TONIX PHARMACEUTICALS

Investor Presentation
March 2026

NASDAQ: TNXP

Cautionary Note on Forward-Looking Statements

Certain statements in this press release 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

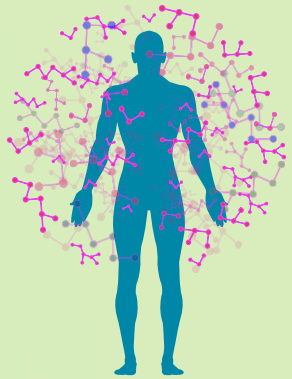
Tonmya™
(cyclobenzaprine HCl) sublingual tablets 2.8mg

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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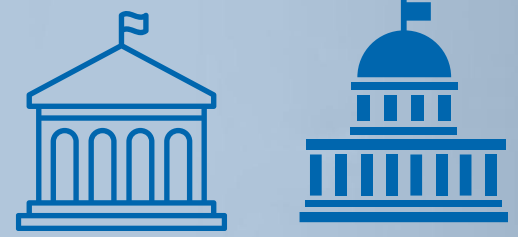
Nasdaq TNXP

- ~$208 M cash as of December 31, 2025
- No debt
- Expected cash runway into Q1’27

Partnerships

with major Universities and the U.S. Federal Government



NOW APPROVED

Tonmya™ (cyclobenzaprine HCl) sublingual tablets 2.8mg

Commercially Available

TONMYA - the First FDA-Approved Treatment for Fibromyalgia in Over 15 Years

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

Considerable Market Size

High unmet need

>10 million adults in the U.S. suffer with fibromyalgia

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

Opportunity

Large market

100% share of voice (no other Rx products marketed to HCPs)

Patent exclusivity into 2034[1]

[1]In the US, issued composition of matter patent extending to 2034; pending method of use patents may extend exclusivity to 2044

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TONMYA Commercial Launch Underway

- **$1.4 million in net sales reported for the period November 17– December 31, 2025** (launch date was November 17th:~6 weeks, including holidays**).**
- **November 17, 2025, through February 27, 2026:**
  - More than 1,500 prescribers have prescribed TONMYA to patients
  - Approximately 2,500 patients have initiated treatment with TONMYA
  - Cumulative prescriptions totaled approximately 4,200, including bridge prescriptions
- **Experienced commercial and sales team in place previously launched CNS products**
  - 90 TONMYA reps have been in the field since early October 2025
  - Focusing on 5% of fibromyalgia-diagnosing HCPs who write 70% of the fibromyalgia prescriptions[1]
  - Data-driven approach to reaching the key players in this particular market
- **TONMYA added to existing contracts with wholesalers and specialty pharmacies**
- **Robust patient access program and support services in place**
  - TONMYA savings card, copay assistance and prior authorization support, intended to reduce patient access barriers during early commercialization
- **Managed care strategy**
  - Focusing on expanded payer engagement and establishing contracts
  - Medicare and Medicaid discussions in process

[1] Paid Rx (APLD) in the recent 12 months (Feb'24 to Jan'25); Rx (FACT) in the recent 12 months (Feb'24 to Jan'25); FBM DX 2020-2025. This 5% also diagnoses 70% of fibromyalgia patients.

The Need:
Fibromyalgia is a Large, Underserved, and Dissatisfied Population

Chronic pain disorder, resulting from amplified sensory and pain signaling in the central nervous system

Fibromyalgia symptoms:

- **Chronic widespread pain**
- **Nonrestorative sleep**
- **Fatigue**

Patients and prescribers have expressed dissatisfaction with currently available therapies[1,2]

85% of first-line treatments fail with patients, citing efficacy and tolerability issues[2]

High patient churn on currently available treatments

Typical for patients to rotate between different therapies

79% of patients are on multiple therapies[2]

[1]Robinson RL, et al. *Pain Med*. 2012 13(10):1366-76. doi: 10.1111; 85% received drug treatment
[2]EVERSANA primary physician research, May 2024; commissioned by Tonix

The Market for TONMYA

>10 million U.S. adults are affected– predominantly women[1,2]

Debilitating and life-altering condition
Significant economic impact

2.7 million patients diagnosed and treated annually[3], majority are dissatisfied[4]

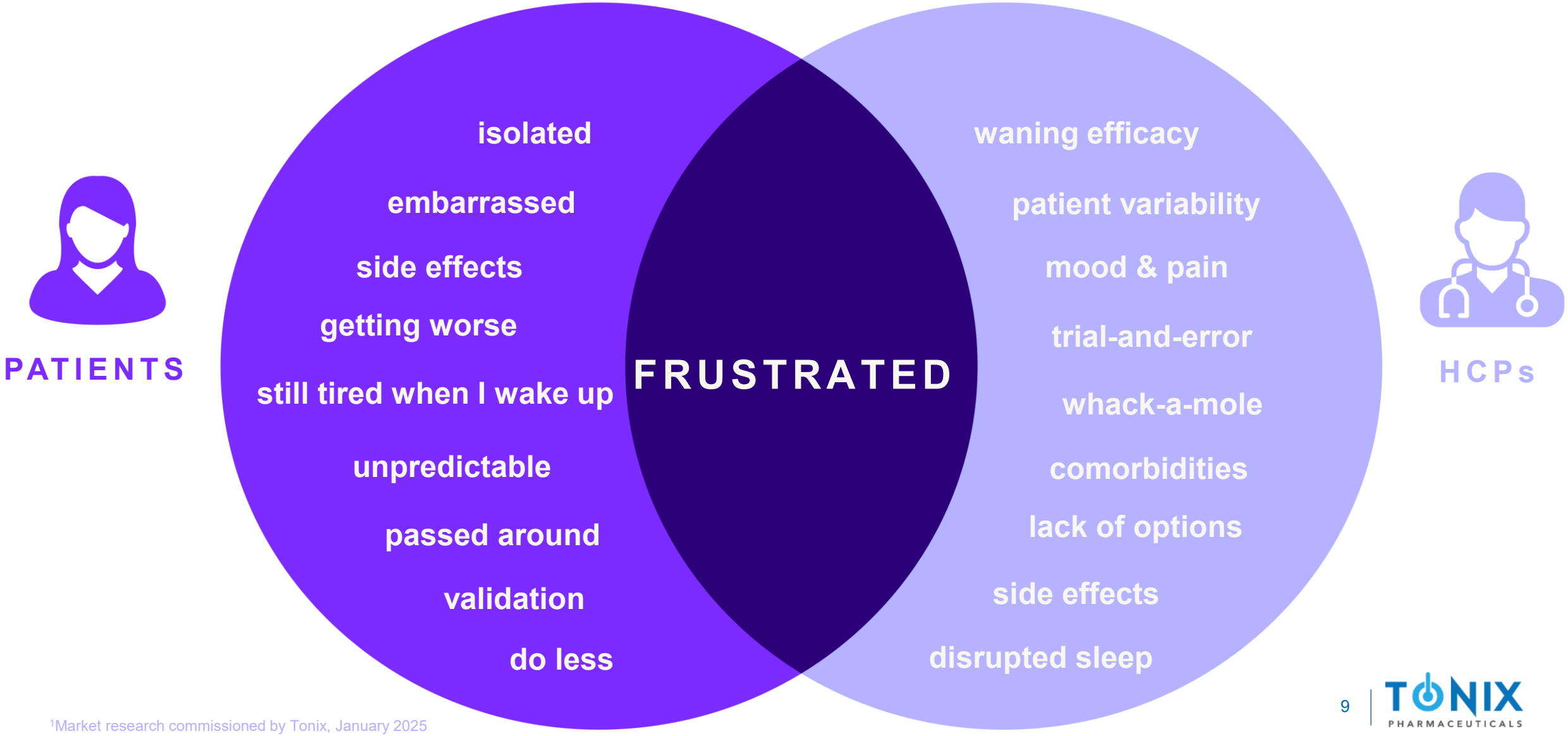
~15 million prescriptions are written for fibromyalgia (on- and off-label usage) each year[5]

Potential for growth

-Potential to increase diagnosis rates with renewed disease awareness and novel medication
-First new drug for fibromyalgia in more than 15 years
-100% share of voice

[1]Fibromyalgia. American College of Rheumatology. Accessed July 3, 2025. www.ACRPatientInfo.org
[2]Fibromyalgia prevalence. National Fibromyalgia Association. Accessed July 3, 2025.
[3]EVERSANA analysis of claims database, May 2024, commissioned by Tonix.
[4]EVERSANA primary physician research, May 2024; commissioned by Tonix
[5]Symphony Market data, May 2025. Prescription data includes on-label FM prescriptions and patients with FM diagnoses who received commonly prescribed off-label therapies.

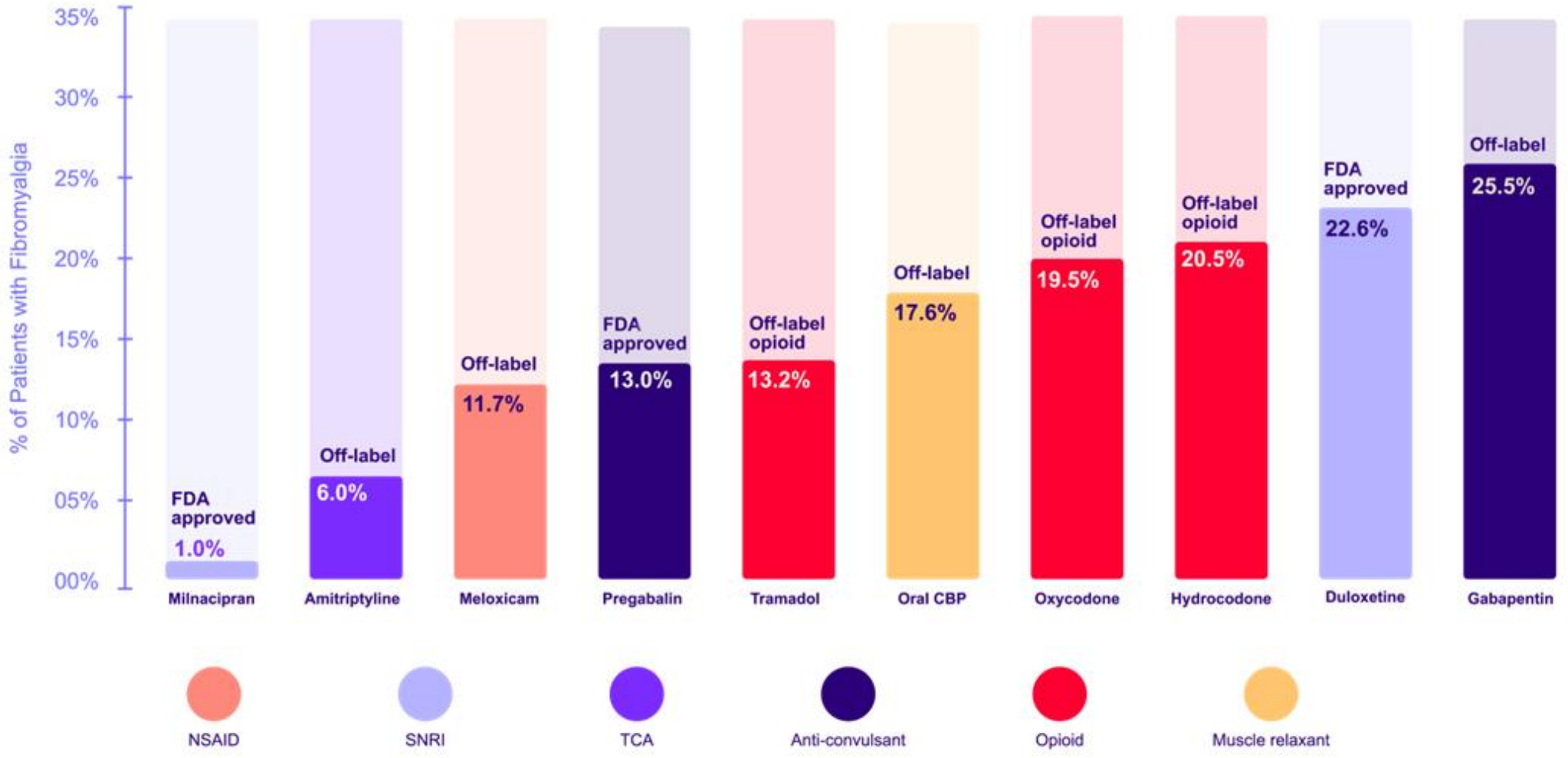
Both Patients and HCPs are Challenged by the Fibromyalgia Journey[1]



[1]Market research commissioned by Tonix, January 2025

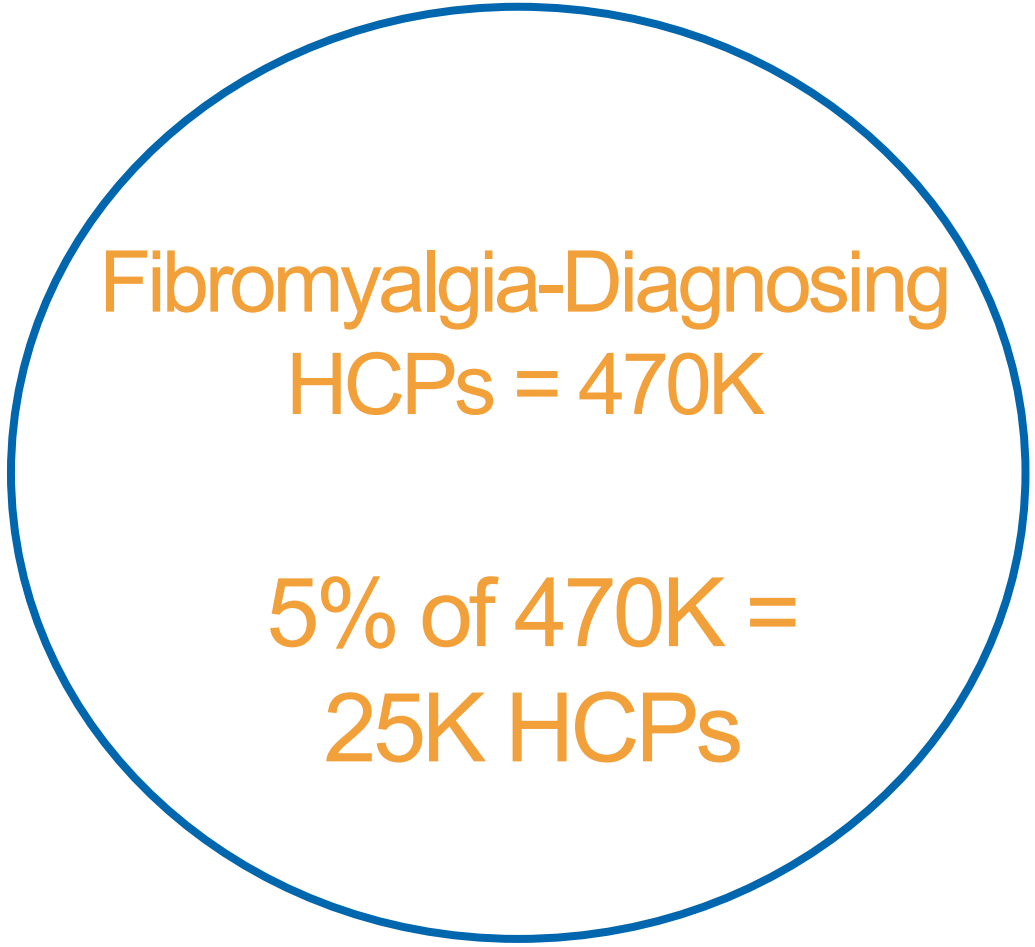
Patient and HCP Dissatisfaction has Led to Significant Off-label Use

Off-label Opioids are Commonly Prescribed within 18 Months of Fibromyalgia Diagnosis



CBP, cyclobenzaprine; NSAID, nonsteroidal anti-inflammatory drug; SNRI, serotonin norepinephrine reuptake inhibitor; TCA, tricyclic antidepressant.
Eversana analysis of claims database, May 2024.

Targeted Commercial Approach:
~5% of Diagnosing HCPs Write ~70% of Prescriptions[1,2]



We will move away from:

Traditional specialty-based decile targeting

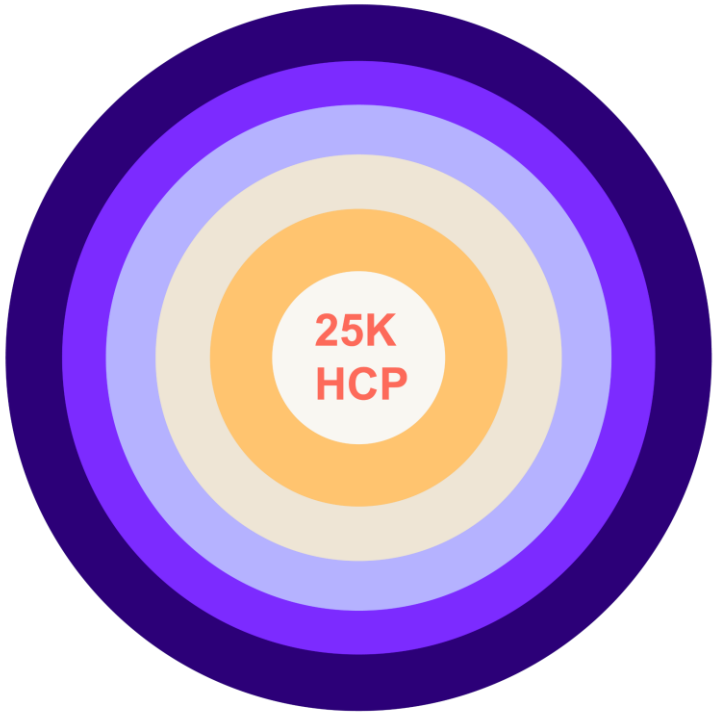
Hyper-focused one-on-one HCP targeting → **To:** **~25K HCPs**

[1,2] Paid Rx (APLD) in the recent 12 months (Feb'24 to Jan'25); Rx (FACT) in the recent 12 months (Feb'24 to Jan'25); FBM DX 2020-2025. This 5% also diagnoses 70% of fibromyalgia patients.
[3] Tonix has engaged Inizio, a leading contract sales organization, to provide the majority of its sales force.

Best Practice Approach to Engage Top-prescribing HCPs

- Earned Media
- Corporate Communications
- Influencer Marketing
- Owned Social Channels
- Reputation Management
- KOL Engagement
- Search Engine Optimization
- Digital Media
- Paid Social
- Machine Learning

Omnichannel Surround Sound



Sales Force[1] ~90 Reps Initially

[1] Tonix has engaged Inizio, a leading contract sales organization, to provide the majority of its sales force.

TONMYA Together™ Provides Robust Patient Access & Support Services

ACCESS PATHWAYS[1]

Payer Education & Engagement

Payer Research and Value Analysis

Burden of Disease & Payer Value Proposition

Engagement underway with commercial payers, Medicare and Medicaid

Digital Pharmacy Experience

Bridge Programs Live

Streamlined Enrollment & Enhanced Prior Authorization Support

Free Home Delivery, Enhancing Convenience and Access

Traditional Pharmacy Savings Program

Copay Support & Savings Program for Eligible Patients
Digital & Text Enrollment

Prior Authorization Support

WAC prices:
$1,860 - 60 count Rx; $930 - 30 count Rx
(for geriatric patients and adults with mild hepatic impairment)

[1] Programs are for patients after their HCP has determined TONMYA is appropriate for them.

TONMYA Leverages Existing Commercial Infrastructure From Our Marketed Migraine Drugs

Tonix Medicines: Complete Commercialization Capabilities & Infrastructure

TOSYMRA®
(sumatriptan nasal spray) 10 mg[2]

ZEMBRACE® SymTouch®
(sumatriptan injection) 3 mg[1]

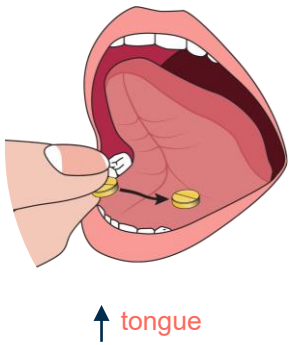
- TOSYMRA® and ZEMBRACE® are each indicated for the ***treatment of acute migraine with or without aura in adults***
- Sumatriptan remains the acute migraine 'gold standard' treatment for many patients and represents the largest segment of the market in terms of unit sales[3]
- Each may provide migraine ***pain relief in as few as 10 minutes*** for some patients[1,2,4,5]

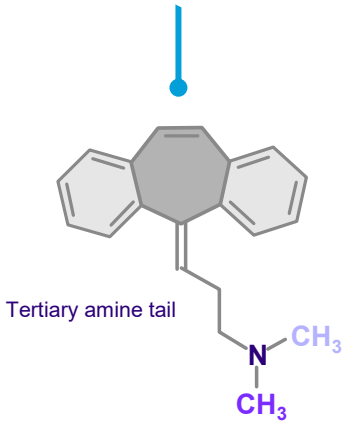
[1]ZEMBRACE SymTouch [package insert]. For more information, talk to your provider and read the Patient Information and Instructions for Use. – Important Safety Information is provided in the appendix
[2]TOSYMRA [package insert]. For more information, talk to your provider and read the Patient Information and Instructions for use– Important Safety Information is provided in the appendix
[3]Tonix Medicines, Inc.; Data On File, 2023
[4]Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. Arch Neurol. 1992;49(12):1271-1276.
[5]Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. Clinical Therapeutics. 2006;28(4):517-526.

TONMYA - Uniquely Designed to Transform the Treatment Landscape

TONMYA's Formulation Delivers the Tertiary Amine Tricyclic by Transmucosal Absorption, Bypassing First-Pass Liver Metabolism

TONMYA is administered sublingually

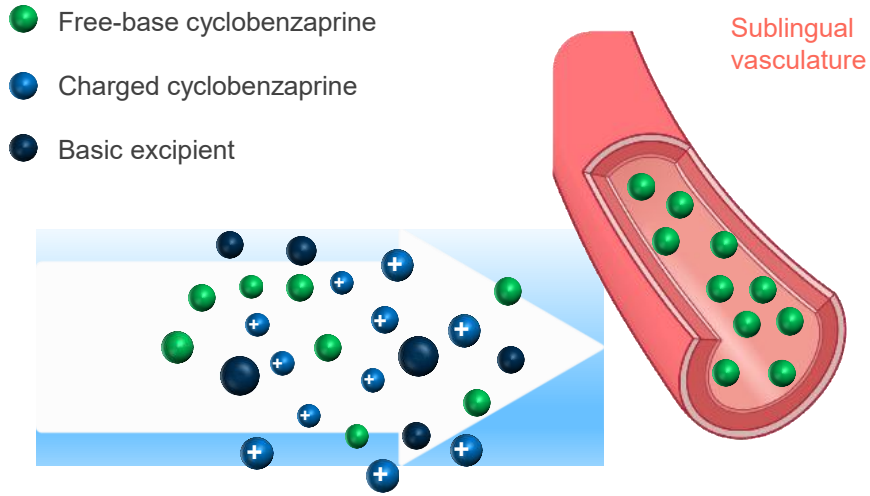




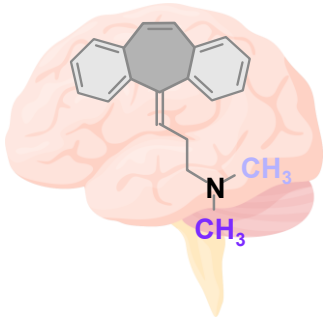
The sublingual tablet rapidly disintegrates, dissolves, and releases solubilized cyclobenzaprine ("CBP") into the saliva adjacent to the mucosal membrane

The base drives formation of CBP free-base, which enters the bloodstream across the mucosal membrane (transmucosal absorption)

Tonix's proprietary formulation contains a basic ingredient which drives transmucosal absorption and a cyclobenzaprine-mannitol eutectic that results in a stable tablet with a 4-year shelf-life.



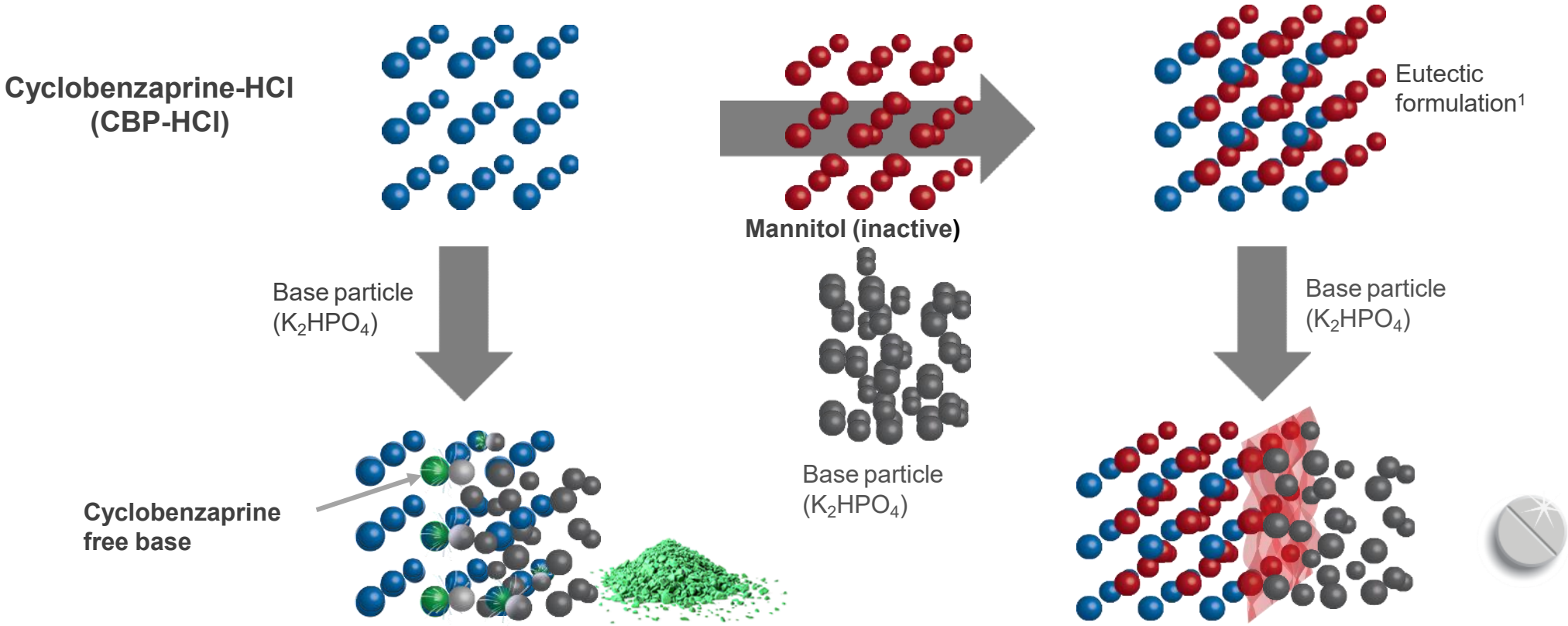
Sublingual CBP enters the bloodstream directly through the mucosal membrane



Transmucosal CBP administered sublingually bypasses "first-pass" liver metabolism, leading to faster absorption and reduced norCBP

TNX-102 SL: Proprietary Eutectic Formulation

Proprietary Cyclobenzaprine HCl Eutectic Mixture Stabilizes Sublingual Tablet Formulation



[1] U.S. Patent issued May 2, 2017

FDA Approval Based on Studies that Demonstrated Durable Improvement in Pain Intensity Scores in Fibromyalgia Patients

Primary Efficacy Endpoint: Mean Change from Baseline in Weekly Average of Daily 24-Hour Recall Pain Intensity Scores at Week 14 in Adult Subjects with Fibromyalgia (Studies 1 and 3)

Study 1 (RELIEF)

	Placebo		TONMYA	
Visit / Statistics	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Trial 1				
Baseline				
N	255		248	
Mean (SD)	6.0 (1.08)		6.1 (1.06)	
(Minimum, Maximum)	(4, 9)		(4, 9)	
Week 14				
LS mean (SE)[1]	4.6 (0.12)	-1.5 (0.12)	4.2 (0.12)	-1.9 (0.12)
95% CI[1]	(4.3, 4.8)	(-1.7, -1.3)	(3.9, 4.4)	(-2.1, -1.7)
Difference in LS mean (SE)				-0.4 (0.16)
95% CI for difference in LS mean				(-0.7, -0.1)
p-value for difference				0.010

Study 3 (RESILIENT)

	Placebo		TONMYA	
Visit / Statistics	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Trial 3				
Baseline				
N	225		231	
Mean (SD)	5.9 (1.08)		5.9 (1.05)	
(Minimum, Maximum)	(4, 9)		(4, 9)	
Week 14				
LS mean (SE)[1]	4.7 (0.12)	-1.2 (0.12)	4.1 (0.12)	-1.8 (0.12)
95% CI[1]	(4.5, 5.0)	(-1.4, -0.9)	(3.8, 4.3)	(-2.0, -1.6)
Difference in LS mean (SE)				-0.7 (0.16)[2]
95% CI for difference in LS mean				(-1.0, -0.3)
p-value for difference				<0.001

CI = confidence interval; LS = least squares; SD = standard deviation; SE = standard error

[1] LS means, differences and CIs were based on a mixed model for repeated measures with fixed, categorical effects of treatment, center, study week, and treatment-by-study week interaction, as well as the fixed covariates of baseline value and baseline value-by-study week interactions. An unstructured covariance matrix was used.

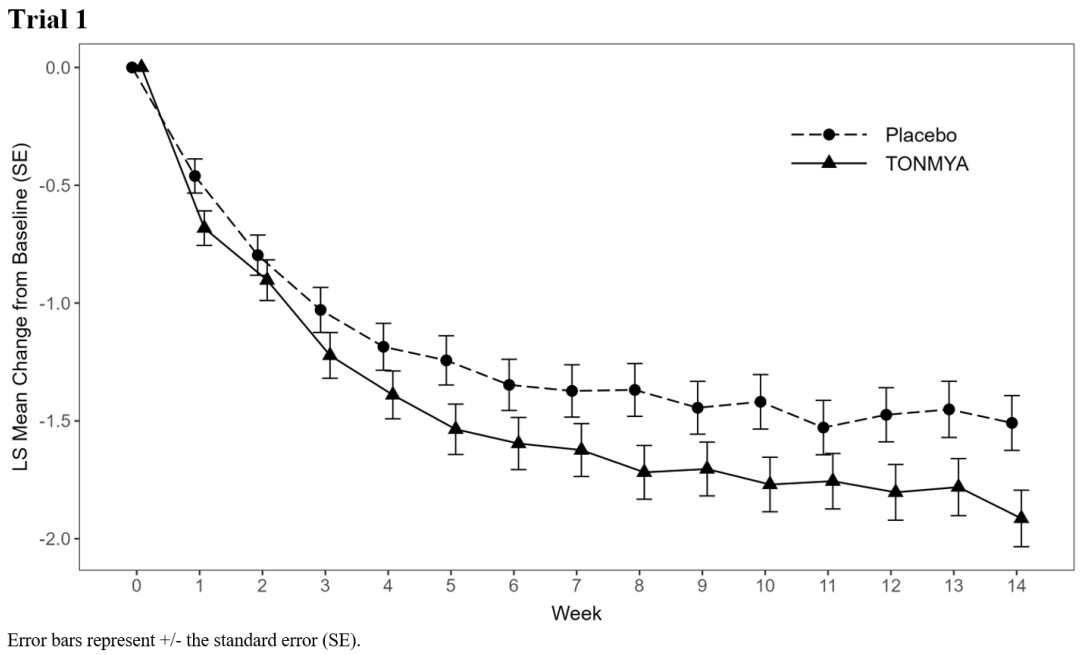
[2] Difference of -0.7 is due to a rounding effect: TONMYA: -1.82, placebo: -1.16, and the difference in LS mean is -0.66.

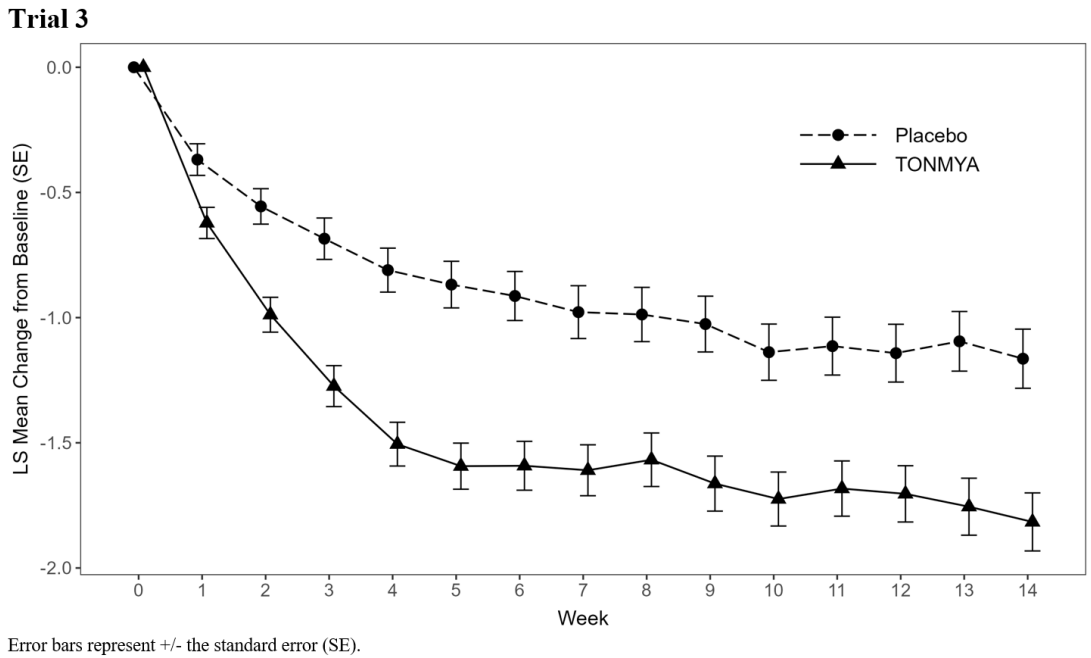
Approval Based on Studies that Demonstrated Significant Improvement in Pain Intensity Scores in Fibromyalgia Patients

Study 1 (RELIEF) n=503

Study 3 (RESILIENT) n=457

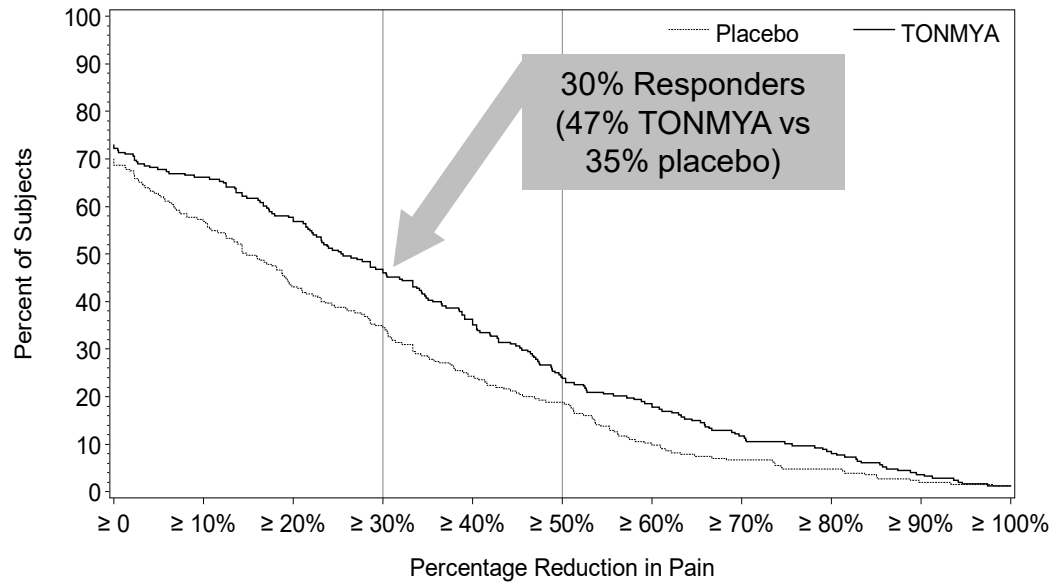
Pivotal Studies Included in Label Demonstrate Statistically Significant Mean Change from Baseline in Weekly Average of Daily 24-hour Recall Pain Intensity Scores at Week 14



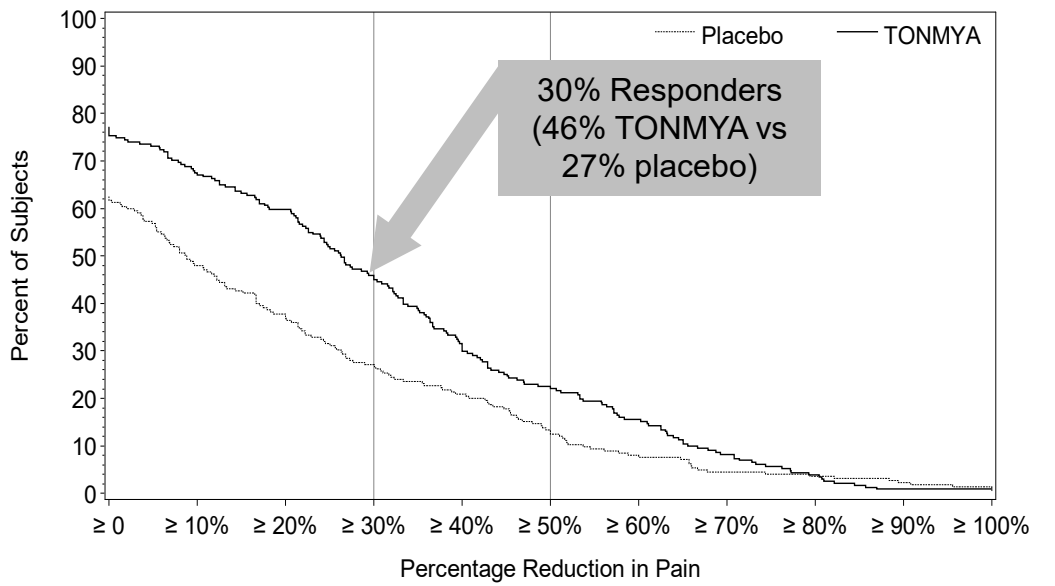


Greater Percentage of Study Participants Taking TONMYA Experienced a Clinically Meaningful (≥30%) Improvement in their Pain after Three Months, Compared to Placebo

Study 1 (RELIEF)* n=503



Study 3 (RESILIENT)* n=457



*The figures shows the percentage of patients in Trials 1 and 3 who achieved various degrees of improvement in the change from baseline to Week 14 in the weekly averages of daily diary pain scores. The figures are cumulative so that patients whose change from baseline is, for example, 30%, are also included at every level of improvement below 30%. Patients who did not complete the trial were assigned 0% improvement.

Generally Well-Tolerated with an Established Safety Profile

- In clinical studies:
  - The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were: oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer
  - Weight gain and blood pressure for drug group were similar to placebo group
  - No reports of cognitive dysfunction or sexual dysfunction
  - No evidence of abuse potential
- Pregnancy testing recommended in females with reproductive potential
- Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome

For full prescribing information and safety information, please visit **www.tonmya.com**

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Clinical Pipeline

Key Clinical Programs

	MOLECULE*	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Infectious disease	**TNX-4800** Human monoclonal Antibody	Seasonal Prevention of Lyme Disease	*Phase 2 Field Study Planned 2027 and Human Challenge (CHIM) Study Planned 2028+*			
CNS	**TNX-102 SL** Cyclobenzaprine HCl Sublingual Tablets	Treatment of Acute Stress Disorder/Acute Stress Disorder	*Phase 2 Topline Data Planned 2H'26***			
		Treatment of Major Depressive Disorder	*Phase 2 Study Planned Mid-'26*			
Immunology and immuno-oncology	**TNX-1500** Anti-CD40L mAb	Prevention of Organ Transplant Rejection	*Phase 2 Study Planned Mid-'26**+*			
Rare disease	**TNX-2900** Intranasal Potentiated Oxytocin (OT) With Magnesium	Treatment of Prader-Willi Syndrome	*Phase 2 Study Planned 1Q'27*			
CNS	**TNX-1300** Recombinant Cocaine esterase	Treatment of Cocaine Intoxication	*Mid-Phase 2*			

*All of Tonix Pharmaceuticals' product candidates are investigational new drugs or biologics; their safety and efficacy have not been established for the listed indication.
**Investigator-initiated study.
+Pending FDA clearance.
+ +Pending FDA clearance of Investigational New Drug (IND) application.

TNX-4800[1]
Monoclonal antibody prophylaxis against Lyme Disease

Long Acting anti-OspA monoclonal antibody[2-4] to block *Borrelia Burgdorferi* infection

Status:
Manufacturing GMP material for human studies in early 2027
Clinical development plans pending FDA clearances:
Adaptive Field Study: 2027
Human Challenge Study (also called Controlled Human Infection Model (CHIM)): 2028

Potential Advantages of TNX-4800 relative to vaccines in development:
Provides immediate protection after one dose
Does not require a host immune response

Ph 1 data showed prolonged levels of TNX-4800 consistent with protection throughout the tick season:
From Spring to Fall in the U.S.

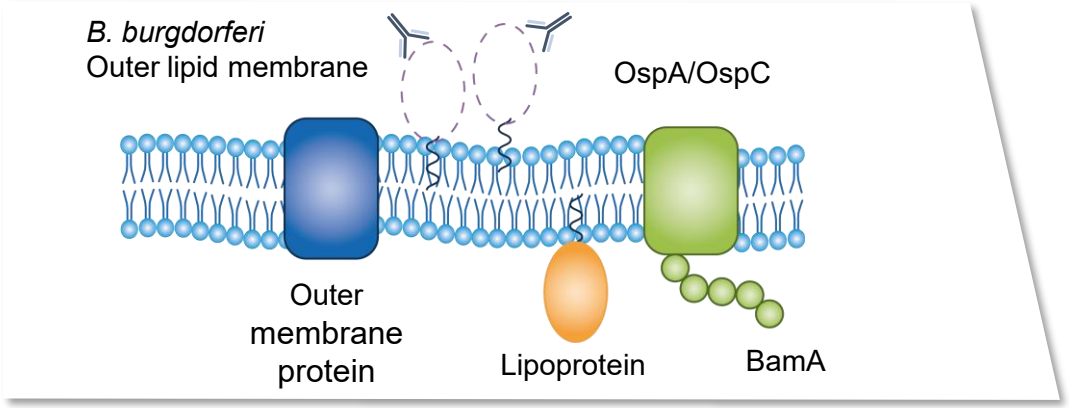
[1]TNX-4800 has not been approved for any indication.
[2]Schiller ZA, al. *J Clin Invest*. 2021;131(11):e144843.
[3]de Silva AM, et al. *J Exp Med*. 1996;183(1):271-275.
[4]Radolf JD, et al. *Nat Rev Microbiol*. 2012;10(2):87-99.

Monoclonal Antibody Attacks *Borrelia*

- When a tick bites a TNX-4800 (mAb anti-OspA) treated animal, the mAb is ingested with blood and enters the tick midgut, binding to OspA protein on *B. burgdorferi*[3,4]
- TNX-4800 is designed to kill *Borrelia* and prevent the bacteria from reaching the tick's salivary glands which protects the animal from infection[2]

Long-Acting Antibody: Seasonal Duration

The TNX-4800 antibody is designed for an extended half-life, allowing a single administration in the spring to potentially provide protection throughout tick season



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TNX-102 SL[1]
For Acute Stress Reaction (ASR) / Acute Stress Disorder (ASD)

ASR/ASD are acute stress conditions resulting from trauma which can affect both civilian and military populations.

Status: Phase 2 Investigator Initiated Study ("OASIS") is enrolling patients

Topline data expected 2H'26

OASIS is built upon the UNC-led, $40M AURORA initiative, a national research program to improve the understanding, prevention, and recovery of people who have experienced a traumatic event

Large unmet need:

- ~60% of men and 50% of women in the US are exposed to at least one traumatic experience[2]
- In the US, 1/3 of emergency dept. visits (40-50 million patients per year) are for trauma exposures[3]

Current standard of care:

- No medications are available at or near the point of care for acute traumatic events and that support long-term health

Ph 2 study in partnership with:

U.S. Department of Defense

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

[1]TNX-102 SL has not been approved for the ASR indication
[2]National Center for PTSD. How Common is PTSD in Adults? https://www.ptsd.va.gov/understand/common/common_adults.asp
[3]Wisco et al. *J Clin Psychiatry*. 2014.75(12):1338-46

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TNX-102 SL[1]
For Major Depressive Disorder (MDD)

TNX-102 SL is believed first-in-class for targeting the disturbed sleep associated with depression

Status: IND cleared by FDA
Potential pivotal Ph 2 study planned to initiate mid-year 2026

Evidence: TNX-102 SL showed activity on the Beck Depression Inventory-II (BDI) in the Ph 3 RESILIENT study in fibromyalgia patients with an uncorrected p-value < 0.05.

Large market opportunity:

- Depression is an unmet need, despite multiple approved drugs[2]
- ~21 million U.S. adults experience at least one major depressive episode annually[3]

Current standard of care:

- SSRIs, SNRIs, dextromethorphan/bupropion
- Secondary amine tricyclic antidepressants
- Tertiary amine tricyclic antidepressants
- Pills can adversely impact weight, blood pressure/heart rate, cognition, and sexual function

[1]TNX-102 SL has not been approved for MDD
[2]Rush, et al Am J Psychiatry. 2006 Nov;163(11):1905-17; Garcia-Marin et al. Annals of General Psychiatry (2023) 22:49
[3]www.nimh.nih.gov/health/statistics/major-depression

TNX-1500[1]

For the Prevention of Allograft and Bone Marrow Transplant Rejection

The α- CD40 Ligand CD40L antibody pathway is a pivotal immune system modulator and a well-established and promising treatment target

Status: Phase 1 study completed and
Mass General Hospital planning to start enrollment in investigator-initiated clinical study mid-year 2026, for kidney allograft, pending FDA clearance

Autoimmune Diseases
Potential indications include:
Sjögren's Syndrome, Systemic Lupus Erythematosus

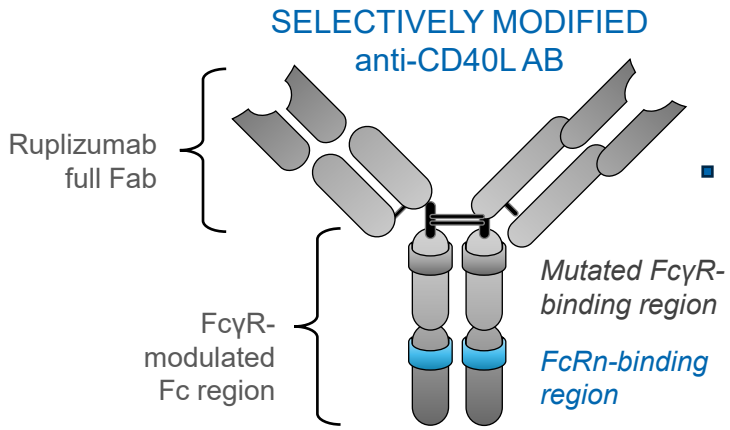
[1]TNX-1500 has not been approved for any indication. Patents filed.

Expected to deliver efficacy without compromising safety

1st Generation: Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (FcγR)

2nd Generation: Eliminated the FcγR TE complication, but potency and half life were reduced

3rd Generation (TNX-1500): Re-engineered to better modulate the binding of FcγR.



Contains the full ruplizumab Fab and the engineered Fc region that modulates FcγR-binding, while preserving FcRn function.

TNX-2900[1]
For Prader-Willi Syndrome

Intranasal Potentiated Oxytocin (OT) with Magnesium

Status: Plan to initiate Phase 2 study 1Q 2027

- TNX-2900 has both Orphan Drug and Rare Pediatric Disease designations in the U.S.

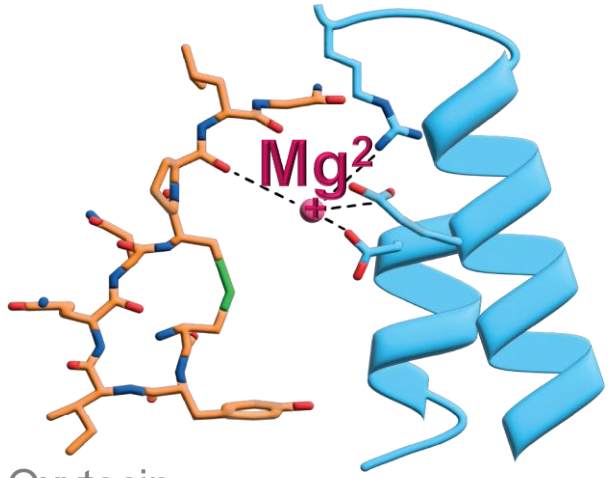
Prader-Willi Syndrome: most common genetic cause of life-threatening childhood obesity

- Rare disease occurring in 1 in 10,000 to 1 in 30,000 births in the US
- Symptoms include lack of suckling as infants, poor muscle strength, and constant hunger (hyperphagia) in adolescents and young adults

Market Entry:
Treatment of children and adolescents with Prader-Willi Syndrome

Differentiators:
Patented potentiated OT formulation is believed to increase activity of OT at OT receptors (OXTR)

Oxytocin Requires Magnesium for Receptor Binding



[1]TNX-2900 has not been approved for any indication

TNX-1300[1]
For Cocaine Intoxication

Cocaine Esterase (CocE)

Status: Phase 2a study completed
- TNX-1300 has FDA Breakthrough Therapy Designation in the U.S.

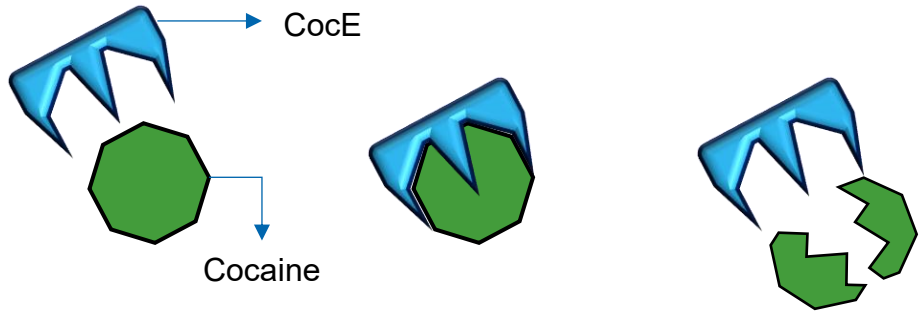
Cocaine is the main cause for drug-related ED visits[2]

CocE is a recombinant protein that degrades cocaine in the bloodstream
- Rapidly reverses physiologic effects of cocaine
- Drops plasma exposure by 90% in 2 minutes

Market entry:
Treatment of cocaine intoxication

Differentiators:
Rapidly metabolizes cocaine in the bloodstream; no other product currently on the market for this indication

CocE Rapidly Inactivates Cocaine



[1]TNX-1300 has not been approved for any indication

[2]Havakuk et al., 2017. *J Am Coll Cardiol*. 70:101-113

Milestones: Recently Completed and Targeted

Aug 2025
Tonmya™
FDA Approval

Q4 2025
TNX-102 SL
IND Cleared
for MDD

Nov 2025
Tonmya™
Commercial
Launch

Mid-2026
TNX-1500
Initiate Ph 2
Study for Kidney
Transplant[1]

Mid-2026
TNX-102 SL
Initiate Ph 2
Study for MDD

2H 2026
TNX-102 SL
Report Ph 2
Topline Data for
ASR/ASD[2]

1Q 2027
TNX-2900
Initiate Ph 2
Study for PWS

2027
TNX-4800
Initiate Field
Study

2028
TNX-4800
Initiate CHIM
Study

[1]IIT with MGH, pending FDA clearance
[2]IIT with University of North Carolina

Tonix Priorities

Strategically Positioned for the Future

Deliver Best-in-Class Launch

Advance Promising Mid-Stage Pipeline Programs

Drive Sustainable Growth to Create Value for All Stakeholders

THANK YOU

PO6127 March 2026 1644

TONMYA (cyclobenzaprine hydrochloride sublingual tablets)
INDICATION: TONMYA is indicated for the treatment of fibromyalgia in adults.
Important Safety Information (1 of 2)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
TONMYA is contraindicated:

In patients with hypersensitivity to cyclobenzaprine or any inactive ingredient in TONMYA. Hypersensitivity reactions may manifest as an anaphylactic reaction, urticaria, facial and/or tongue swelling, or pruritus. Discontinue TONMYA if a hypersensitivity reaction is suspected.

With concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after discontinuation of an MAO inhibitor. Hyperpyretic crisis seizures and deaths have occurred in patients who received cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitors drugs.

During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure.

In patients with hyperthyroidism.

WARNINGS AND PRECAUTIONS
Embryofetal toxicity: Based on animal data, TONMYA may cause neural tube defects when used two weeks prior to conception and during the first trimester of pregnancy. Advise females of reproductive potential of the potential risk and to use effective contraception during treatment and for two weeks after the final dose. Perform a pregnancy test prior to initiation of treatment with TONMYA to exclude use of TONMYA during the first trimester of pregnancy.

Serotonin syndrome: Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome, a potentially life-threatening condition. Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Treatment with TONMYA and any concomitant serotonergic agent should be discontinued immediately if serotonin syndrome symptoms occur and supportive symptomatic treatment should be initiated. If concomitant treatment with TONMYA and other serotonergic drugs is clinically warranted, careful observation is advised, particularly during treatment initiation or dosage increases.

Tricyclic antidepressant-like adverse reactions: Cyclobenzaprine is structurally related to TCAs. TCAs have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke. If clinically significant central nervous system (CNS) symptoms develop, consider discontinuation of TONMYA. Caution should be used when TCAs are given to patients with a history of seizure disorder, because TCAs may lower the seizure threshold. Patients with a history of seizures should be monitored during TCA use to identify recurrence of seizures or an increase in the frequency of seizures.

Atropine-like effects: Use with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic drugs.

CNS depression and risk of operating a motor vehicle or hazardous machinery: TONMYA monotherapy may cause CNS depression. Concomitant use of TONMYA with alcohol, barbiturates, or other CNS depressants may increase the risk of CNS depression. Advise patients not to operate a motor vehicle or dangerous machinery until they are reasonably certain that TONMYA therapy will not adversely affect their ability to engage in such activities.

Oral mucosal adverse reactions: In clinical studies with TONMYA, oral mucosal adverse reactions occurred more frequently in patients treated with TONMYA compared to placebo. Advise patients to moisten the mouth with sips of water before administration of TONMYA to reduce the risk of oral sensory changes (hypoesthesia). Consider discontinuation of TONMYA if severe reactions occur.

TONMYA (cyclobenzaprine hydrochloride sublingual tablets)
INDICATION: TONMYA is indicated for the treatment of fibromyalgia in adults.
Important Safety Information (2 of 2)

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer.

DRUG INTERACTIONS
MAO 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, TONMYA may cause fetal harm when administered to a pregnant woman. The limited amount of available observational data on oral cyclobenzaprine use in pregnancy is of insufficient quality to inform a TONMYA-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women about the potential risk to the fetus with maternal exposure to TONMYA and to avoid use of TONMYA two weeks prior to conception and through the first trimester of pregnancy. Report pregnancies to the Tonix Medicines, Inc., adverse-event reporting line at 1-888-869-7633 (1-888-TNXPMED).

Lactation: A small number of published cases report the transfer of cyclobenzaprine into human milk in low amounts, but these data cannot be confirmed. There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TONMYA and any potential adverse effects on the breastfed child from TONMYA or from the underlying maternal condition.

Pediatric use: The safety and effectiveness of TONMYA have not been established.

Geriatric patients: Of the total number of TONMYA-treated patients in the clinical trials in adult patients with fibromyalgia, none were 65 years of age and older. Clinical trials of TONMYA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

Hepatic impairment: The recommended dosage of TONMYA in patients with mild hepatic impairment (HI) (Child Pugh A) is 2.8 mg once daily at bedtime, lower than the recommended dosage in patients with normal hepatic function. The use of TONMYA is not recommended in patients with moderate HI (Child Pugh B) or severe HI (Child Pugh C). Cyclobenzaprine exposure (AUC) was increased in patients with mild HI and moderate HI compared to subjects with normal hepatic function, which may increase the risk of TONMYA-associated adverse reactions.

Please see additional safety information in the full Prescribing Information.

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.

ZEMBRACE® Important Safety Information (1 of 2)

ZEMBRACE SymTouch (ZEMBRACE) can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- Discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw or stomach; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; feeling lightheaded

ZEMBRACE is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use ZEMBRACE if you have:

- History of heart problems; narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease); uncontrolled high blood pressure; hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; severe liver problems; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, dihydroergotamine; are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- An allergy to sumatriptan or any of the components of ZEMBRACE.

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

ZEMBRACE can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

ZEMBRACE® Important Safety Information (2 of 2)

ZEMBRACE may cause serious side effects including:

- Changes in color or sensation in your fingers and toes; sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever; cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet; increased blood pressure including a sudden severe increase even if you have no history of high blood pressure; medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- Serotonin syndrome, a rare but serious problem that can happen in people using ZEMBRACE, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- Hives (itchy bumps); swelling of your tongue, mouth, or throat
- Seizures even in people who have never had seizures before

The most common side effects of ZEMRACE include: pain and redness at injection site; tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of ZEMBRACE. For more information, ask your provider.

This is the most important information to know about ZEMBRACE but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. For full Prescribing Information, visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e5b104f-2b9e-416e-92fb-ef1bdaea867d

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ZEMBRACE is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

ZEMBRACE is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.

TOSYMRA® Important Safety Information (1 of 2)

TOSYMRA® can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop TOSYMRA and get emergency medical help if you have any signs of heart attack:

- Discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw, or stomach; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; feeling lightheaded

TOSYMRA is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Do not use TOSYMRA if you have:

- History of heart problems; narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease); uncontrolled high blood pressure; severe liver problems; hemiplegic or basilar migraines. If you are not sure if you have these, ask your healthcare provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider if you are not sure if your medicine is listed above
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure
- An allergy to sumatriptan or any ingredient in TOSYMRA

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements. TOSYMRA can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

TOSYMRA® Important Safety Information (2 of 2)

TOSYMRA may cause serious side effects including:

- Changes in color or sensation in your fingers and toes; sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever; cramping and pain in your legs or hips, feeling of heaviness or tightness in your leg muscles, burning or aching pain in your feet or toes while resting, numbness, tingling, or weakness in your legs, cold feeling or color changes in one or both legs or feet; increased blood pressure including a sudden severe increase even if you have no history of high blood pressure; medication overuse headaches from using migraine medicine for 10 or more days each month. **If your headaches get worse, call your provider**.
- Serotonin syndrome, a rare but serious problem that can happen in people using TOSYMRA, especially when used with anti-depressant medicines called SSRIs or SNRIs. **Call your provider right away if you have**: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- Seizures even in people who have never had seizures before

The most common side effects of TOSYMRA include:

tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.
Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of TOSYMRA. For more information, ask your provider.
This is the most important information to know about TOSYMRA but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for use. For full Prescribing Information, visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=015a5cf9-f246-48bc-b91e-cd730a53d8aa.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
TOSYMRA is a prescription medicine used to treat acute migraine headaches with or without aura in adults.
TOSYMRA is not used to treat other types of headaches such as hemiplegic or basilar migraines or cluster headaches.
TOSYMRA is not used to prevent migraines. It is not known if TOSYMRA is safe and effective in children under 18 years of age.