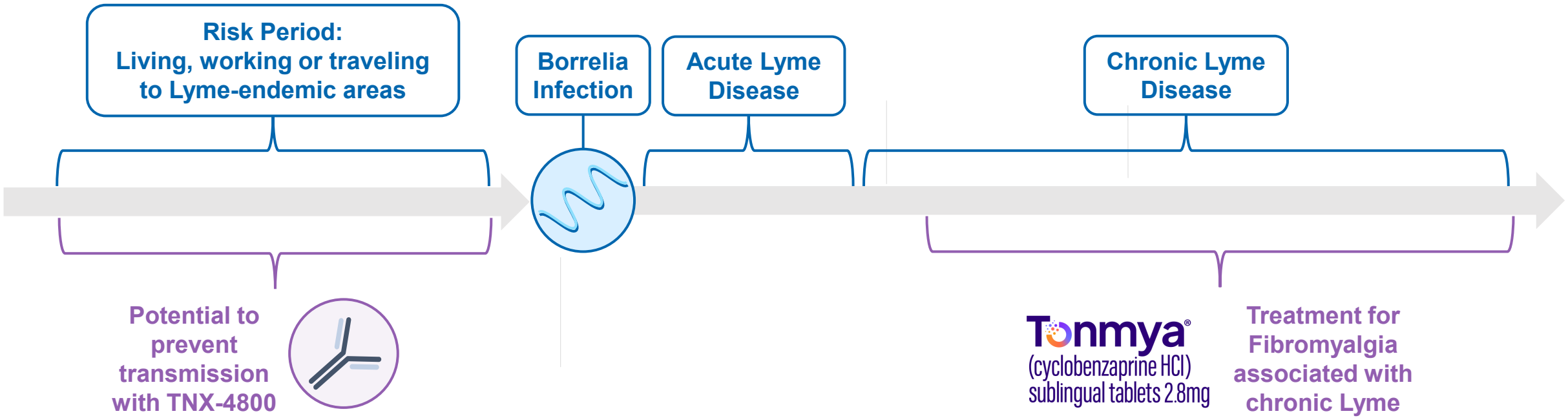
Overlap of Fibromyalgia and Chronic Lyme Disease

Fibromyalgia is a diagnosable condition in:

- ✓ *Long COVID*
- ✓ *Chronic Lyme disease*
- ✓ *Other Infection Associated Chronic Illness (IACI)*



Addressing the Lyme Disease Spectrum

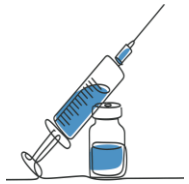


H Dinerman, Steer AC 1992
doi: 10.7326/0003-4819-117-4-281

Introducing TNX-4800

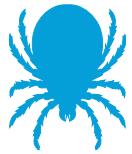
TNX-4800[1,2] is a human anti-OspA monoclonal antibody (HuMAb) with engineered Fc domain for extended half-life, licensed from UMass Chan Medical School in 2025 (Formerly 2217LS)

Expected Mechanism of Action



Two-dose Regimen

Two SC doses (day 1 and 56) expected to provide ≥ 6 months protection

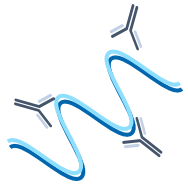


Tick Attaches

Infected tick feeds on protected individual

Antibody Ingested

TNX-4800 enters tick midgut via blood meal



OspA Binding

Antibody binds OspA on Borrelia

Transmission Blocked

Bacteria killed or trapped in midgut—cannot reach human tissue

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.
2. TNX-4800 is protected by Issued US Patent US 10,457,721 , which is licensed from UMass Chan with expiry in January 2036 (with PTA), excluding any possible patent term extension.

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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™ (clesrovimab),[1]
BEYFORTUS®), (nirsevimab)[2]
PEMGARDA™ (pemivibart)[3]

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

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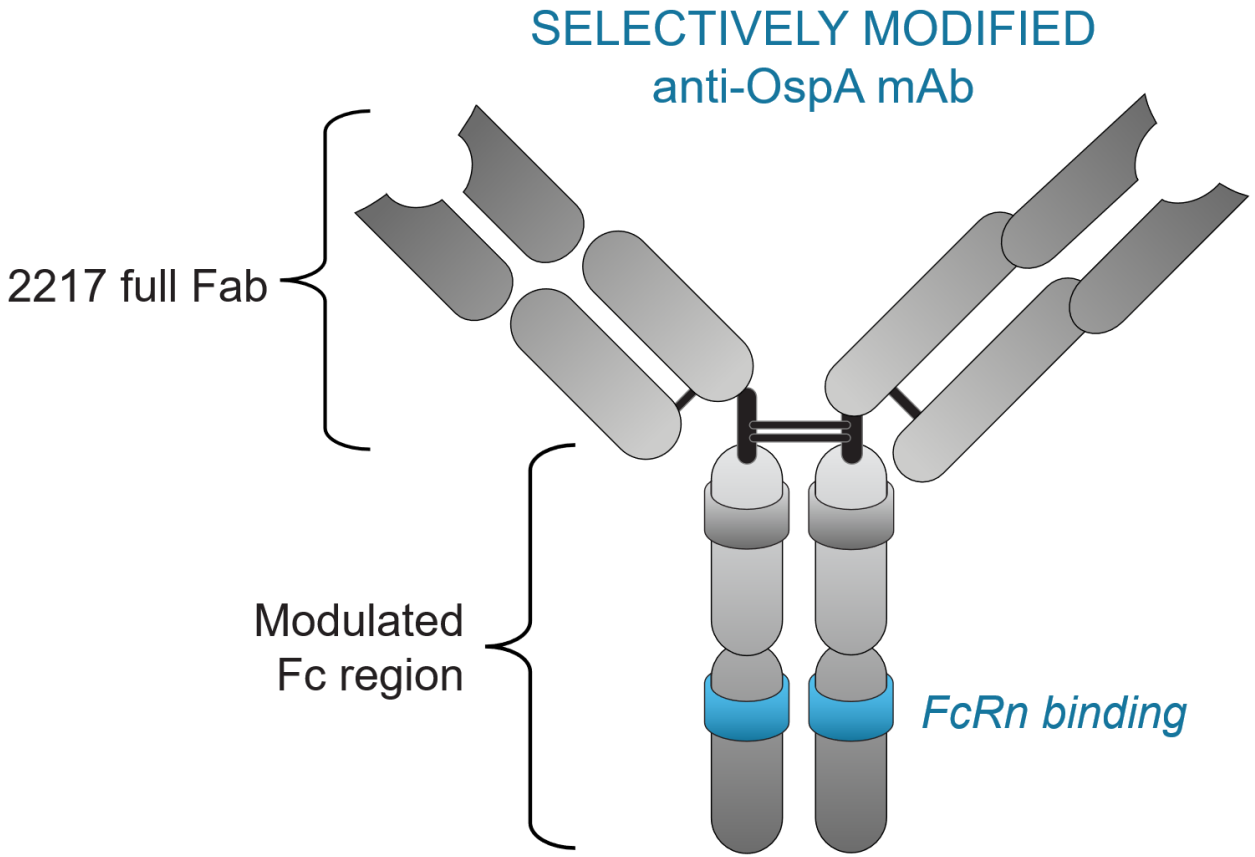
TNX-4800 Long-acting anti-OspA Monoclonal Antibody Design



Engineered Fc domain (LS) binding to FcRn for an extended half-life that targets OspA of *Borrelia burgdorferi*[1,2]

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

1. Schiller ZA, et al. *J Clin Invest.* 2021;131(11):e144843.
2. Wang Y, et al. *J Infect Dis.* 2016;214(2):205-211.

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TNX-4800 is Not a Vaccine

Limitations of OspA vaccines

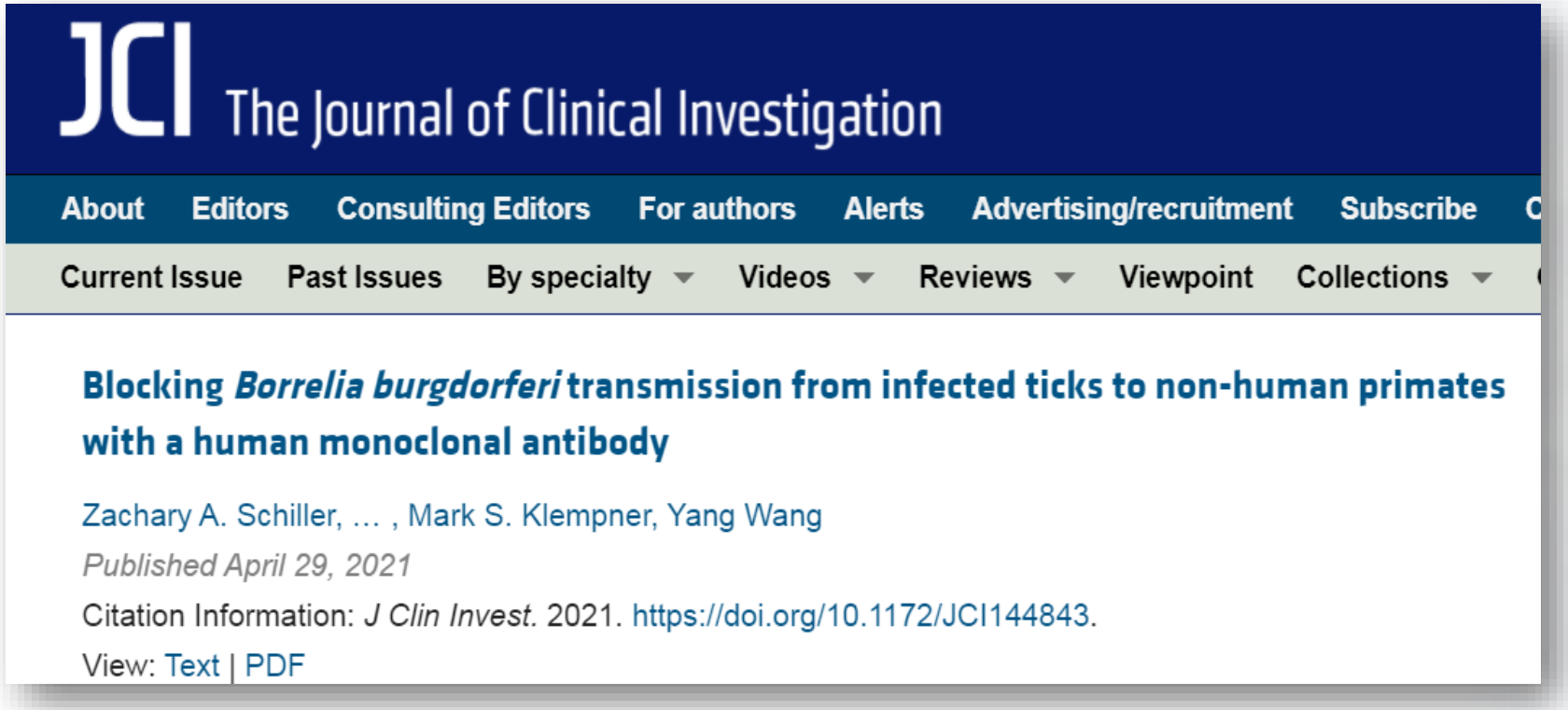
- Protection depends on titer of OspA at the moment the deer tick sucks blood
- High-titer vaccine responses require onerous immunization schedule
- Little or no “memory” response on *Borrelia* exposure
  - OspA-expressing *Borrelia* is sequestered in the tick midgut
- Protection depends on patient’s immune status
- Results in heterogeneous polyclonal antibody response to vaccine
- “Titer” of polyclonal response has uncertain correlation with individual protection
- Associated with typical side-effects of vaccination

Prophylactic Monoclonal Antibody (mAb) Characteristics

Potential attributes of anti-OspA mAb TNX-4800

- Nearly-immediate protection (within 2 days)
- Not reliant on patient's immune status
- Replaces heterogeneous polyclonal response of vaccine with homogeneous monoclonal agent with defined properties
- Replaces "titer" of polyclonal response with quantifiable serum levels
- Potential for quantifying serum mAb levels as immune correlate of protection
- Avoids side-effects of vaccination

Analysis of Minimum Effective Concentration (MEC) – Method # 1 – *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.

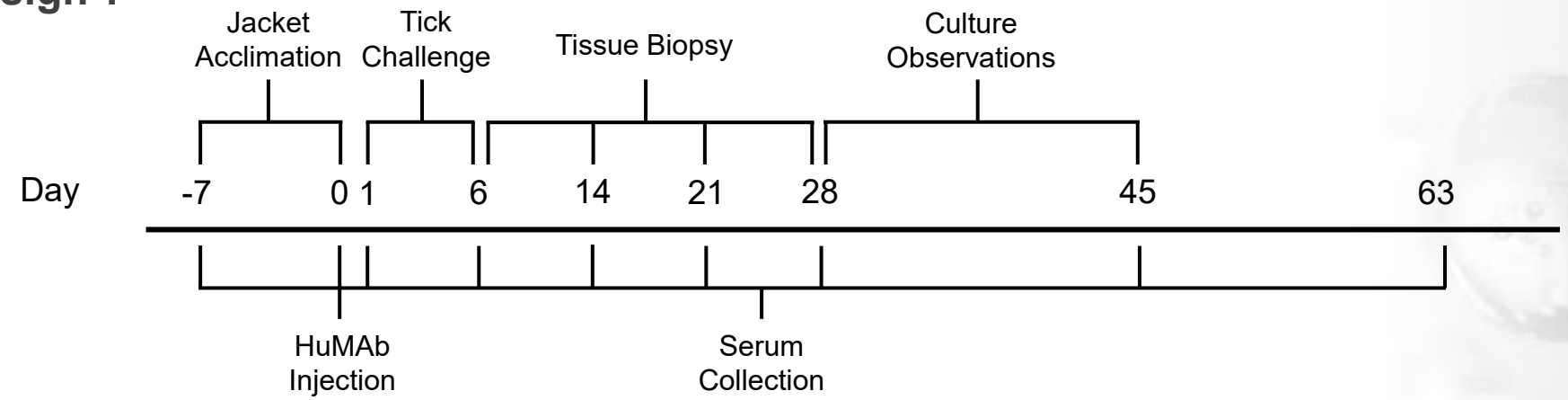
View: Text | PDF

Three Models for MEC determination used:

- *in vitro* borreliacidal activity
- *in vitro* tick feeding assays
- *in vivo* NHP challenge

Nonhuman Primate Challenge Model: Protocol and Protection by Dosage Level

Study Design[1]:



- Dose escalation study: 4 cohorts, 1 irrelevant IgG control
- 4 to 6 animals per cohort; challenged with 20 infected ticks
- 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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Analysis of Minimum Effective Concentration (MEC) –Three Methods

- **Serum ~5 µg/mL – *in vitro* bactericidal activity (not shown)**
  - 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 (not shown)**
  - 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.

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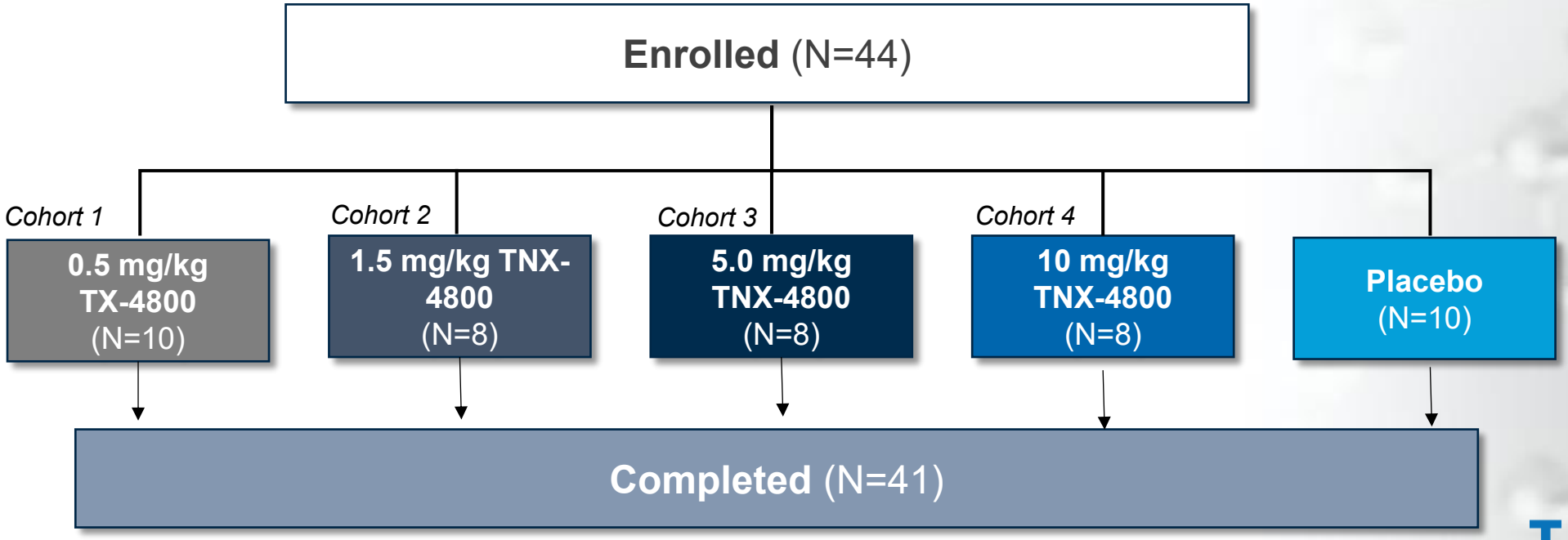
PHASE 1 CLINICAL TRIAL

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 volunteers 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. Dose delivered SC.
- 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 objectives and population

Primary Objective:

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

Secondary Objective:

- Evaluate pharmacokinetics of a SC dose of TNX-4800 when administered to healthy volunteers

Study Population:

- Healthy male and female volunteers, age 19 to 65 years, inclusive
- Median age of 39 years
- 52% male and 48% female
- White 77%, 16% African–American, non-Hispanic/Latino 91%
- Seronegative to *B. burgdorferi* } limit existing Lyme immunity
- Nebraska site to minimize prior }

Phase 1 Safety Summary

- 1 serious adverse event (SAE); in placebo group [1]
- Total of 61 TEAEs reported by 21/34 (62%) participants compares to 3/10 (30%) in placebo
- Large majority of drug related Treatment-Emergent Adverse Events (TEAEs) were mild (82%); remainder moderate (18%)
- Transient ADAs were detected in 3/34 (9%) treated subjects, with no impact on PK
- No safety signal or clustering of events observed

TNX-4800 was safe and well tolerated with no treatment-related serious adverse events and predominately mild adverse events

[1] Celerion CSR CA29655 Table 14.3.2.1 (SAE Safety population)

Related TEAE Summary[1]

Adverse Event	Severity Grade	# Subjects
Dysgeusia	1	1
Feeling hot/ flush	1	2
Injection site reaction*	1	7
Injection site reaction	2	1
Palpitations	1	1
Paresthesia	1	1

Severity Grading:
Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life Threatening

*Injection site reaction includes erythema, hemorrhage, edema, pain, pruritus

[1] Celerion CSR CA29655 Table 14.3.1.3 (TEAE Safety Population)

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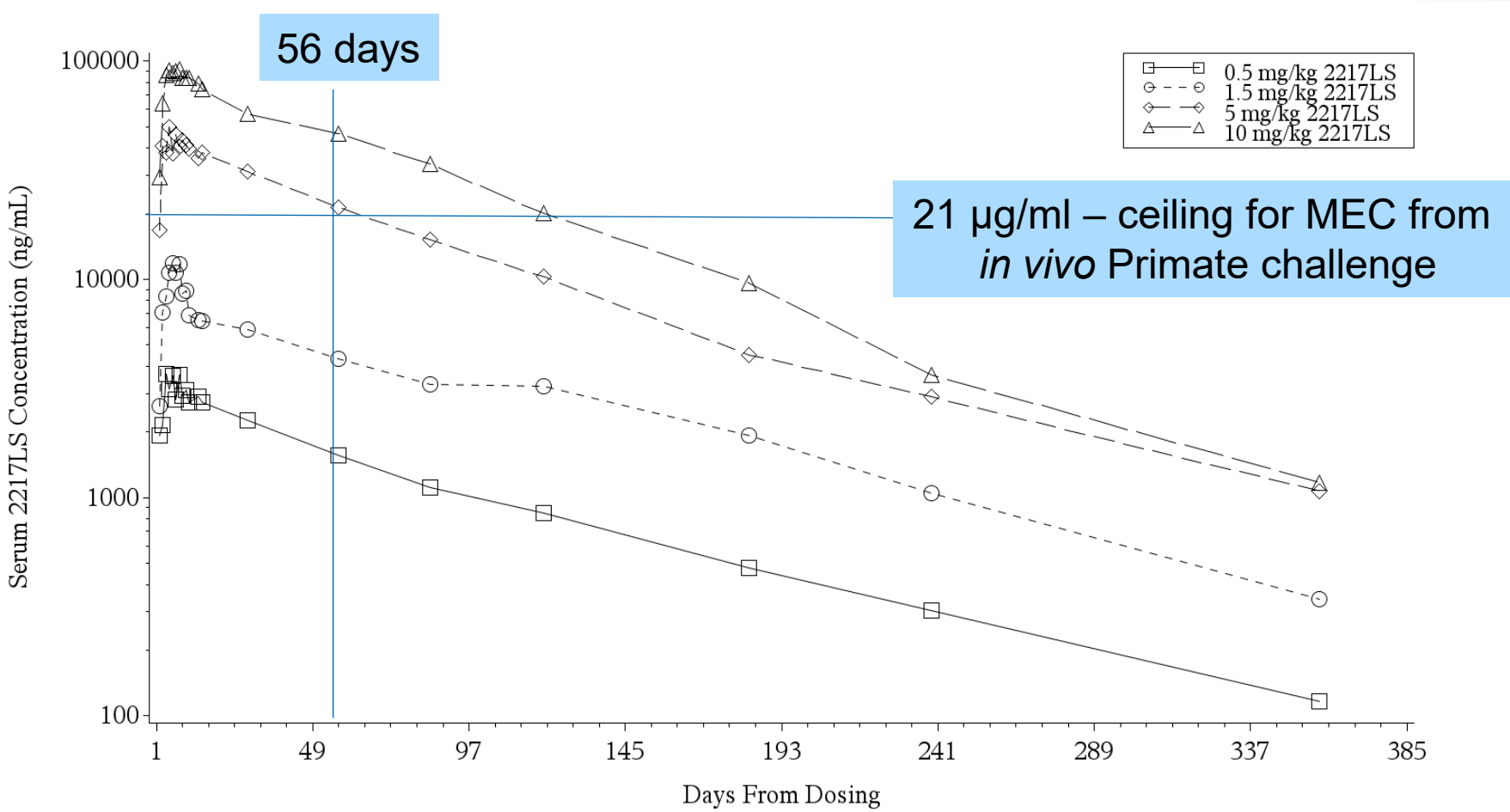
Observed Phase 1 Pharmacokinetics



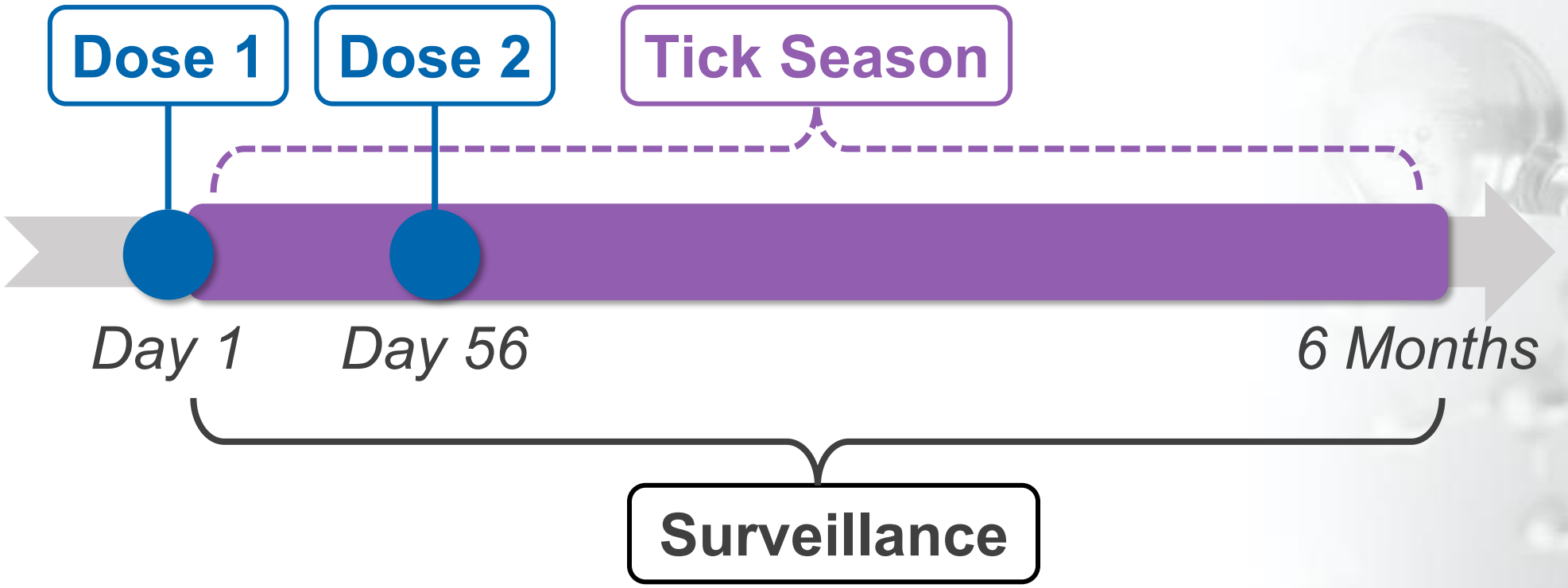
Each point represents a mean for the cohort at the specified timepoint and dose.

Phase 1 Summary

- No significant clinical or laboratory signals were identified at any dose level.
- Drug exposure increased by approximately 25 times for a 20-times increase in dose, indicating dose proportional PK.
- Serum TNX-4800 was measurable at 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 volunteers. Mean exposure for the 10 mg/kg cohort was less than 17% of the highest exposures in a rat toxicology study, indicating a wide safety margin.
- Transient low levels of anti-drug antibodies were detected in 3 participants (<10% of treated volunteers) with no impact on PK.
- Adverse events associated with the active were mild or moderate : injection site reactions(7) and feeling hot/flushed (2) were the most frequent
- TNX-4800 was safe and well tolerated

FUTURE PLANS

Design of Planned Adaptive Phase 2 Field Study* in 2027

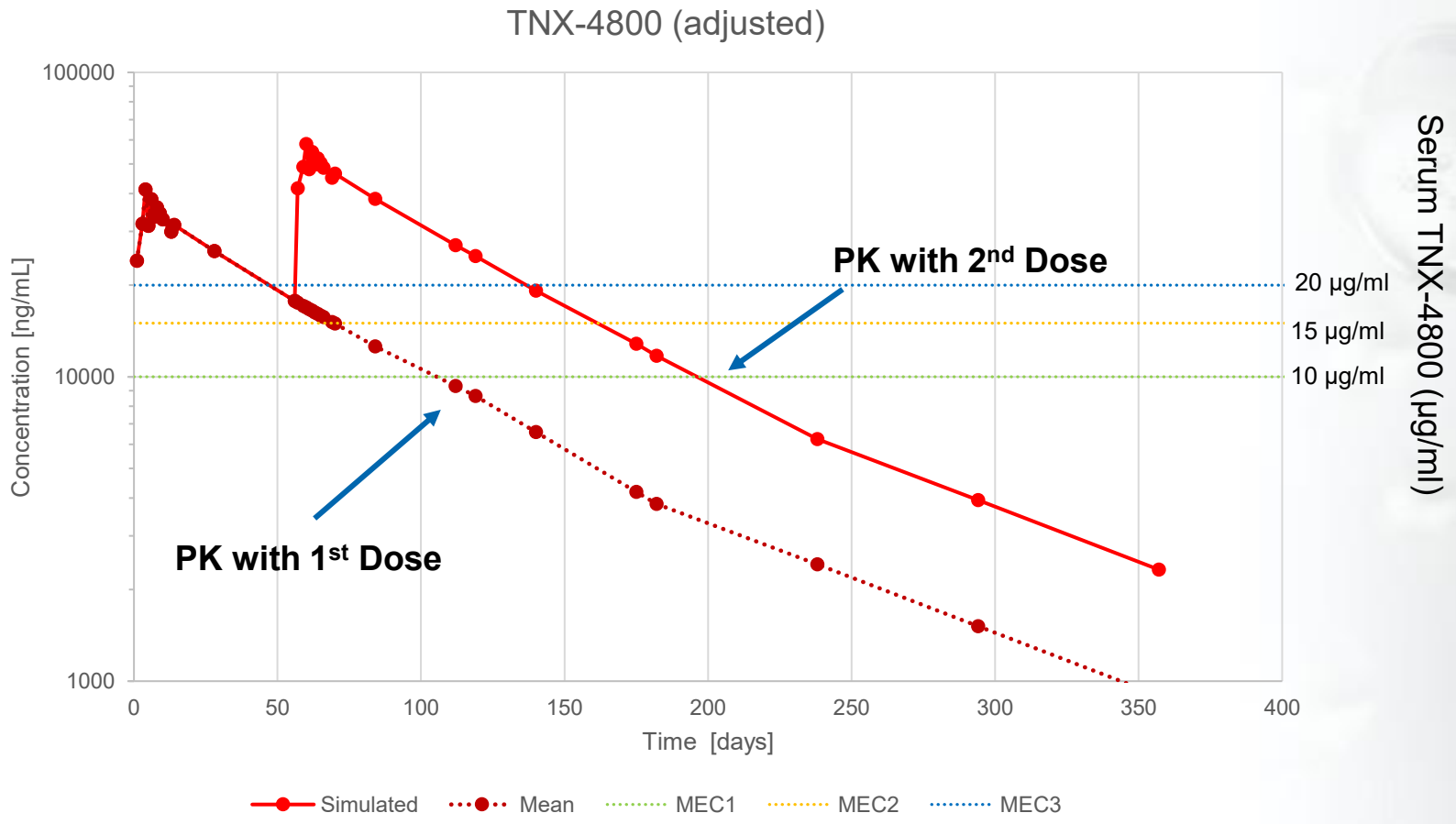


Study participants randomized 1:1 to receive TNX-4800 or placebo

*Pending FDA agreement.

Mean Predictions: 350mg SC on Day 1 and 56 Days

Preliminary Modeling



Minimum Effective Concentration - 1 (MEC_1)(10 µg/mL): 196 days; MEC_2 (15 µg/mL): 161 days; MEC_3 (20 µg/mL): 136 days and MEC4 (5 µg/mL): 265 days

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Planned Adaptive Phase 2 Field Trial 2027

Adaptive, randomized, double-blind, placebo-controlled study

- **Objective:**
  - 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 6 following administration)
- **Inclusion:**
  - Adolescents and adults >16 years of age from Lyme-endemic areas in the U.S.
- **Primary endpoint:**
  - Prevention of Lyme disease at six months (comparison of TNX-4800 group and placebo group)
- **Dose:**
  - Two SC doses of TNX-4800 or placebo at day 1 and day 56

1. Average patient is assumed to be approximately 70kg.
2. Pending FDA agreement

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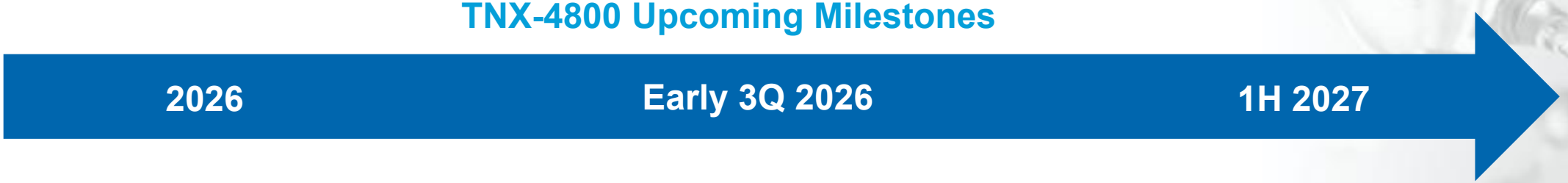
Addressing the Significant Public Health Challenge of Lyme Disease in the U.S.

- ✓ Phase 1 study complete, showing favorable safety, tolerability, immunogenicity, and pharmacokinetics
- ✓ Phase 2 adaptive field study planning and GMP manufacturing underway for 1H 2027

TNX-4800 Upcoming Milestones



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

Scheduled Type C Meeting with the FDA to Discuss the Planned Ph 2 Study Design

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

GMP = Good Manufacturing Process

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Development of TNX-4800 (formerly 2217 LS)

ACKNOWLEDGEMENTS

Inventors: UMass Chan School of Medicine

- Mark S. Klempner, MD
- Yang Wang MD, PhD
- William D. Thomas MD
- Naomi K. Boatright PhD

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- DOD Tick Borne Disease Research Program
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Phil Krause MD

Cathy Panozzo PhD

Bernd Meibohm, PhD

Martha Nason PhD

THANK YOU

TONMYA Important Safety Information (ISI)

Indication

- Tonmya is indicated for the treatment of fibromyalgia in adults.

Contraindications:

- Hypersensitivity to cyclobenzaprine or any inactive ingredient in cyclobenzaprine HCl sublingual tablets
- Concomitant use of monoamine oxidase inhibitors or within 14 days after their discontinuation
- During acute recovery phase of myocardial infarction and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure
- Hyperthyroidism

Warnings and Precautions:

- Embryofetal toxicity: Cyclobenzaprine HCl sublingual tablets may cause neural tube defects when used 2 weeks prior to conception and during the first trimester of pregnancy (animal data). Advise female patients of reproductive potential of the potential risk and to use effective contraception during treatment and for 2 weeks after the final dose. Perform a pregnancy test prior to initiation of treatment
- Serotonin syndrome: Concomitant use of serotonergic drugs with cyclobenzaprine HCl sublingual tablets increases the risk of serotonin syndrome, which may be life threatening. Treatment with cyclobenzaprine sublingual HCl tablets and serotonergic drugs should be closely monitored, particularly during treatment initiation and dosage increases, and should be immediately discontinued if serotonin syndrome symptoms occur, including mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms
- Tricyclic antidepressant-like adverse reactions: Given the structural similarity of cyclobenzaprine to tricyclic antidepressants (TCAs), discontinuation of cyclobenzaprine HCl sublingual tablets should be considered for patients experiencing clinically significant central nervous system (CNS) symptoms, such as arrythmia, sinus tachycardia, myocardial infarctions, or stroke, and caution is advised for patients with a history of seizure disorder, as TCAs may lower the seizure threshold
- Atropine-like adverse reactions: Caution is advised for patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and those taking anticholinergic drugs
- CNS depression and risk of operating a motor vehicle or hazardous machinery: Cyclobenzaprine HCl sublingual tablets may cause CNS depression, which may be exacerbated by concomitant use of alcohol, barbiturates, or other CNS depressants. Patients should not operate motor vehicles/heavy machinery until they are reasonably certain that cyclobenzaprine HCl sublingual tablets will not impair their ability to operate them
- Oral mucosal adverse reactions: The risk of oral sensory changes can be reduced by moistening the mouth with sips of water prior to administration of cyclobenzaprine HCl sublingual tablets

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TONMYA ISI (Continued)

Drug Interactions:

- **Monoamine oxidase inhibitors:** Life-threatening interactions may occur
- **Other serotonergic drugs:** Serotonin syndrome has been reported
- **CNS depressants:** CNS depressant effects of alcohol, barbiturates, and other CNS depressants may be enhanced
- **Tramadol:** Seizure risk may be enhanced
- **Guanethidine or other similar acting drugs:** The antihypertensive action of these drugs may be blocked

Use in Specific Populations:

- **Pregnancy:** Based on animal data, cyclobenzaprine HCl sublingual tablets may cause fetal harm when administered to a pregnant patient; pregnant women should be advised of the potential risk to the fetus and avoid use of cyclobenzaprine HCl sublingual tablets two weeks prior to conception and through the first trimester of pregnancy
- **Lactation:** There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production
- **Pediatric use:** The safety and effectiveness of cyclobenzaprine HCl sublingual tablets have not been established
- **Geriatric patients:** Clinical trials of cyclobenzaprine HCl sublingual tablets did not include sufficient numbers of patients ≥65 years of age to determine whether they respond differently from younger adult patients
- **Hepatic impairment (HI):** The recommended dose of cyclobenzaprine HCl sublingual tablets in patients with mild HI (Child Pugh A) is 2.8 mg daily. The use of cyclobenzaprine HCl sublingual tablets is not recommended in patients with moderate or severe HI (Child Pugh B and C, respectively) due to increased adverse reaction risk

- **To report suspected adverse reactions, contact Tonix Medicines, Inc. at 1-888-869-7633, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

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