TONIX PHARMACEUTICALS

Corporate Presentation

Biotech Showcase
January 14, 2025

NASDAQ: TNXP

PO6035, January 13, 2025 (Doc 1551)

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.

Key Clinical Programs

Molecule*	Indication	Phase 1	Phase 2	Phase 3	NDA Submission
TNX-102 SL Cyclobenzaprine HCl Sublingual Tablets	**Fibromyalgia** *Granted FDA Fast Track Designation*	*PDUFA** goal date of August 15, 2025*			
	Acute Stress Disorder	*Phase 2 Study*** Start Expected 1Q'25*			
TNX-1300 Cocaine Esterase *NIDA Funded*	**Cocaine Intoxication** *Granted FDA Breakthrough Therapy Designation*	*Phase 2 Study Ongoing*			
TNX-2900 Intranasal Potentiated Oxytocin	**Prader-Willi Syndrome** *FDA Orphan Drug and Rare Pediatric Disease Designations*	*Phase 2 Ready*			
TNX-1500 Anti-CD40L mAb	**Organ Transplant Rejection/ Autoimmune Conditions**	*Phase 1 Study Ongoing*	*Clinical Stage Completed*		

**All of Tonix's product candidates are investigational new drugs or biologics; their safety and efficacy have not been established, and none has been approved for any indication.*
***PDUFA=Prescription Drug User Fee Act*
****Investigator-initiated study*

TNX-102 SL*

(Cyclobenzaprine HCl Sublingual Tablets) 5.6 mg

A unique, sublingual formulation of cyclobenzaprine (CBP) designed to optimize absorption and delivery

- Non-opioid analgesic – Tertiary Amine Tricyclic (TAT)
- Rapid drug exposure following once-nightly sublingual administration
- Reduction in persistent active metabolite norCBP with chronic dosing
- Durable (14 week) reduction in fibromyalgia pain in two pivotal studies
- Generally well tolerated
- PDUFA goal date August 15, 2025

*5.6 mg once-daily at bedtime, TNX-102 SL is an investigational new drug, its efficacy and safety have not been established and it has not been approved for any indication
norCBP = norCyclobenzaprine

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TNX-102 SL: Sublingual Formulation is Designed for Long-Term Daily Administration at Bedtime and Transmucosal Absorption

- **TNX-102 SL: Proprietary sublingual formulation of cyclobenzaprine (CBP) with transmucosal absorption**
  - Innovation by design with patent-protected eutectic formulation
  - Rapid systemic exposure of CBP – Tertiary Amine Tricyclic (TAT)
  - Increases CBP bioavailability during sleep
  - Avoids first-pass metabolism
  - Lowers exposure to long-lived active major metabolite, norCyclobenzaprine (norCBP)

- **norCBP is a persistent active metabolite generated in the liver by de-methylation**
  - Reduced levels after TNX-102 SL administration relative oral CBP
  - Long half-life (~72 hours) – Secondary Amine Tricyclic (SAT)
  - Less selective for target receptors (5-HT2A, α1-adrenergic, histamine H1)
  - More selective for norepinephrine transporter

TNX-102 SL (5.6 mg) Fibromyalgia Pivotal Clinical Trial Results

- **Activity**
  - First pivotal Phase 3 study (*RELIEF*) reported – December 2020[1]
    - Statistically significant reduction in daily pain compared to placebo ($p = 0.010$)
  - Second Phase 3 study (*RALLY*) missed primary endpoint – July 2021
  - Confirmatory pivotal Phase 3 study (*RESILIENT*) reported – December 2023
    - Statistically significant reduction in daily pain compared to placebo ($p = 0.00005$)

- **Tolerability in two pivotal trials**
  - Generally well tolerated with an adverse event profile comparable to prior studies and with no new safety signals observed
  - The most common treatment-emergent adverse event was tongue or mouth numbness at the administration site, which was temporally related to dosing, self-limited, never rated as severe, and rarely led to study discontinuation (one participant in each study)
  - Excluding COVID-19, rates of systemic adverse events in each of the two studies were all below 4.0%

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

TNX-102 SL (5.6 mg) Fibromyalgia Regulatory Status

- **NDA can be filed without abuse potential assessment studies**
  - April 2017
- **Granted FDA Fast Track Designation**
  - July 2024
- **Submitted NDA to FDA**
  - October 2024
- **NDA assigned a PDUFA goal date of August 15, 2025**[1]
  - December 2024

Next Milestone:

FDA decision on marketing authorization expected August 15, 2025

[1]PDUFA = Prescription Drug User Fee Act

About Fibromyalgia

*Fibromyalgia is a **chronic pain disorder** resulting from amplified sensory and pain signaling within the CNS – now recognized as **nociplastic pain**[1-4]*

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

Fibromyalgia is considered a **chronic overlapping pain condition (COPC)**[5]
*- the **only COPC** with any **FDA-approved drugs**[6]*

Fibromyalgia is the prototypic nociplastic syndrome

[1]Trouvin AP, et al. *Best Pract Res Clin Rheumatol*. 2019;33(3):101415.
[2]Fitzcharles MA, et al. *Lancet* 2021;397:2098-110
[3]Kaplan CM, et al. *Nat Rev Neurol.* 2024 20(6):347-363..
[4]Clauw DJ. *Ann Rheum Dis.* 2024 ard-2023-225327. doi: 10.1136/ard-2023-225327.
[5]Maixner W, et al. *J Pain*. 2016;17(9 Suppl):T93-T107.
[6]The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica®); Duloxetine (Cymbalta®); Milnacipran (Savella®)

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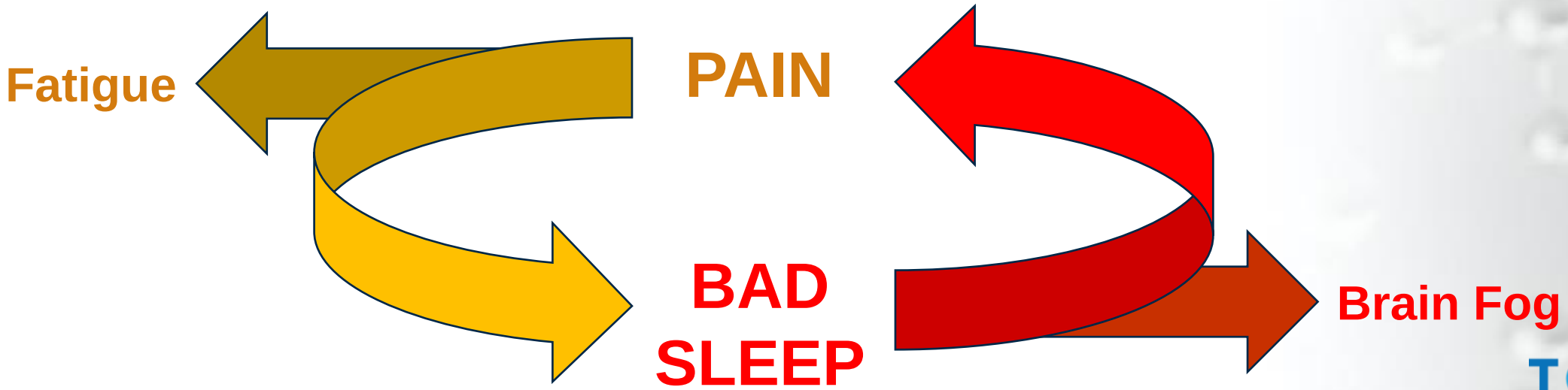
Fibromyalgia is a Large, Underserved and Dissatisfied Population

- **More than 10 million U.S. adults are affected – predominantly women[1,2]**
  - Debilitating and life altering condition
  - Significant economic impact
- **Patients have expressed dissatisfaction, despite three FDA approved drugs[3,4]**
  - 85% of patients fail first-line therapy[5]: efficacy variability, tolerability issues especially when used long-term and lack of broad-spectrum activity
  - Typical for patients to rotate between drugs and be on multiple drugs at the same time; 79% of FM patients are on multiple therapies[5]
- **~2.7 million FM patients diagnosed and treated[6]**
  - >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year[7,8]
- **No new R*x* product since 2009**
- *The treatment objective is to **restore functionality** and **quality of life** while avoiding intolerable side effect burden*

[1]American College of Rheumatology (www.ACRPatientInfo.org accessed May 7, 2019) – prevalence rate of 2-4% for U.S. adult population (~250 million)
[2]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
[3]Robinson RL, et al. *Pain Med*. 2012 13(10):1366-76. doi: 10.1111; 85% received drug treatment
[4]The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica); Duloxetine (Cymbalta); Milnacipran (Savella)
[5]EVERSANA primary physician research, May 2024; commissioned by Tonix
[6]EVERSANA analysis of claims database, May 2024; commissioned by Tonix
[7]Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.
[8]Market research by Frost & Sullivan, commissioned by Tonix, 2011

Poor Sleep and Pain have Bi-directional Reinforcing Effects[1]

- **Harvey Moldofsky – recognition of unrefreshing/non-restorative sleep in fibromyalgia**
- **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[1,2]



[1]Moldofsky H, et al. *J Rheumatol*. 1996;23:529–533.
[2]Grönbald M, et al. *Clin Rheumatol*. 1993;12(2):186–191

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Cyclobenzaprine (CBP) as an Oral Immediate Release (IR) Tablet for Muscle Spasm and Investigational Product for Fibromyalgia

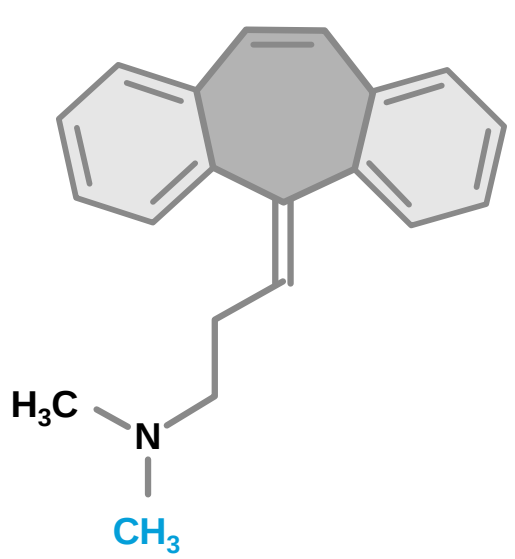
1977 — Flexeril® approved in 1977 for the treatment of muscle spasm[1]

1988 — 6 published studies of oral CBP in fibromyalgia: Short-term, but not sustained benefit[2-8]

1999 — Postmarketing surveillance program[1]

2004 — AMRIX® controlled release oral CBP approved for muscle spasm

2007

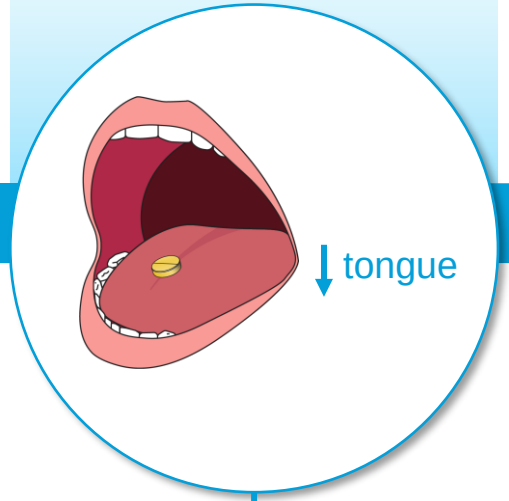


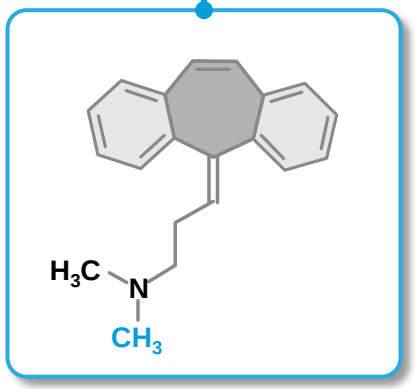
Oral CBP has an **extensive safety record** in humans for **over 45 years**[9]

1. 1999 Merck OTC AdCom Briefing Package. 2. Bennett RM, et al. *Arthritis Rheum* 1988; 31:1535–42. 3. Quimby LG, et al. *J Rheumatol Suppl.* 1989; Nov 19:140–3. 4. Reynolds WJ, et al. *J Rheumatol.* 1991; 18:452–4. 5. Santandrea S, et al. *J Int Med Res.* 1993; 21:74–80. 6. Cantini F, et al. *Minerva Med.* 1994; 85:97–100. 7. Carette S, et al. *Arthritis Rheum.* 1994; 37:32–40. 8. Tofferi JK, et al. *Arthritis Rheum.* 2004; 51:9–13. 9. IMS report 2011 of cyclobenzaprine use in 2009 – Data on File.

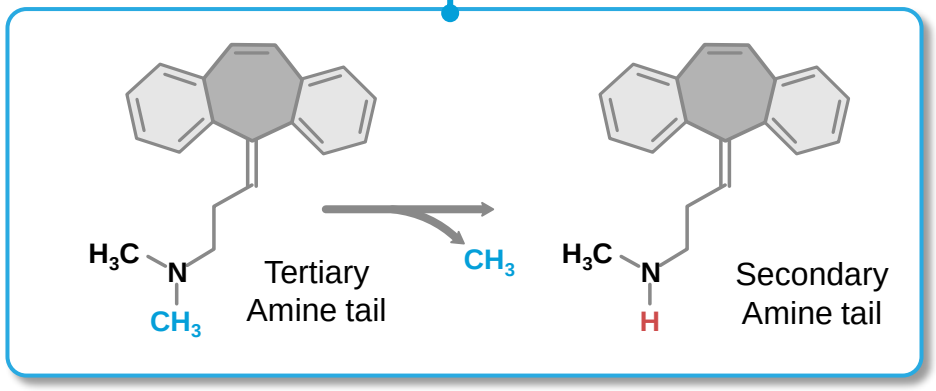
Oral CBP Undergoes First-Pass Metabolism

CBP administered as a swallowed oral dose

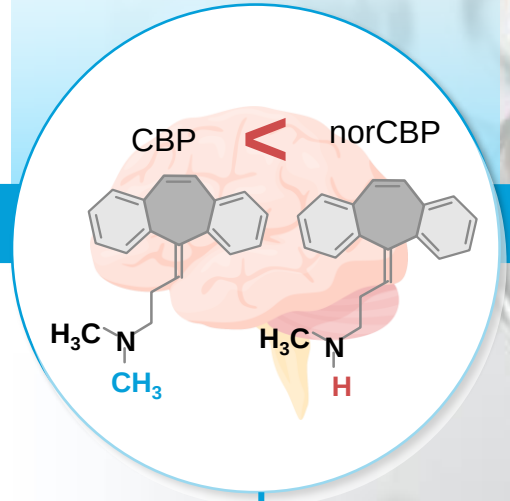




CBP undergoes “first pass” hepatic metabolism and is ~50% converted to the persistent active metabolite norCyclobenzaprine (norCBP)



CBP and norCBP enter the brain



A swallowed oral dose leads to increased concentrations of norCBP relative to CBP over time

CNS PORTFOLIO

CBP Binding Affinities for Receptors and Transporters

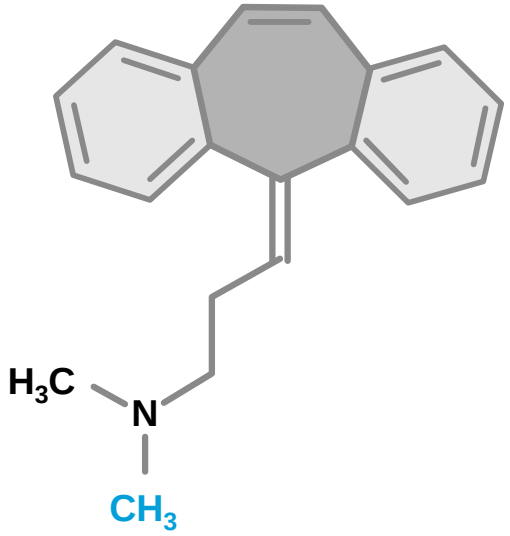
	H_1	5-HT_{2A}	α_{1A}	α_{1B}	M_1	SERT	NET
Cyclobenzaprine (CBP)	**1.3**	**5.2**	**5.6**	**9.1**	**7.9**	**29**	**35**
norCyclobenzaprine (norCBP)	**5.6**	**13**	**34**	**11**	**30**	**91**	**2.6**

CBP/norCBP Activity: Antagonist | Inhibitor

CBP: more active (lower K_d) at the key receptors involved in sleep quality
norCBP: more active on the norepinephrine transporter (NET)
Note: inhibitors of NET are generally “activating”

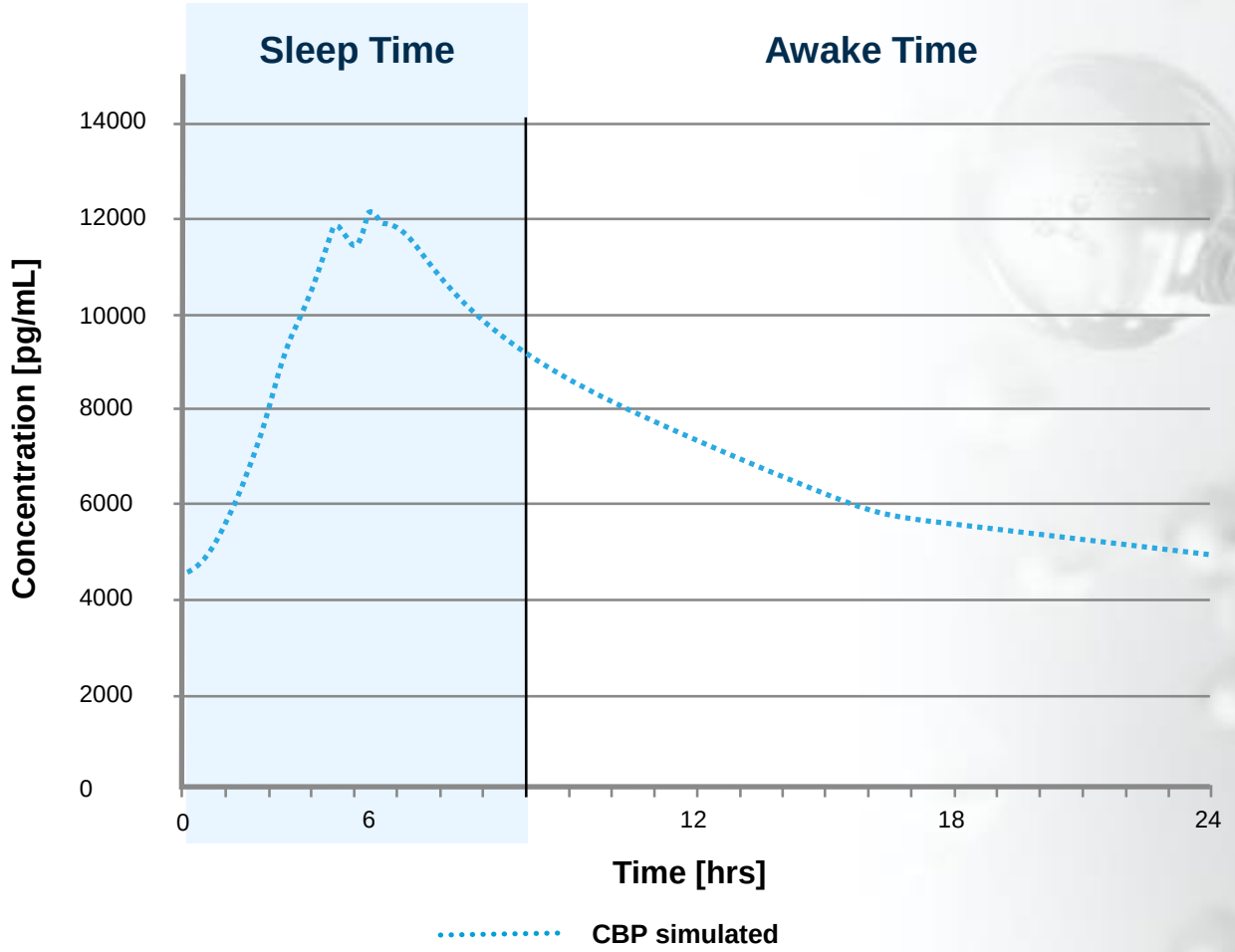
Oral Dosing of CBP Immediate Release (IR) 10 mg In Simulated Pharmacokinetics (PK) of Day 20 Daily Bed-time Administration

Cyclobenzaprine (CBP)
Tertiary Amine Tricyclic (TAT)



Dynamic pharmacokinetics

Bed time dosing – blood levels peak while sleeping and fall during waking



CBP has dynamic changes in blood levels – eliminated by *N*-glucuronidation

CNS PORTFOLIO

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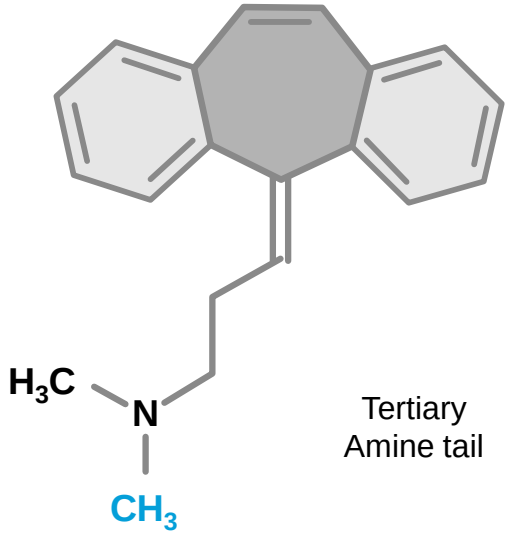
~50% of Oral CBP is Converted to norCBP by the Liver

norCBP has "Flat" PK and Accumulates with Chronic Dosing

Cyclobenzaprine (CBP)



Dynamic pharmacokinetics

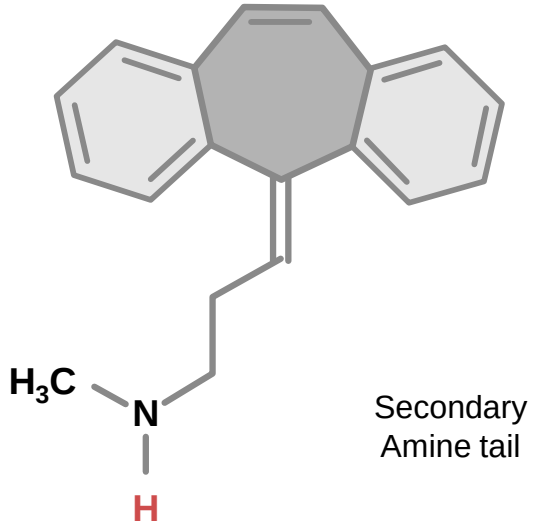
Bed time dosing – blood levels peak ~5 hours after dosing and then rapidly fall to waking

"First pass" hepatic metabolism

CH_3

demethylation

norCyclobenzaprine (norCBP)



"Flat" pharmacokinetics

Accumulates with oral dosing – little diurnal variation in blood levels

Many CNS drugs have pharmacodynamic effects from rising and falling drug blood levels

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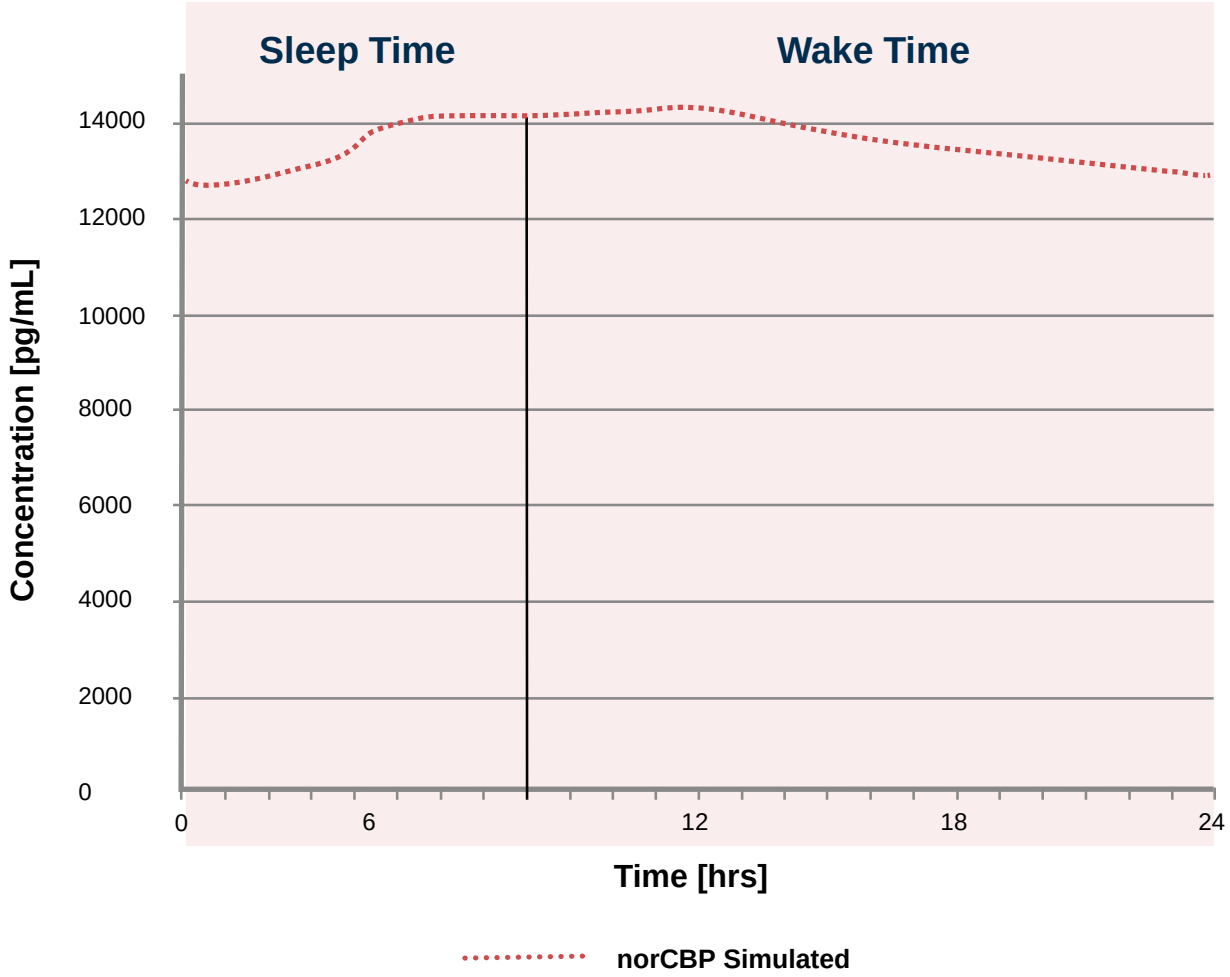
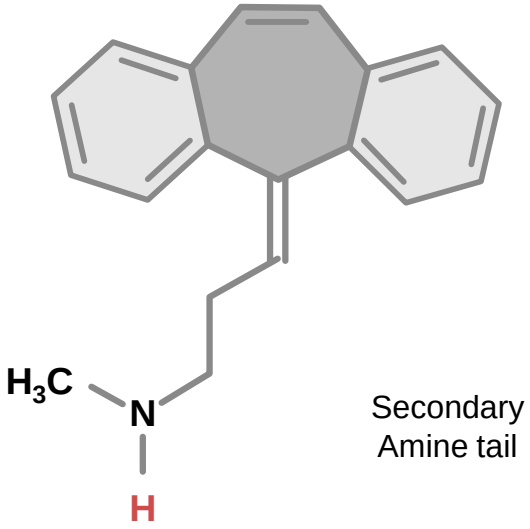
norCBP has “Flat” Blood Levels Over Time With Chronic Dosing of CBP IR 10 mg Over 20 Days (Simulated)



norCyclobenzaprine



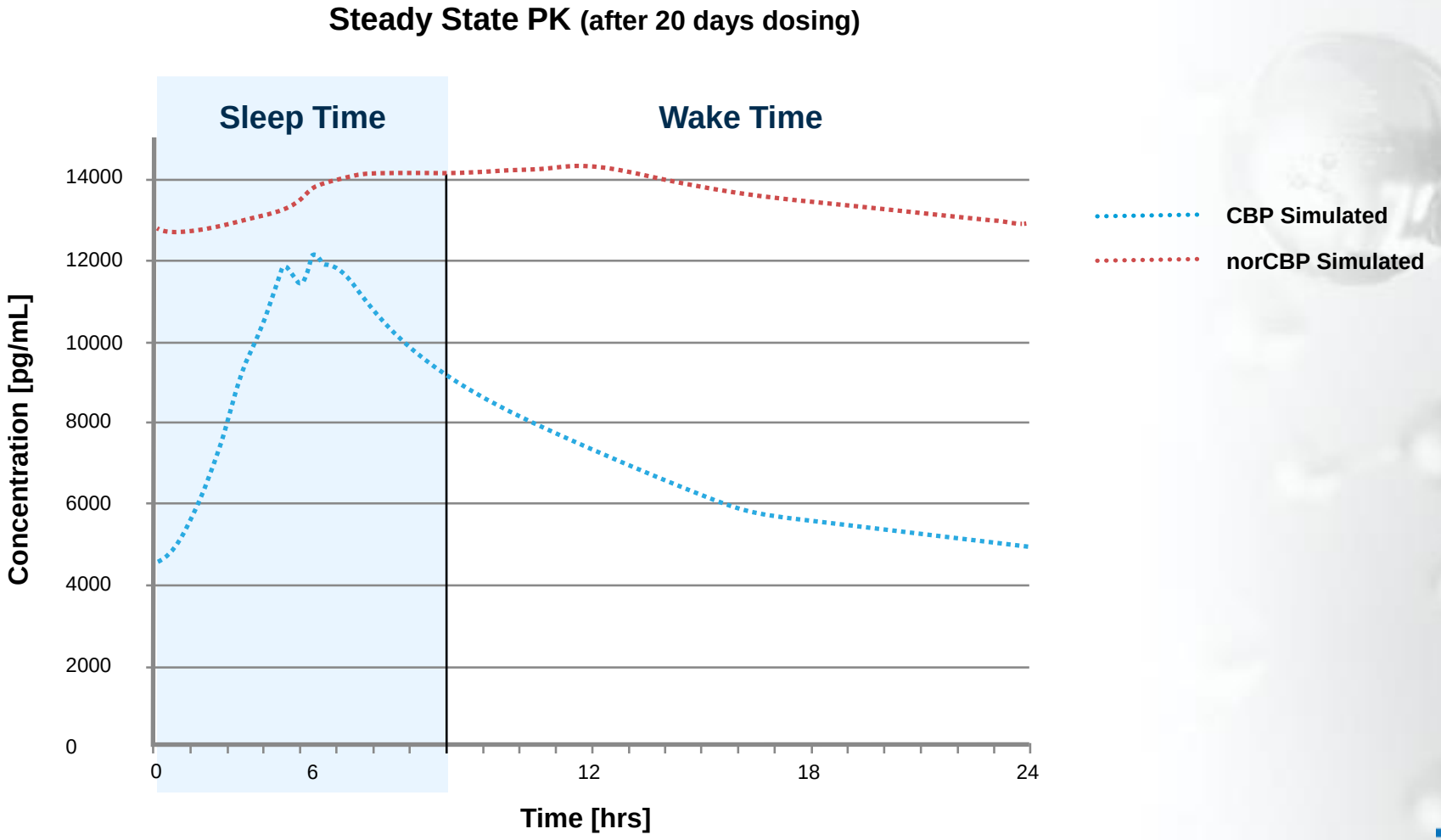
“Flat” pharmacokinetics

Accumulates with oral dosing – little diurnal variation in blood levels[1]

norCBP has “flat” blood levels – *NOT* eliminated by N-glucuronidation

[1]Half-life of nCBP is ~3days, which results in the relatively flat curve and accumulation over weeks

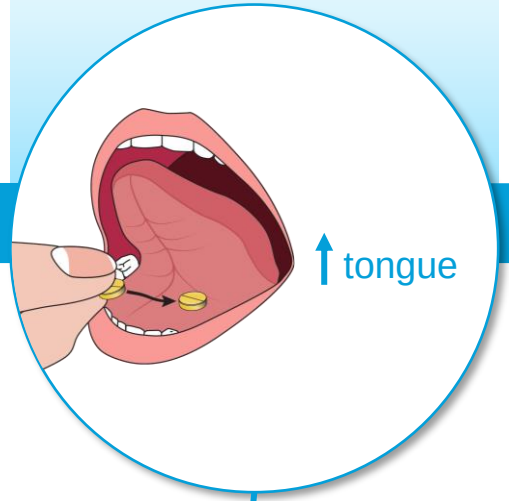
Simulated Multi-Dose PK of Oral CBP-IR 10 mg Steady State at Day 20

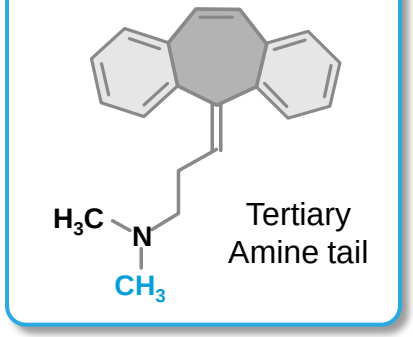


PK = pharmacokinetics
IR = immediate release

TNX-102 SL: Transmucosal CBP Bypasses First-Pass Metabolism

TNX-102 SL is administered sublingually

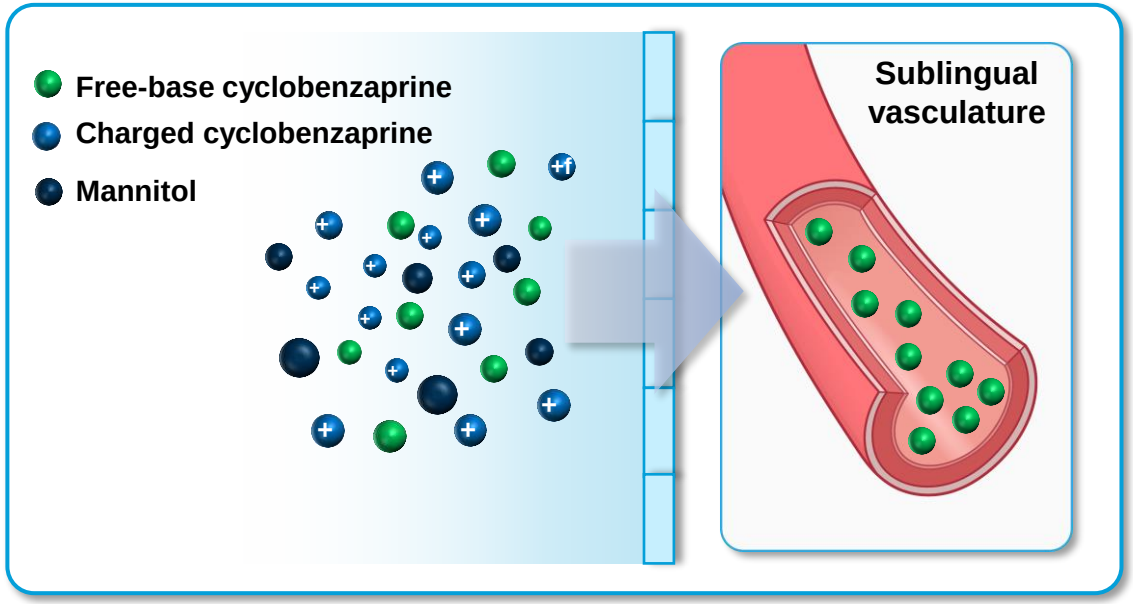




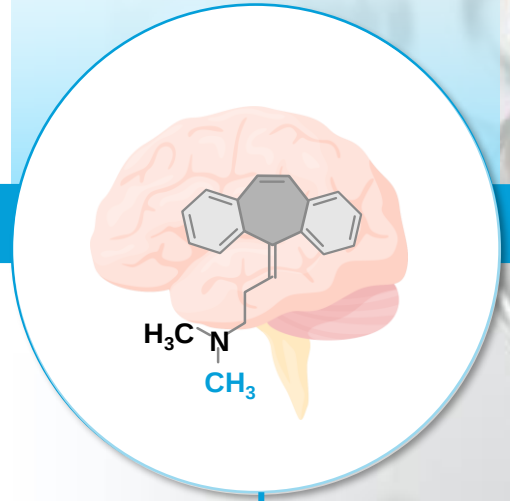
The sublingual tablet rapidly disintegrates, dissolves and releases solubilized CBP into the saliva adjacent to the mucosal membrane.

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

Tonix's proprietary eutectic formulation contains a basic ingredient which enhances efficient transmucosal absorption and results in a stable tablet with long shelf-life



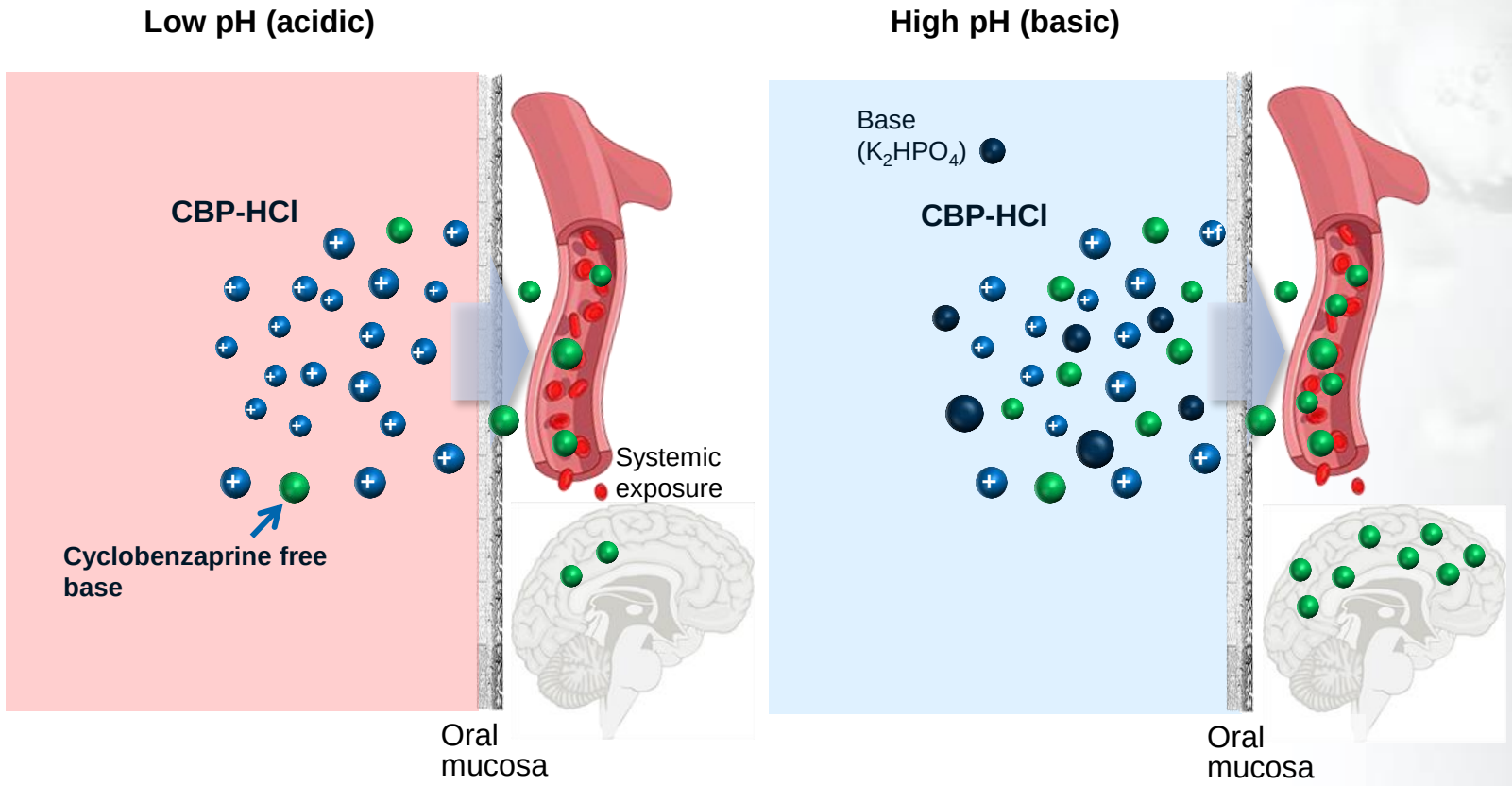
CBP enters the brain directly *via* the circulatory system



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

Formulation with Basic Excipient Increases Systemic Absorption of Sublingual Cyclobenzaprine[1]

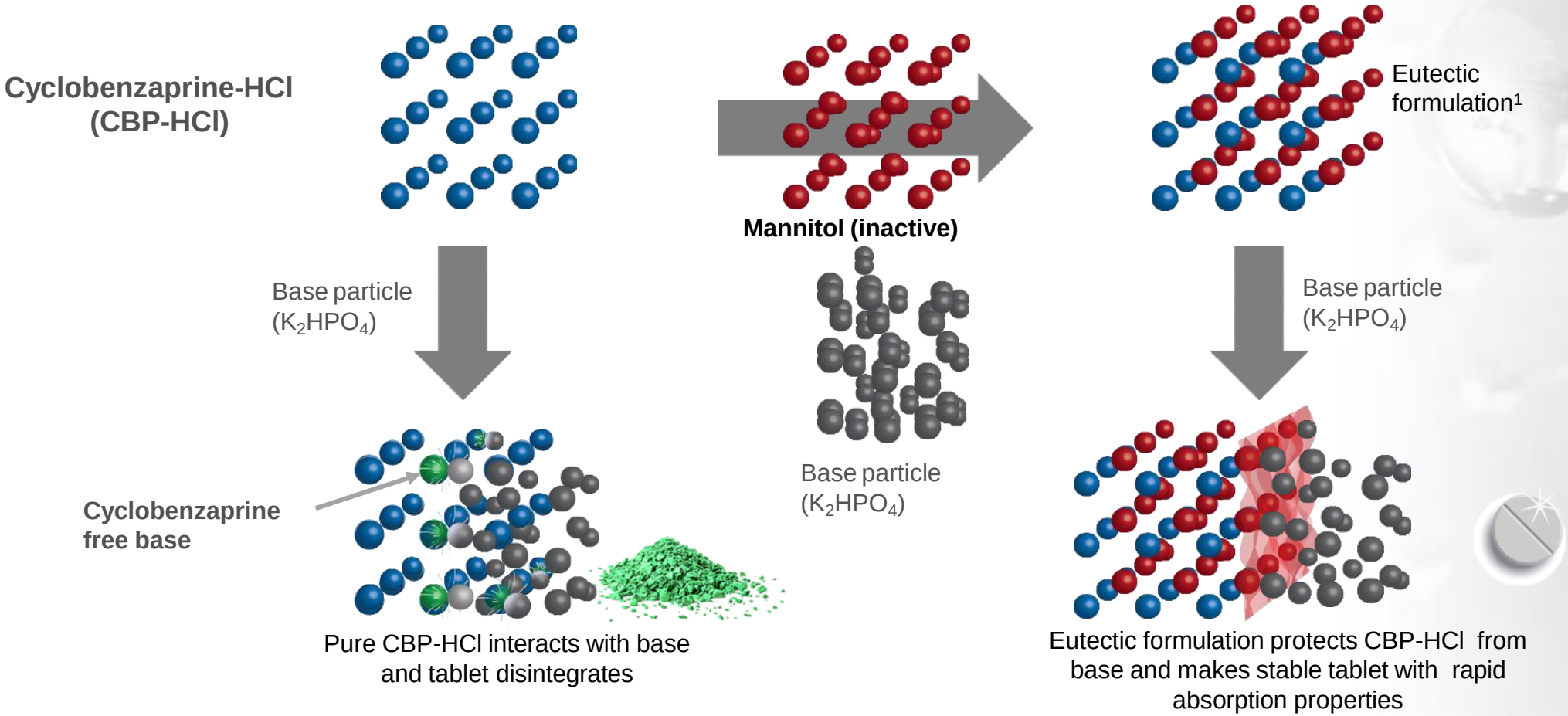
Concentration gradient increases diffusion of free base across oral mucosa (Le Chatelier's Principle)



[1]US Patent applications 13/918,692. 14/214,433 and 14/776,624 - Eutectic Formulations

TNX-102 SL: Proprietary Eutectic Formulation

Proprietary Cyclobenzaprine HCl Eutectic Mixture Stabilizes Sublingual Tablet Formulation



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

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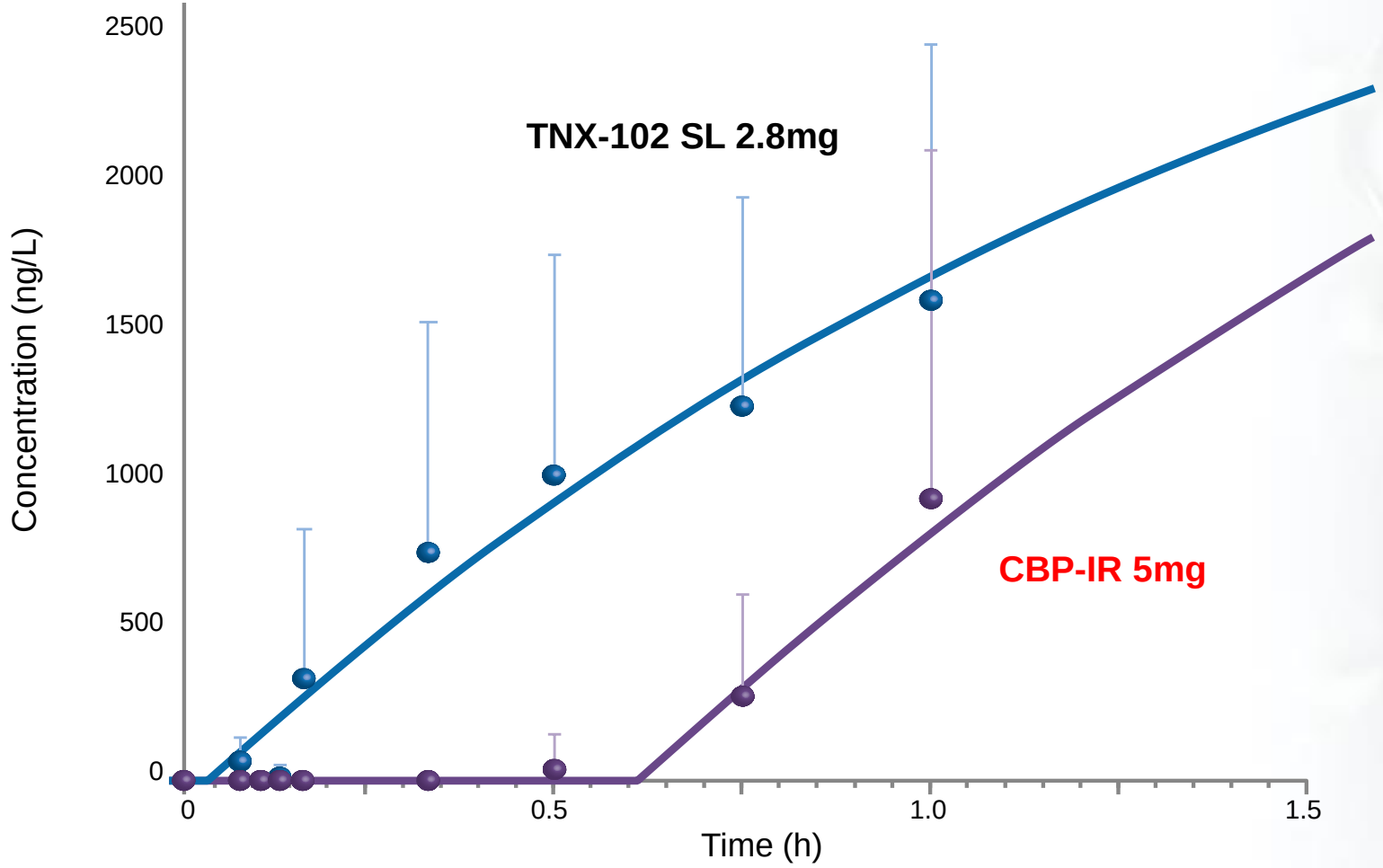
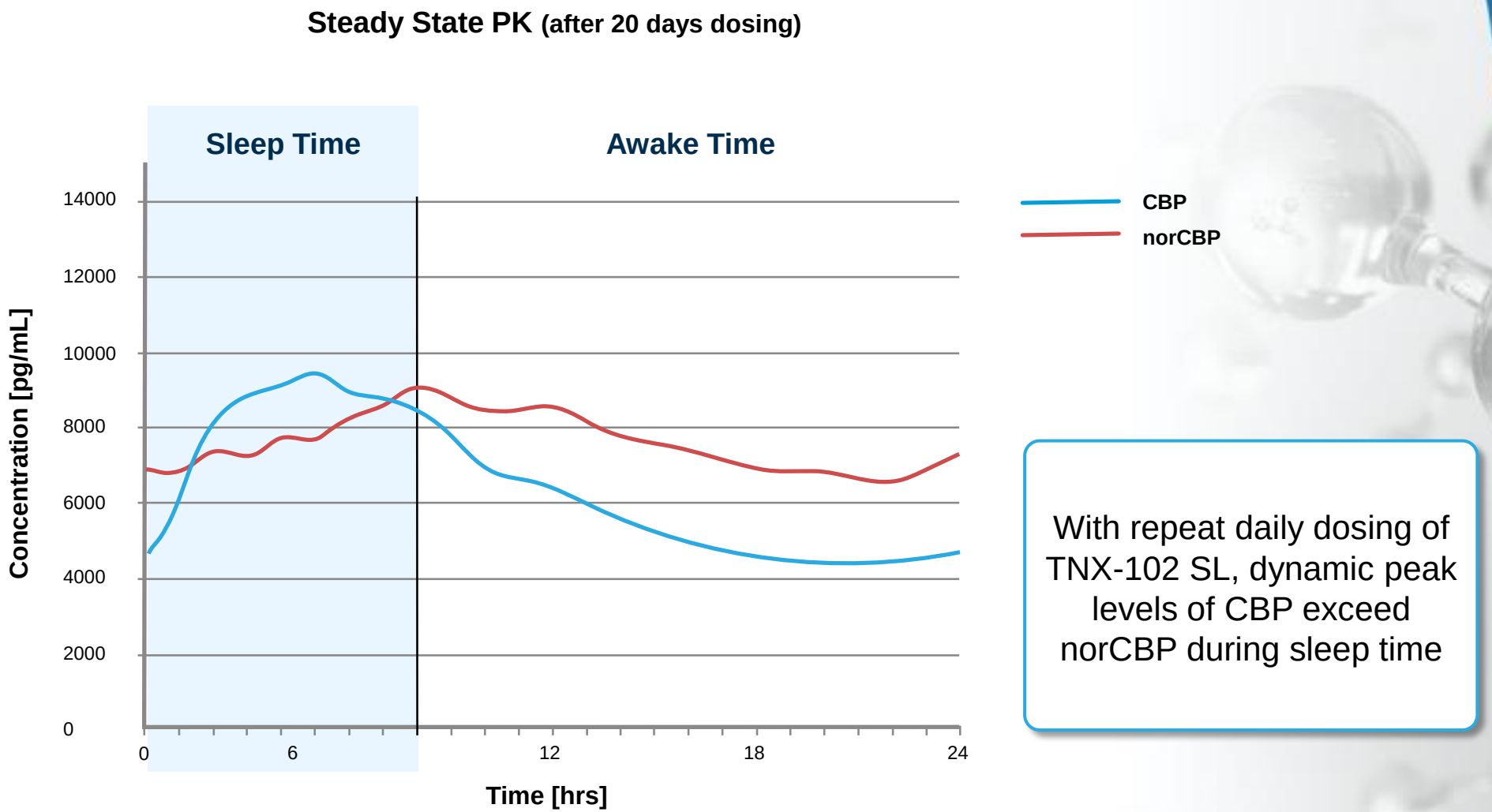
TNX-102 SL: CBP Detected in Plasma Within Minutes Following Sublingual Administration

Plasma Concentration Versus Time of TNX-102 SL Compared to CBP-IR



Steady State PK on Day 20 of Daily Sublingual TNX-102 SL (5.6 mg)



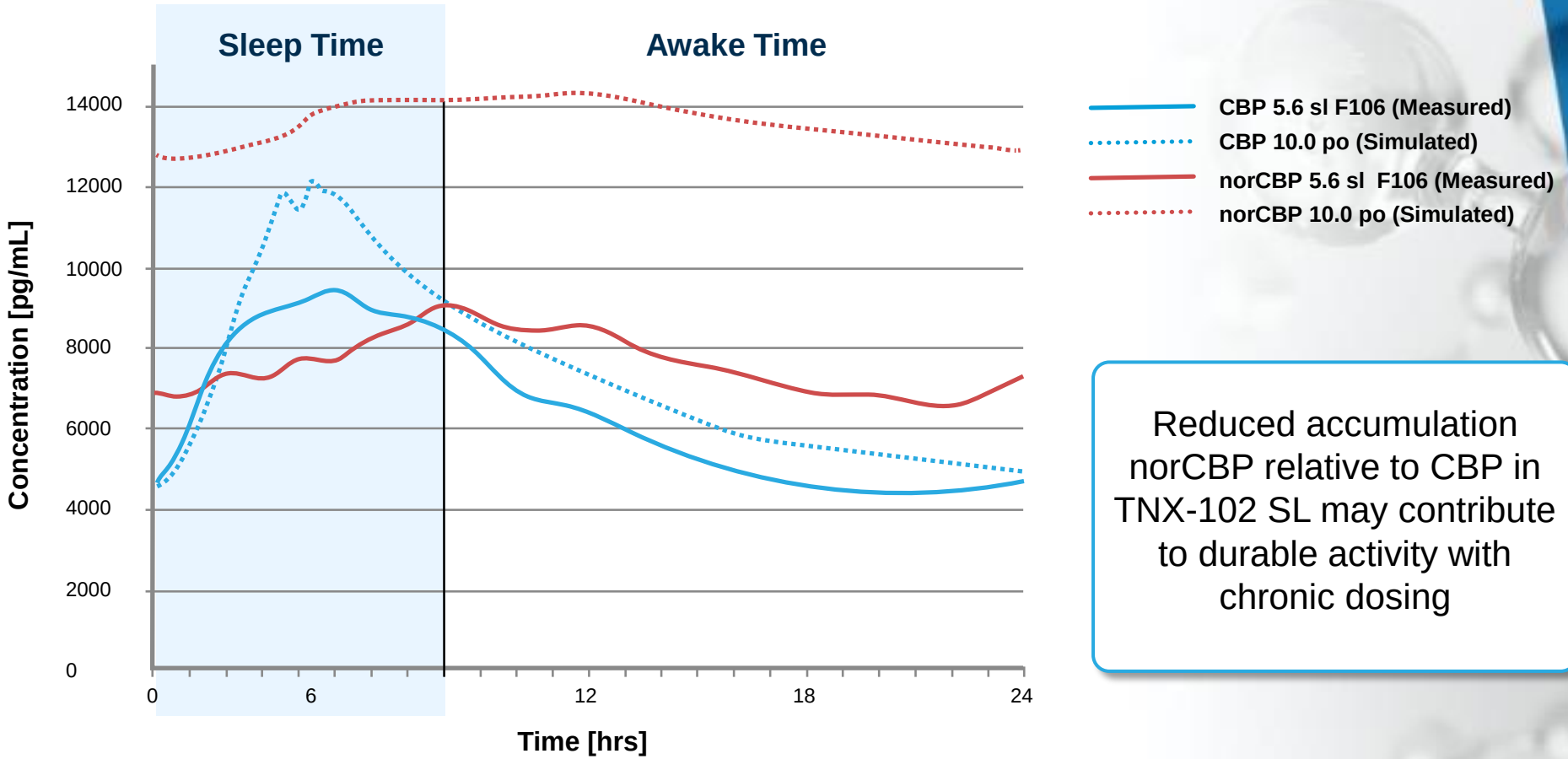
With repeat daily dosing of TNX-102 SL, dynamic peak levels of CBP exceed norCBP during sleep time

Many CNS drugs have pharmacodynamic effects from rising and falling drug blood levels

TNX-102 SL: Multi-Dose PK Differentiation from Simulated Oral CBP-IR

Steady State PK (after 20 days dosing)

Day 20 TNX-102 SL 5.6 mg v. Simulated Oral IR 10 mg



Reduced accumulation norCBP relative to CBP in TNX-102 SL may contribute to durable activity with chronic dosing

Accumulation of norCBP may blunt dynamic effects of oral CBP after repeated daily dosing

sl = sublingual
po = by mouth

TNX-102 SL: Sublingual Formulation is Designed for Long-Term Daily Administration at Bedtime and Transmucosal Absorption

- **Cyclobenzaprine (CBP) - Tertiary Amine Tricyclic (TAT)**
  - Dynamic pharmacokinetics (PK)
    - Elimination by *N*-glucuronidation
- **Oral administration results in first-pass metabolism**
  - Generation of active metabolite, norCBP
- **NorCyclobenzaprine (norCBP) – Secondary Amine Tricyclic (SAT)**
  - Flat pharmacokinetics (PK)
    - No elimination by *N*-glucuronidation
- **TNX-102 SL delivers CBP by transmucosal absorption and is designed to bypass first-pass hepatic metabolism and lower norCBP accumulation**
  - Provides rapid absorption for bedtime dosing

TNX-102 SL: Patents and Patent Applications

- **U.S. Composition:***
  - A 75:25 cyclobenzaprine HCl - mannitol eutectic (dependent claims add a basifying agent).
    - 5 US Patents (Expire November 2034)
    - 1 Pending US Application (Would expire November 2034)
  - A composition of a cyclobenzaprine HCl and a basifying agent suitable for sublingual absorption.
    - 1 Pending US Application (Would expire June 2033)

- **U.S. Methods of Use* (Specific Indications):**
  - Fibromyalgia
    - Pain, Sleep Disturbance, Fatigue
      - 1 Pending US Application (Would expire December 2041)
    - Early Onset Response
      - 1 Pending US Provisional Application (Would expire December 2044)
    - Depressive Symptoms
      - 1 Pending US Application (Would expire March 2032)
  - Sexual Dysfunction
    - 1 Pending US Application (Would expire October 2041)
  - PASC
    - 1 Pending US Application (Would expire June 2043)
  - PTSD
    - 1 US Patent (Expires November 2030)
  - Agitation (Dementia)
    - 1 US Patent (Expires December 2038)
    - 1 Pending US Application (Would expire December 2038)
  - Alcohol Use Disorder
    - 1 Pending US Application (Would expire November 2041)

- **Foreign Filings**
  - Corresponding foreign patents have been filed and some have issued:
    - Composition (25 patents, 3 allowed applications, 16 pending applications)
    - Methods of Use (9 patents, 54 pending applications)

Patents based on TNX-102 SL's eutectic composition and its properties have issued in the U.S., E.U., Japan, China and many other jurisdictions around the world and provide market protection into 2034.

The European Patent Office's Opposition Division maintained Tonix's European Patent EP 2 968 992 in unamended form after an Opposition was filed against it by a Sandoz subsidiary, Hexal AG. Hexal AG did not appeal that decision.

*US Patents: Issued: US Patent Nos. 9,636,408; 9,956,188; 10,117,936; 10,864,175; 11,839,594; 9,918,948; 11,826,321. Pending: US Patent Application Nos. 13/918,692; 18/385,468; 13/412,571; 18/265,525; 63/612,352; 18/382,262; 18/037,815; 17/226,058; 18/212,500.

Fibromyalgia Market Characteristics

Fibromyalgia: Market Characteristics

Prevalence

- One of the more common chronic pain disorders (2-4% of US Population)[1]

Diagnosed population

- Large population but underdiagnosed[2] relative to prevalence rate
- Majority receive drug treatment[3]

Treatment Pattern

- Polypharmacy the norm - average 2.6 drugs/patient[3]
- Rotation through therapy common: average ~5 drugs/year[3]
- Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year[4,5]

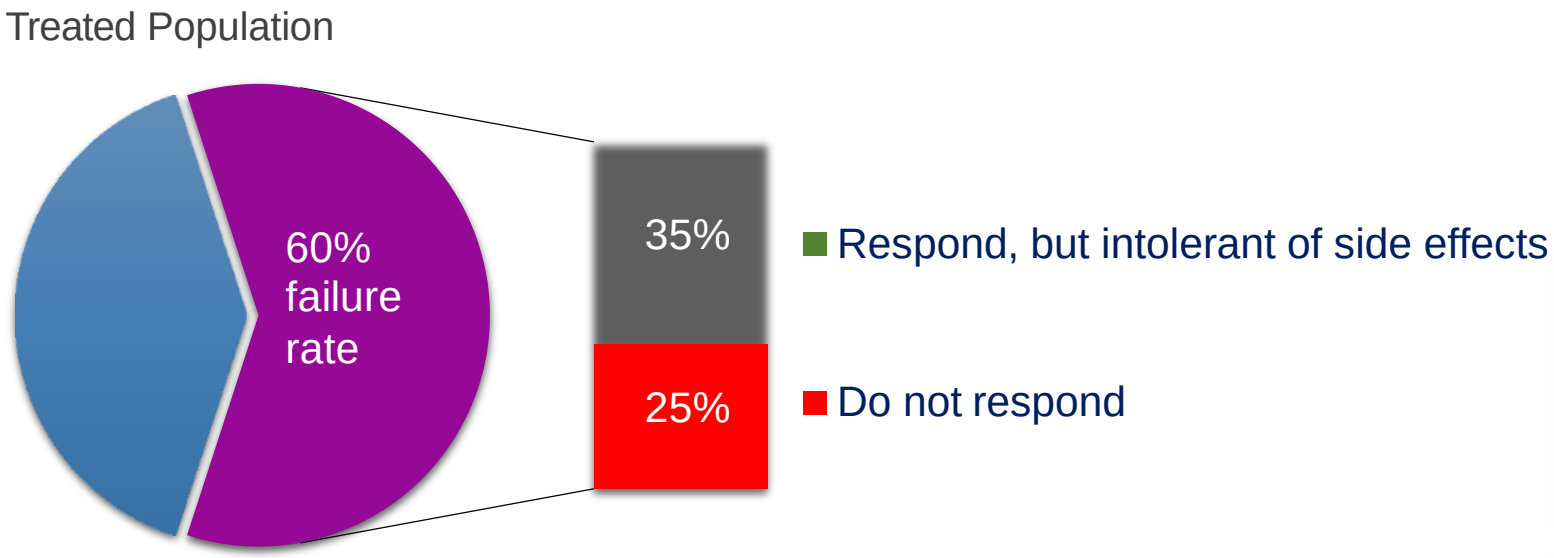
Unmet Need

- Majority of patients do not respond or cannot tolerate therapy[6]

[1]American College of Rheumatology (www.ACRPatientInfo.org accessed May 7, 2019) – prevalence rate of 2-4% for U.S. adult population (~250 million)
[2]Vincent et al., 2013; diagnosed prevalence rate was 1.1% of adult population or 50% of the prevalent population
[3]Robinson, et al., 2012; 85% received drug treatment
[4]Vincent et al, Arthritis Care Res 2013;65:786
[5]Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.
[6]Market research by Frost & Sullivan, commissioned by Tonix, 2011

Fewer than Half of Those Treated for Fibromyalgia Receive Sustained Benefit from the Three FDA-Approved Drugs[1]

- The treatment objective is to **restore functionality** and **quality of life** while avoiding significant side effects
- The majority fail therapy due to **lack of a response** or **poor tolerability**[2]



[1] The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica); Duloxetine (Cymbalta); Milnacipran (Savella)
[2] Market research by Frost & Sullivan, commissioned by Tonix (2011)

Current FDA-Approved Fibromyalgia Drugs[1]

Improvement in fibromyalgia pain was primary endpoint for approval

- No current product addresses pain, poor sleep and fatigue
- Tolerability issues limit long term use for many patients

Drug		Pregabalin	Duloxetine Milnacipran
Class		Gabapentinoid	SNRI
Fibromyalgia Activity	**Pain Reduction**	**YES**	**YES**
	Sleep Improvement	**YES**	**-**
	Fatigue Reduction	**-**	**YES**
Tolerability Issues	Fatigue increase	**YES**	**-**
	Sleep problems	**-**	**YES**
	Weight gain	**YES**	-
	Blood Pressure increase	**-**	**YES**
	Sexual impairment	**-**	**YES**
	GI issues	**-**	**YES**
	Hip Fractures[2]	**YES**	**-**
	DEA Scheduled	**YES**	**-**

[1]The three drugs with FDA approval for the management of fibromyalgia are Pregabalin (Lyrica®); Duloxetine (Cymbalta®); and Milnacipran (Savella®)

[2]Leung MTY, et al. *JAMA Netw Open*. 2024;7(11):e2444488. doi: 10.1001/jamanetworkopen.2024.44488. PMID: 39535796; PMCID: PMC11561685.

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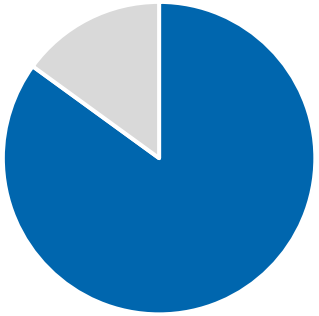
Large Need for New Fibromyalgia Therapies that Provide Symptom Improvement with Better Tolerability

- Currently-approved medications may have side effects that limit long-term use[1]
  - Many patients skip doses or discontinue altogether within months of treatment initiation
- Medication-related side effects may be similar to fibromyalgia symptoms
- High rates of discontinuation, switching and augmentation
  - Attempt to treat multiple symptoms and/or avoid intolerable side effects
  - Average of 2-3 medications used simultaneously[2]
  - The typical patient has tried six different medications[3]
- Substantial off-label use of narcotic painkillers and prescription sleep aids[3]
  - Among those diagnosed, more than one-third have used prescription opioids as a means of treatment[4]
- TNX-102 SL is a non-opioid, centrally-acting analgesic that could provide a new therapeutic option for fibromyalgia patients

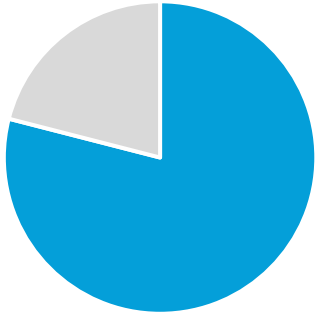
[1] Nuesch et al, Ann Rheum Dis 2013;72:955-62.
[2] Robinson RL et al, Pain Medicine 2012;13:1366.
[3] Patient Trends: Fibromyalgia", Decision Resources, 2011.
[4] Berger A, Dukes E, Martin S, Edelsberg J, Oster G, Int J Clin Pract, 2007; 61(9):1498–1508.

Prescribers Interviewed Expressed Broad Dissatisfaction with Available Fibromyalgia Medications: Results of Primary Research[1]

Perspectives on FM Therapies from Prescribers Interviewed		
Drug	**Positives**	**Negatives**
Duloxetine *(Cymbalta, generic)*	• Relatively high efficacy (compared to alternatives) • Can be titrated slowly from 20mg to 120mg	• Tolerability issues: worsening depression, insomnia • Seldom used as a monotherapy; often requires adjunct
Pregabalin *(Lyrica, generic)*	• Relatively high efficacy (compared to alternatives) • Can often be safely combined with other medications	• Suboptimal for long-term use (e.g., weight gain) • Schedule V status makes some HCPs more cautious to Rx
Savella *(milnacipran)*	• Offers another option if patient fails Cymbalta or Lyrica	• Subpar efficacy does not counterbalance tolerability issues • High cost and access constraints (~$50/month)
Cyclobenzaprine *(Flexeril, generic; oral formulation, off-label)*	• Active for initiating and sustaining sleep; can be titrated up • Active for pain driven by stiffness and muscle spasms	• Mixed perspectives on pain benefit independent of sleep • Suboptimal long-term results as efficacy wanes



85% of patients (avg) fail first line therapy



79% of FM patients (avg) are on multiple therapies

[1]EVERSANA primary physician research, May 2024; commissioned by Tonix

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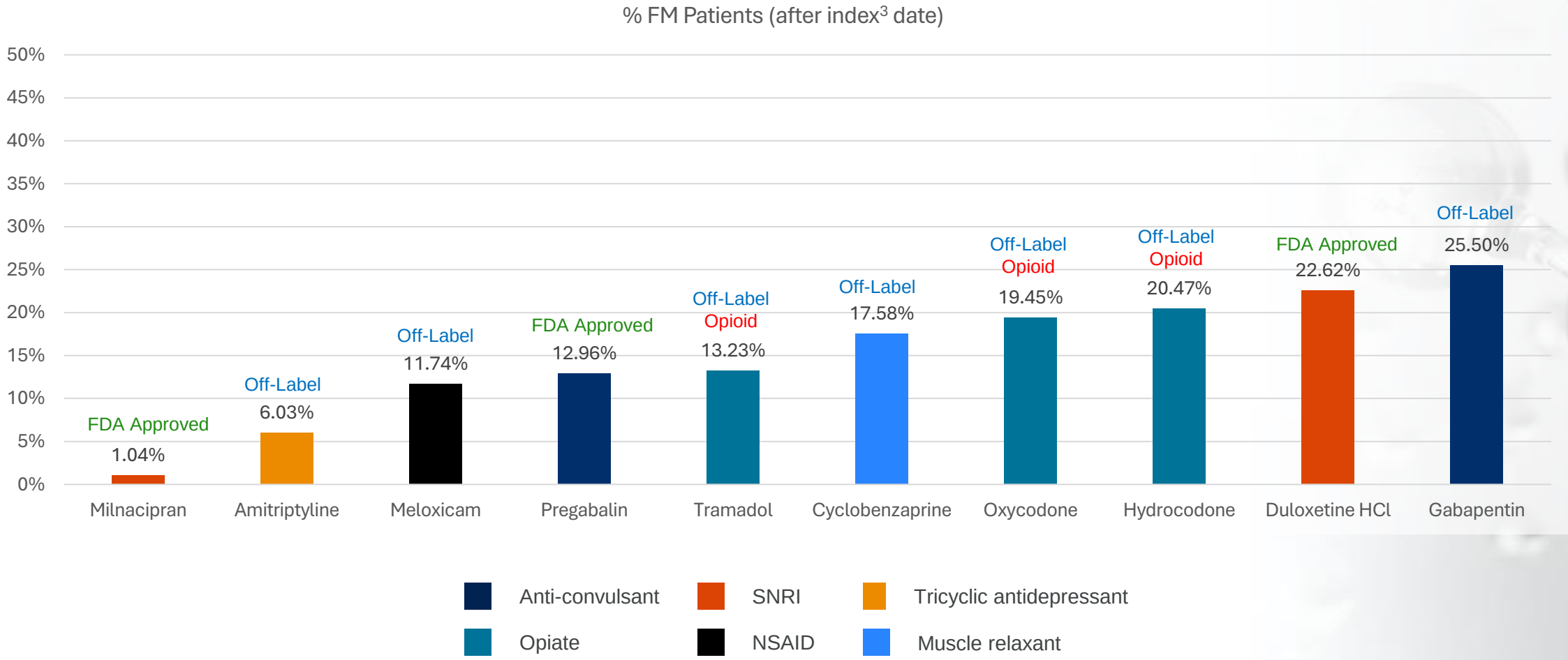
Many Fibromyalgia Patients are Prescribed Off-Label Drugs; ~53% FM Patients Prescribed Opioids Off-Label[1,2]



[1] 2022-2023
[2] EVERSANA analysis of claims database, May 2024; commissioned by Tonix
[3] Index date refers to date when ICD10 code was entered into database

TNX-102 SL Pre-Launch Activities

Potential for Tonix to Launch and Market TNX-102 SL

Decline in personal promotion ("Detailing") of prescription drugs

- The pandemic accelerated transition to non-personal promotion
  - Omnichannel is more important and more sophisticated
    - Tele-sales
    - Digital
    - Direct mail
- Growth in need to support patients with payers to seek reimbursement

Fibromyalgia experts are a subset of Rheumatologists

- New prescriptions for fibromyalgia drugs originate in a subset of doctors
  - Refills may be written by general practitioners

Channels for distribution of prescription drugs are evolving

- Growth of specialty pharmacies who distribute products by mail

Tonix markets two prescription products for the acute treatment of migraine

- Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the acute treatment of migraine with or without aura in adults

Milestones and Summary

Milestones: Recently Completed and Upcoming

TNX-102 SL for the Management of Fibromyalgia Milestones

☑ 4th Quarter 2023	Statistically significant topline results of Phase 3 RESILIENT study – 2nd statistically significant Phase 2 trial
☑ 2nd Quarter 2024	Type B CMC and clinical pre-NDA meetings with FDA
☑ 3rd Quarter 2024	FDA Fast Track Designation granted by FDA
☑ October 2024	Submitted NDA to FDA for TNX-102 SL for fibromyalgia in October 2024
☑ December 2024	FDA assigned a PDUFA* goal date of August 15, 2025
❑ **August 15, 2025**	**FDA decision expected on market authorization**

*PDUFA = Prescription Drug User Fee Act

TNX-102 SL*
Cyclobenzaprine HCl

Non-opiate analgesic

A unique, sublingual formulation of cyclobenzaprine designed for bedtime dosing with sublingual delivery and transmucosal absorption, bypassing 1st pass metabolism**

Potent binding and antagonist activities at the serotonergic-5-HT_{2A}, adrenergic-α_1, histaminergic-H_1, and muscarinic-M_1 cholinergic receptors to facilitate restorative sleep

Rapid drug exposure following once nightly sublingual administration

Differentiators:

Relative to Oral Cyclobenzaprine
- Lower daytime exposure
- Avoids first-pass metabolism
- Reduces risk of pharmacological interference from major metabolite

Relative to Standard of Care
- Potential for better tolerability while maintaining efficacy
- Not scheduled, without recognized abuse potential

*TNX-102 SL is an investigational drug and has not been approved for any indication.
**5mg once-daily at bedtime.

Indications with Active Programs

Fibromyalgia

Status: Two statistically significant Phase 3 studies completed; FDA granted Fast Track Designation
- First pivotal Phase 3 study (RELIEF) completed
- Second Phase 3 study (RALLY) missed primary endpoint
- Confirmatory pivotal Phase 3 study (RESILIENT) completed
- Submitted New Drug Application (NDA) to FDA in October 2024
- FDA decision on market authorization expected August 15, 2025

Next Steps: Support FDA review; pre-launch activities

Acute Stress Reaction/ Acute Stress Disorder

- Phase 2 ready investigator-initiated study
- U.S. Department of Defense funded / UNC will perform study

Next Steps: Expect to start Phase 2 in 1Q 2025

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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. 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.

TONIX PHARMACEUTICALS

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.