



# Corporate Presentation

## Abbreviated

**Focus on: Tonmya™\* (TNX-102 SL) in  
Development for the Management of  
Fibromyalgia**

**April 2024**

NASDAQ: TNXP

\*Tonmya is conditionally accepted by FDA as the tradename for TNX-102 SL for the management of fibromyalgia



# Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are “forward-looking statements” as defined by 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” 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, the risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; 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. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (the “SEC”) on April 1, 2024, and periodic reports and current 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.

# Who We Are

Tonix is committed to developing and marketing therapeutics to treat pain, neurologic, psychiatric and addiction conditions through our ***central nervous system portfolio*** and within other areas of ***high unmet need***, including immunology, infectious disease, and rare disease

With a Focus on:

***Filing a New Drug Application (NDA) with the US Food and Drug Administration (FDA) for Tonmya™ (TNX-102 SL) for the management of Fibromyalgia***



# Key Clinical Programs

Molecule*	Indication	Phase 1	Phase 2	Phase 3	NDA Submission
<b>Tonmya™</b> <b>TNX-102 SL</b> Cyclobenzaprine HCl Protectic® Sublingual Tablets	Fibromyalgia		Statistically Significant Phase 3 Topline Results Reported 4Q'23		Submission expected 2H'24
	Long COVID		Phase 2 Topline Results Reported 3Q'23		
	Acute Stress Disorder		Phase 2 Study** Start Expected 2Q'24		
<b>TNX-1300</b> Cocaine Esterase NIDA Funded	Cocaine Intoxication		Phase 2 Study Start Expected 2Q'24		
<b>TNX-2900</b> Intranasal Potentiated Oxytocin FDA Orphan Drug and Rare Pediatric Disease Designation	Prader-Willi Syndrome		Phase 2 Ready		
<b>TNX-1500</b> Anti-CD40L mAb	Organ Transplant Rejection/ Autoimmune Conditions		Phase 1 Study Ongoing	Clinical Stage complete	

\*All of Tonix's product candidates are investigational new drugs or biologics and none has been approved for any indication.

\*\*Investigator-initiated study



# Tonmya™

## TNX-102 SL

### Cyclobenzaprine (Protectic®)

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***A unique, sublingual formulation of cyclobenzaprine  
designed to optimize delivery and absorption***

Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

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**TONIX**  
PHARMACEUTICALS



# About Fibromyalgia

Fibromyalgia is a chronic pain disorder resulting from amplified sensory and pain signaling within the CNS<sup>1</sup>

Fibromyalgia is a syndrome comprised of the **symptoms**: chronic widespread pain, **nonrestorative sleep**, and fatigue



Multisite pain



Non-Restorative Sleep



Fatigue

**Fibromyalgia is considered a chronic overlapping pain condition (COPC)**  
**- the *only COPC* with any FDA-approved drugs<sup>3</sup>**

**Fibromyalgia is the prototypic nociplastic syndrome**

<sup>1</sup>American Chronic Pain Association (www.theacpa.org, 2019)  
<sup>3</sup>CFS/ME = chronic fatigue syndrome/myalgic encephalomyelitis  
<sup>3</sup>The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica®); Duloxetine (Cymbalta®); Milnacipran (Savella®)  
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# Fibromyalgia is a Large, Underserved and Dissatisfied population

- **~10 million U.S. adults are affected – predominantly women<sup>1,2</sup>**
  - Debilitating and life altering condition
  - Significant economic cost
- **Patients are dissatisfied, despite three FDA approved drugs<sup>3,4</sup>**
  - Average patient has 20 physician office visits per year<sup>2</sup>
  - Typical for patients to rotate between drugs<sup>3</sup>
  - Polypharmacy (multiple drugs at the same time) common<sup>3</sup>
  - Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year<sup>5,6</sup>
- **Prescription opiate use declining because of availability**
  - Unknown number of patients using ‘street drugs’
- **No new Rx product since 2009**

<sup>1</sup>American College of Rheumatology ([www.ACRPatientInfo.org](http://www.ACRPatientInfo.org) accessed May 7, 2019) – prevalence rate of 2-4% for U.S. adult population (~250 million)

<sup>2</sup>Vincent A, et al. *Arthritis Care Res (Hoboken)*. 2013 65(5):786-92. doi: 10.1002; diagnosed prevalence rate was 1.1% of adult population or 50% of the prevalent population

<sup>3</sup>Robinson RL, et al. *Pain Med*. 2012 13(10):1366-76. doi: 10.1111; ; 85% received drug treatment

<sup>4</sup>The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica); Duloxetine (Cymbalta); Milnacipran (Savella)

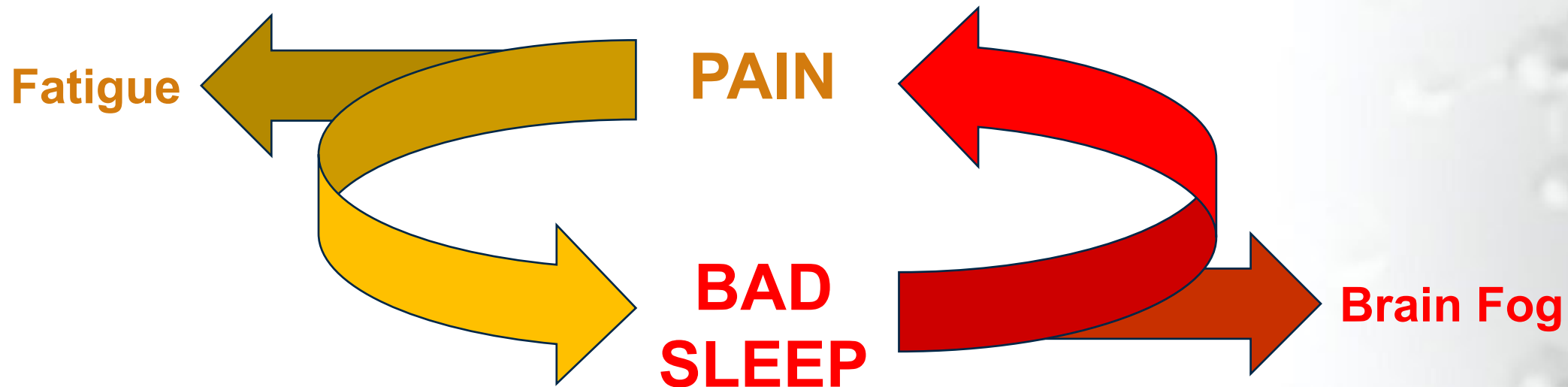
<sup>5</sup>Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.

<sup>6</sup>Market research by Frost & Sullivan, commissioned by Tonix, 2011



## Poor Sleep and Pain have Bi-directional Reinforcing Effects<sup>1</sup>

- Poor sleep and pain form a vicious cycle in driving fibromyalgia decompensation
  - Can't sleep → worse pain / In pain → can't sleep
  - Poor sleep and pain contribute to persistence, chronicity and severity
  - Syndrome includes symptoms of fatigue and brain fog
- Treating sleep disturbance in fibromyalgia has the potential to break the vicious cycle
  - Potential to remove an obstacle to recovery
  - Using the right medicine is important – some sedative/hypnotics don't work<sup>1,2</sup>



<sup>1</sup>Moldofsky H, et al. *J Rheumatol*. 1996;23:529–533.

<sup>2</sup>Grönwald M, et al. *Clin Rheumatol*. 1993;12(2):186–191





## Tonmya™ (TNX-102 SL, Cyclobenzaprine HCl Sublingual Tablets)<sup>1</sup>

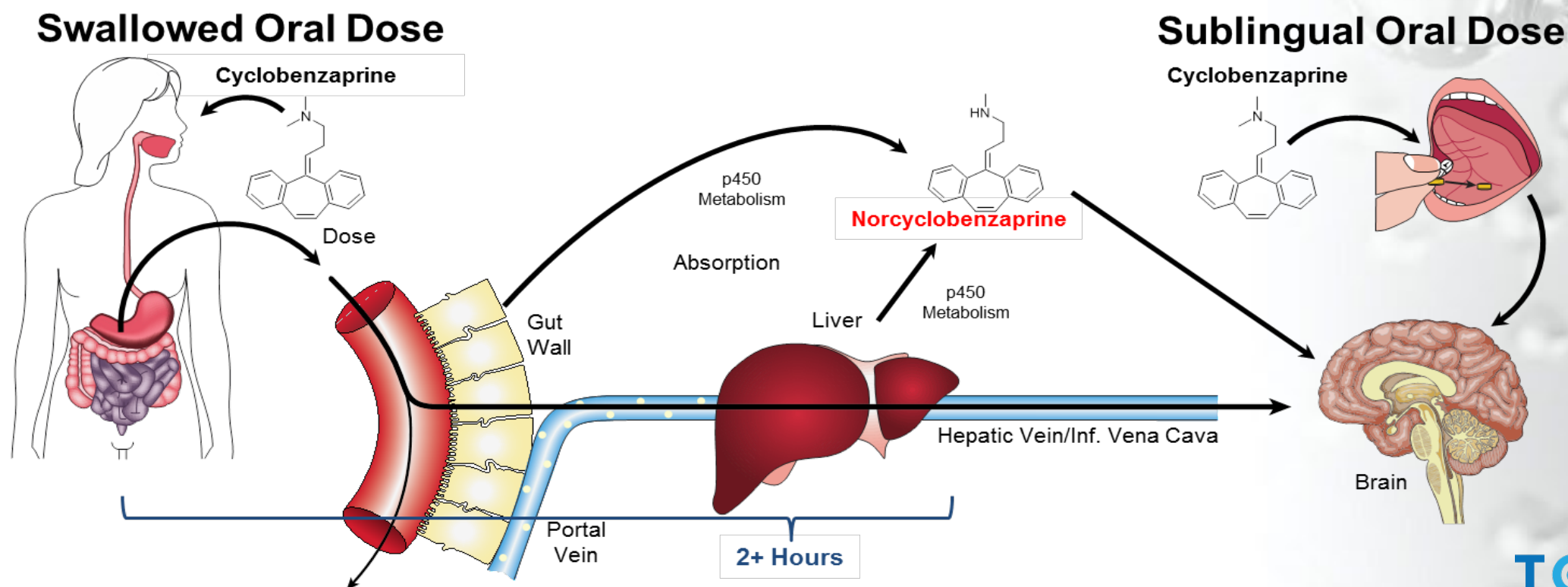
- **Non-opioid analgesic designed for long-term daily bedtime use in fibromyalgia patients**
  - Targets non-restorative sleep
  - Potent binding and antagonist activities at four post-synaptic receptors
    - serotonin-5-HT<sub>2A</sub>
    - $\alpha$ <sub>1</sub>-adrenergic
    - histaminergic-H<sub>1</sub>
    - muscarinic-M<sub>1</sub>
  - No recognized risk for abuse
- **Improves sleep quality, does not increase sleep quantity:**
  - Not a traditional hypnotic or sedative
- **Proprietary, sublingual transmucosal formulation of cyclobenzaprine designed to optimize delivery and absorption**
  - Protectic® formulation based on eutectic composition of matter
    - Rapid absorption
    - Decrease in major metabolite by bypassing first-pass hepatic metabolism

<sup>1</sup>Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. \*Tonmya has not been approved for any indication.



# TNX-102 SL: Sublingual Administration and Transmucosal Delivery

- Advantages of the sublingual route
- Faster absorption provides PK that is ideal for bedtime dosing
- Bypasses “first-pass” hepatic metabolism
- Reduced metabolism of parent CBP to active metabolite norcyclobenzaprine (nCBP)





# Fibromyalgia Program Status

**Tonmya™\***  
**(TNX-102 SL)**  
Cyclobenzaprine Protectic®  
Sublingual Tablets

**Fibromyalgia**

**Statistically Significant 2<sup>nd</sup> Phase 3 Topline Results  
Reported 4Q'23**

- **Statistically significant Phase 3 study (*RELIEF*) reported – December 2020<sup>1</sup>**
- **Second Phase 3 study (*RALLY*) missed primary endpoint – July 2021**
- **Statistically significant 2<sup>nd</sup> (confirmatory) Phase 3 study (*RESILIENT*) reported – December 2023**

**Next Steps:**

- **Type B Pre-NDA meeting scheduled with FDA in 2Q'24**
- **NDA filing expected 2H'24**
- **FDA decision on NDA approval expected 2H'25**

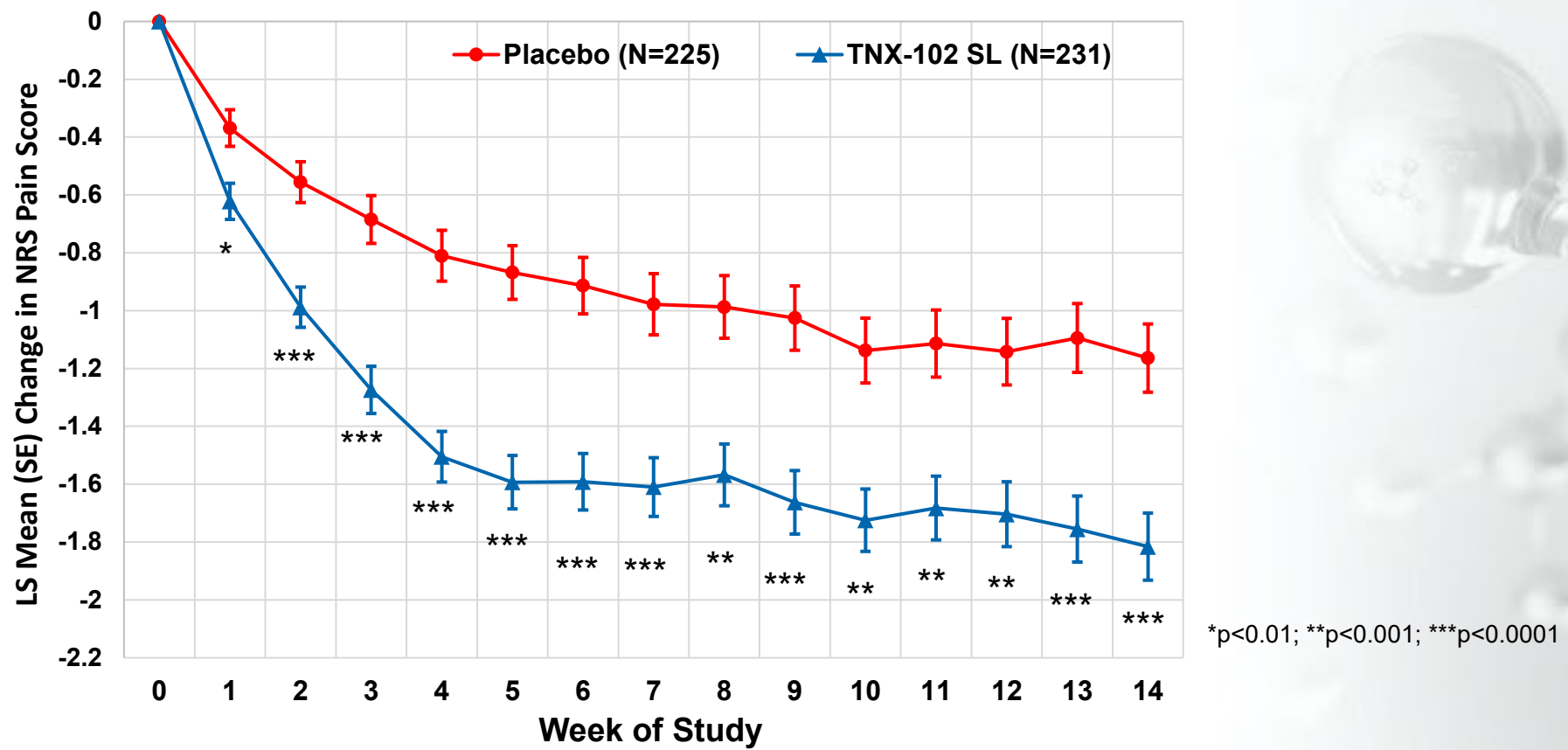
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<sup>1</sup>Lederman S, et al. *Arthritis Care Res (Hoboken)*. 2023 Nov;75(11):2359-2368. doi: 10.1002/

# RESILIENT Primary Outcome Measure

## Reduction in Widespread Pain

Weekly Average of Daily Diary NRS Ratings of Average Pain Over Prior 24 Hours



Week 14 LS mean (SE) change from baseline for TNX-102 SL -1.82 (0.12) and for placebo -1.16 (0.12); LSMD from placebo -0.65 (0.16); **p=0.00005<sup>#</sup>**

<sup>#</sup>Based on Mixed Model Repeated Measures with Multiple Imputation, with fixed categorical effects of treatment, center, study week, and treatment by study week interaction, as well as baseline value and baseline value-by-study week interaction. Abbreviations: LS, least squares; LSMD, least squares mean difference; NRS, numerical rating scale; SE, standard error



# RESILIENT Summary of Endpoints



Endpoint	P-value	Effect Size (ES)
<b>Primary Endpoint</b>		
Daily Diary Pain ratings	$p = 0.00005^{**}$	ES = 0.38
<b>Key Secondary Endpoints*</b>		
Patient Global Impression of Change (PGIC), responders	$p = 0.00013^{**}$	--
Fibromyalgia Impact Questionnaire – Symptoms domain	$p = 0.000002^{**}$	ES = 0.44
Fibromyalgia Impact Questionnaire – Function domain	$p = 0.001^{**}$	ES = 0.30
PROMIS Sleep Disturbance instrument	$p = 0.0000001^{**}$	ES = 0.50
PROMIS Fatigue instrument	$p = 0.00009^{**}$	ES = 0.37
Diary Sleep Quality ratings	$p = 0.0007^{**}$	ES = 0.32

\*In order of statistical serial gate-keeping hierarchy (or, “waterfall”) to control overall Type 1 error

\*\*Statistical significance met

# RESILIENT – Cognitive Dysfunction or “Brain Fog”

## Brain Fog assessed by the FIQ-R<sup>1</sup> item on memory

- Patients rated their level of memory problems
- 11-pt scale going from “Good Memory” to “Very Poor Memory”
- Prespecified endpoint, but not in the “waterfall” with the key secondary endpoints
- TNX-102 SL patients vs PBO change from baseline LS mean (SE) difference of  $-0.8$  ( $0.23$ )
- $p = 0.001$  (not corrected for multiple comparisons)
- Cohen’s  $d$  effect size =  $0.31$



Fatigue



<sup>1</sup>FIQ-R = Fibromyalgia Impact Questionnaire - Revised



## Tonmya™ Showed Broad-Spectrum Activity and was Well Tolerated

		Lyrica®	Cymbalta® Savella®	Tonmya™
Activity	Pain	YES	YES	YES
	Sleep	YES	-	YES
	Fatigue	-	YES	YES
Systemic Tolerability Issues	Insomnia	-	+	-
	Fatigue	+	-	-
	Weight	+	-	-
	Blood Pressure	-	+	-
	Sexual function	-	+	-
	GI issues	-	+	-

- Tonmya showed activity in all three measures of pain, sleep, and fatigue
- Tonmya is not associated with any of the commonly reported side effects



## Safety and Tolerability

- **Completion Rate (safety population): TNX-102 SL 81.0% and Placebo 79.2%**
- **No new safety signals observed**
- **Only systemic adverse events (AEs) at rate  $\geq 3.0\%$  (TNX-102 SL v. Placebo)**
  - COVID-19 (4.3% v. 3.1%), somnolence (3.0% v. 1.3%), and headache (3.0% v. 1.8%)
- **As previously observed TNX-102 SL associated with administration site reactions**
  - Hypoaesthesia oral (23.8% v. 0.4%), product taste abnormal (11.7% v. 0.9%), paraesthesia oral (6.9% v. 0.9%), and tongue discomfort (6.9% v. 0%)
- **No effect on weight or blood pressure (BP)**
  - Weight: Week 14 change from baseline for TNX-102 SL of +0.04 lbs.; and for Placebo of +0.44 lbs.
  - Systolic BP: Week 14 change from baseline for TNX-102 SL of +0.7 mmHg; and for Placebo of +0.5 mmHg
  - Diastolic BP: Week 14 change from baseline for TNX-102 SL of +1.1 mmHg; and for Placebo of +0.2 mmHg
- **No sexual dysfunction AEs and improved female sexual functioning**
  - No reported AEs of any type of sexual dysfunction
  - Improvement in female sexual function using Changes in Sexual Functioning Questionnaire (p=0.010)



## Treatment-Emergent Adverse Events (TEAEs) at Rate of $\geq 3\%$ in Either Treatment Group

System Organ Class Preferred Term	TNX-102 SL N=231	Placebo N=226	Total* N=457
<b>Systemic Adverse Events</b>			
COVID-19	10 (4.3%)	7 (3.1%)	17 (3.7%)
Somnolence	7 (3.0%)	3 (1.3%)	10 (2.2%)
Headache	7 (3.0%)	4 (1.8%)	11 (2.4%)
<b>Oral Cavity Adverse Events</b>			
Hypoaesthesia oral	55 (23.8%)	1 (0.4%)	56 (12.3%)
Product taste abnormal	27 (11.7%)	2 (0.9%)	29 (6.3%)
Paraesthesia oral	16 (6.9%)	2 (0.9%)	18 (3.9%)
Tongue discomfort	16 (6.9%)	0 (0.0%)	16 (3.5%)

\*Safety Population



## Additional Potential Indications for Tonmya™ (TNX-102 SL)

### Fibromyalgia-Type Long COVID

- Status: Phase 2
- Phase 2 study (*PREVAIL*) completed
- Topline results reported 3Q 2023

**Next Steps:** Meet with FDA

### Acute Stress Reaction/ Acute Stress Disorder

- Phase 2 ready investigator-initiated study
- Department of Defense funded
- UNC will perform study
- Received IND clearance from FDA

**Next Steps:** Expect to start Phase 2 in 2Q 2024

# CNS-Focused Biopharma with Preclinical, Clinical and Commercial Stage Products



## **Tonmya™ for Fibromyalgia: Preparing New Drug Application (NDA)**

- Two Phase 3 trials completed with statistical significance on primary endpoint
- NDA filing expected 2H'24
- FDA decision on NDA approval expected 2H'25



## **Marketed Products**

- Zembrace® and Tosymra® indicated for the treatment of acute migraine



## **Pipeline**

- Phase 2 biologic cocaine antidote, FDA “Breakthrough Therapy Designation”
- Phase 1 anti-CD40L monoclonal antibody to prevent organ transplant rejection



## **Strategic Partnerships**

- With government institutions, world-class academic & research organizations



## **Internal Capabilities**

- Commercial prescription drug sales
- R&D and clinical-trial scale manufacturing

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# Planning for Tonmya™ Launch and Marketing

**Several companies that successfully developed CNS drugs have launched them**

- Big Pharma wants the commercial launch de-risked before acquisition (e.g., Nurtec®)

Company		Mkt Cap <sup>1</sup>	Product	Indication	FDA Approval	Exit
Axsome	AXSM	\$4.4 B	Auvelity®	Depression	8/2022	
Biohaven	BHVN	\$3.8 B	Nurtec®	Migraine	2/2020	Sold to PFE for \$12 B in Oct 2022
IntraCellular	ITCI	\$7.1 B	Caplyta®	Schizophrenia	12/2019	
Supernus	SUPN	\$1.5 B	Oxtella-XR®	Seizures	1/2019	
Neurocrine	NBIX	\$13.2 B	Ingrezza®	Tardive Dyskinesia	4/2017	
Acadia	ACAD	\$4.1 B	Nuplazid®	Parkinson's psychosis	4/2016	

**To prepare for the launch of Tonmya, Tonix acquired two marketed Rx drugs: Zembrace® and Tosymra®**

- Both are indicated for the acute treatment of migraine

<sup>1</sup> Feb 21, 2024





## Two Marketed Proprietary Migraine Drugs Non-oral Formulations of Sumatriptan

### Zembrace® SymTouch® (sumatriptan injection) 3 mg<sup>1</sup>



- 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 continues to represent the largest segment of the market in terms of unit sales<sup>3</sup>
- Each may provide migraine **pain relief in as few as 10 minutes** for some patients<sup>1,2,4,5</sup>
- Patents to 2036 (Zembrace) and 2031 (Tosymra)

### Tosymra® (sumatriptan nasal spray) 10 mg<sup>2</sup>



### Acquired from Upsher-Smith Laboratories which has managed care contracts covering ~200 M lives

- Contract includes a transition period during which Tonix expects to secure its own contracts

### Tonix Medicines Commercial Subsidiary

- Complete commercialization capability
  - Manage supply chain and contract manufacturer
  - Distribution
  - Trade, Managed Care & Government contracting
- Team of professionals including Sales & Marketing personnel

<sup>1</sup>Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC: February 2021 - For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). – Important Safety Information is provided in the appendix

<sup>2</sup>Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC: Feb 2021. For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). – Important Safety Information is provided in the appendix

<sup>3</sup>Tonix Medicines, Inc.; Data On File, 2023

<sup>4</sup>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.

<sup>5</sup>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.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines, Inc. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc.

# Additional Programs and Pipeline Strategy

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## **Focusing on government and academic collaborations**

- Validates Tonix's scientific expertise and technology
- Reduces internal spend
- Increases number of trials
- Potentially speeds time to market
- Grants, contracts, cost-sharing or “in-kind” arrangements

# TNX-1500: Next Generation anti-CD40L mAb

*Re-engineered to better modulate the binding of FcγR and mitigate risk of thrombosis*

*Clinical Stage of Phase 1 study completed*

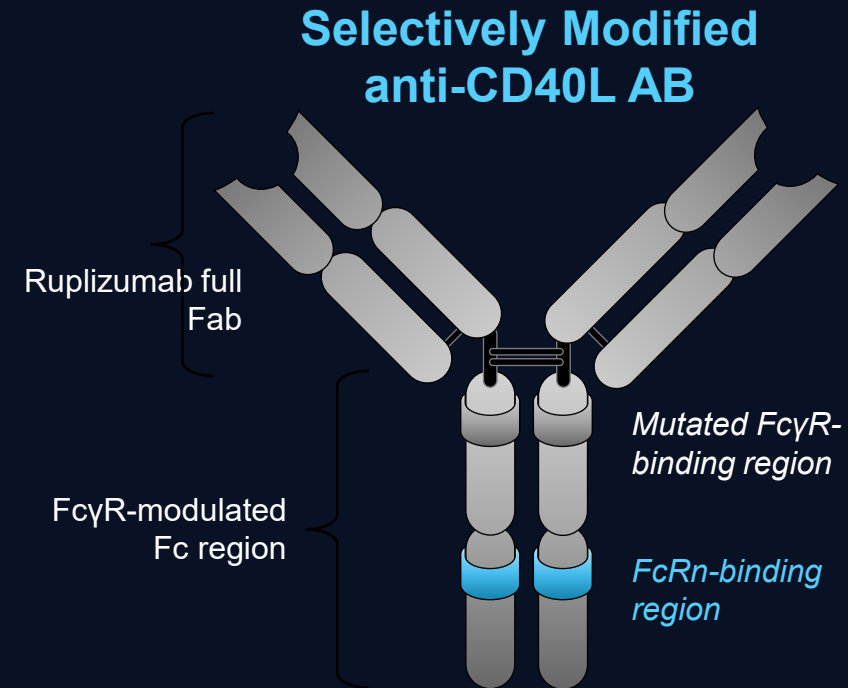
## Key Differentiators

*Expected to deliver efficacy without compromising safety*

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

**Second Generation:** Eliminated the FcγR TE complication but potency and half life was reduced, limiting utility

**Third 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

# External Partnerships

## **Government partners providing direct funding, cost sharing or in-kind support include:**

- National Institutes of Health (NIH)
- National Institute of Allergy and Infectious Disease (NIAID)
  - TNX-1800 selected for Project NextGen
- National Institute on Drug Abuse (NIDA)
  - TNX-1300 for cocaine intoxication; Phase 2 study funding
- Department of Defense (DoD)
  - TNX-102 SL for ASD; Phase 2 study funding

## **Academic partners sponsoring clinical trials of Tonix's investigational drug products include:**

- Massachusetts General Hospital (MGH)
- University of Washington
- University of North Carolina





# TNX-801

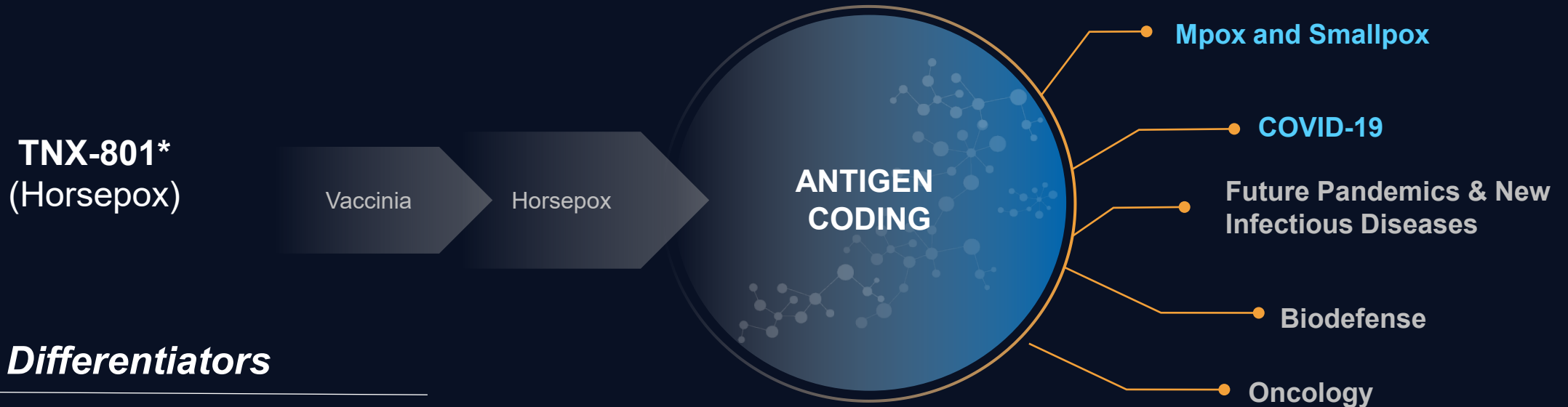
## Live Virus Vaccine

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***Live virus vaccine platform with multitude of potential applications***

# TNX-801: Recombinant Pox Vaccine (RPV) Platform Using Live Virus Technology

*Cloned version of horsepox<sup>1</sup> purified from cell culture*



## Key Differentiators

### Live virus vaccines are the most established vaccine technology

- Prevents forward transmission
- Effective in eliciting durable or long-term immunity

### Economical to manufacture at scale

- Low dose because replication amplifies dose *in vivo*
- Single administration

### Standard refrigeration for shipping and storage



## TNX-1800: Designed to Express the SARs-CoV-2 Spike Protein

TNX-1800 (recombinant horsepox virus) is a live virus vaccine based on Tonix's TNX-801 that is designed to express the spike protein of the SARS-CoV-2 virus and to elicit a predominant T cell response

- Immunogenic and well tolerated<sup>1</sup>
- Showed promise in protecting animals from challenge with SARS-CoV-2 delivered directly into the lungs<sup>1</sup>

**Status:** *National Institute of Allergy and Infectious Diseases (NIAID) will conduct a Phase 1 clinical trial with TNX-1800*

- First vaccine candidate using Tonix's live virus recombinant pox virus (RPV) platform technology to enter clinical trials
- "Project NextGen" is an initiative by the U.S. Department of Health and Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics for COVID-19. NIAID will be conducting clinical trials to evaluate several early-stage vaccine candidates, including TNX-1800
- Phase 1 study is designed to assess safety and immunogenicity in approximately 60 healthy adult volunteers
- Upon completion of the trial, NIAID and Tonix will assess the results and determine the next steps for the development of TNX-1800

<sup>1</sup>Awasthi, M. et al. *Viruses*. 2023. 15(10):2131.

<sup>2</sup>Awasthi, M. et al. *Vaccines (Basel)*. 2023. 11(11):1682.



# Broad-Spectrum Antiviral Discovery Programs

## Host-directed antiviral discovery programs

### CD45 targeted therapeutics

- Small molecule therapeutics that reduce endogenous levels of CD45, a protein tyrosine phosphatase
- Reduction in CD45 protects against many viruses including the Ebola virus

### Cathepsin inhibitors

- Small molecule therapeutics that inhibit **essential cathepsins** which are required by viruses such as coronaviruses and filoviruses to infect cells
- Activity as monotherapy and in combination with other antivirals

## Virus-directed antivirals discovery program

### Viral glycan-targeted engineered biologics

- Bind to viral densely branched high-mannose (DBH) glycans
- **Neutralize circulating virus** and stop the entry of the progeny virus into cells
- Antiviral activity against a broad range of RNA viruses
- Activity as monotherapy and in combination with other antivirals

# Key Partnerships

## TNX-1500: ALLOGRAFT REJECTION



## TNX-1300: COCAINE INTOXICATION



## TNX-102 SL: ACUTE STRESS DISORDER



U.S. Department of Defense



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

## TNX-1800: COVID-19 VACCINE



## TNX-2900: PRADER-WILLI SYNDROME







**TONIX**  
PHARMACEUTICALS

**TEAM,  
NETWORK, &  
UPCOMING  
MILESTONES**



# Management Team



**Seth Lederman, MD**  
Co-Founder, CEO & Chairman



**Gregory Sullivan, MD**  
Chief Medical Officer



**Bradley Saenger, CPA**  
Chief Financial Officer



**Jessica Morris**  
Chief Operating Officer



# Milestones: Recently Completed and Upcoming

## Financial Milestones

- ✓ 4<sup>th</sup> Quarter 2023      Financing: \$144 M facility: \$30 M upfront

## Tonmya™ Milestones

- ✓ 4<sup>th</sup> Quarter 2023      Statistically significant topline results of Phase 3 RESILIENT study for Tonmya™ for the management of fibromyalgia
- 2<sup>nd</sup> Quarter 2024      Type B Pre-NDA meeting with FDA for Tonmya™ for fibromyalgia scheduled
- 2<sup>nd</sup> Half 2024      Submit NDA to FDA for Tonmya™ for fibromyalgia

## Other Key Program Milestones

- 2<sup>nd</sup> Quarter 2024      Initiate Phase 2 study of TNX-102 SL for acute stress disorder
- 2<sup>nd</sup> Quarter 2024      Initiate Phase 2 study of TNX-1300 for the treatment of cocaine intoxication





THANK YOU



## 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 Zembrace 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](#). You can also visit [www.upsher-smith.com](http://www.upsher-smith.com) or call 1-888-650-3789. 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](http://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](#). You can also visit [www.upsher-smith.com](http://www.upsher-smith.com) or call 1-888-650-3789. 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](http://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.