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Tonix Pharmaceuticals Announces Publication of Steady-State Pharmacokinetics of TONMYA® After 20 Days of Daily Dosing in the Peer-Reviewed Journal, Clinical Pharmacology in Drug Development

TONMYA (cyclobenzaprine HCl sublingual tablets) for long-term daily dosing at bedtime, is the first new FDA-approved treatment for fibromyalgia in adults in more than 15 years

TONMYA commercially launched in the U.S. in November 2025

BERKELEY HEIGHTS, N.J., April 15, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully-integrated, commercial stage biotechnology company, today announced the publication of a paper, "Steady-State Pharmacokinetic Properties of TNX-102 SL, a Sublingual Tablet Formulation of Cyclobenzaprine Hydrochloride (HCl), With Daily Dosing in Healthy Volunteers: A Randomized, Open-Label Trial," in *Clinical Pharmacology in Drug Development*, the peer-reviewed journal of the American College of Clinical Pharmacology (ACCP). TONMYA® (cyclobenzaprine HCl sublingual tablets) was investigated under the designation TNX-102 SL. The manuscript can be accessed at https://accp1.onlinelibrary.wiley.com/doi/10.1002/cpdd.70060.

"TONMYA's sublingual tablet was developed for long-term daily dosing at bedtime to target the nonrestorative sleep associated with fibromyalgia," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Therefore, the steady-state pharmacokinetic (PK) profile at Day 20 is more relevant to the product's indicated dosing regimen than single dose PK. The dynamic changes in cyclobenzaprine concentrations from sublingual tablet dosing over 24 hours at Day 20 are believed to provide pharmacodynamic effects on the brain owing to rapid absorption and distribution. The sublingual tablet was designed with a basifying ingredient and cyclobenzaprine–mannitol eutectic to provide transmucosal absorption to speed uptake, deliver maximum plasma levels of cyclobenzaprine during the middle of the sleep phase, and bypass first-pass liver metabolism. This study supported TONMYA's approval for the treatment of fibromyalgia in adults by the U.S. Food and Drug Administration (FDA) and elucidates how TONMYA's pharmacokinetic profile is consistent with long-term daily dosing at bedtime."

Dr. Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals added, "The

dynamic changes in cyclobenzaprine concentrations are magnified by the higher predicted percentage of receptors by cyclobenzaprine relative to norcyclobenzaprine occupied (i.e., 5-HT_{2A}, α1-adrenergic, H_1, and M_1) during sleep hours after bedtime dosing. For example, 5-HT_{2A} antagonism increases slow wave sleep (SWS) activity during non–rapid eye movement (NREM) sleep, and α1-adrenergic antagonism increases the time and continuity in REM sleep and reduces noradrenergic sympathetic tone, which has the potential to impair the quality of SWS."

The publication reports findings from a single-center, randomized, open-label, multiple-dose, parallel-group pharmacokinetic study conducted in 60 healthy adult volunteers. Participants were randomized 1:1 to receive either sublingual cyclobenzaprine HCl 5.6 mg (two 2.8 mg tablets, the FDA approved dose of TONMYA for adults) or oral cyclobenzaprine HCl extended-release (ER) 30 mg capsules (AMRIX®) once daily for 20 consecutive days.

At steady state, exposure to both plasma cyclobenzaprine and norcyclobenzaprine for sublingual tablets (TNX-102 SL) 5.6 mg was substantially lower than that to the comparator listed drug, oral cyclobenzaprine HCl ER 30 mg capsules. Importantly, when exposures were normalized by dose, cyclobenzaprine bioavailability is higher for sublingual tablets at 5.6 mg relative to oral ER 30 mg capsules. Both treatments had comparable metabolic profiles of Phase I and II metabolites in human plasma. These pharmacokinetic results are consistent with the use of sublingual cyclobenzaprine HCl tablets at 5.6 mg to target nonrestorative sleep in fibromyalgia, reduce pain, and potentially improve other symptoms of the condition.

On Day 1, sublingual cyclobenzaprine was detectable within one hour of administration, with median time to peak plasma concentration (t_{max}) approximately three hours earlier than the oral ER capsule formulation (five vs. eight hours). At steady state on Day 20, the sublingual t_{max} remained two hours earlier (five vs. seven hours). The sublingual formulation demonstrated markedly higher cyclobenzaprine bioavailability when exposures were normalized by dose.

Daily morning administration of sublingual cyclobenzaprine HCl 5.6 mg over 20 days was generally safe and well tolerated. There were no serious adverse events or treatment discontinuations due to adverse events. All treatment-emergent adverse events were mild or moderate in severity. The most commonly reported adverse events with sublingual tablets occurring at rates higher than oral ER capsules were oral hypoesthesia, abnormal product taste, somnolence, back pain, and fatigue. Since TONMYA is intended for bedtime administration, the effects of somnolence are expected to be an attribute for bedtime dosing when sleepiness effects are beneficial. No metabolites unique to the sublingual route of administration were identified.

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 6-12 million adults in the U.S., approximately 90% of whom are women. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled. Physicians and patients report common dissatisfaction with currently marketed products.

About TONMYA® (cyclobenzaprine HCl sublingual tablets)
TONMYA (cyclobenzaprine HCl sublingual tablets) is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride which, compared to the immediate-release oral cyclobenzaprine, provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. The reduction in norcyclobenzaprine, a potent inhibitor of the norepinephrine transporter (NET), is thought to be key to the durability of treatment response as NET inhibition is activating and disruptive to slow wave sleep. As a multifunctional agent with potent binding and antagonist activities at the 5-HT_{2A} serotonergic, α_1-adrenergic, H_1-histaminergic, and M_1-muscarinic receptors, TONMYA was approved on August 15, 2025, by the FDA for the treatment of fibromyalgia in adults. TONMYA is the first new prescription medicine approved for fibromyalgia in more than 15 years. TONMYA was investigated as TNX-102 SL. TNX-102 SL is also being developed to treat acute stress reaction (ASR)/acute stress disorder (ASD), and major depressive disorder (MDD). The United States Patent and Trademark Office (USPTO) issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary TONMYA composition. These patents are expected to provide TONMYA with U.S. market exclusivity until 2034/2035.

Tonix Pharmaceuticals Holding Corp.
Tonix Pharmaceuticals* is a fully-integrated, commercial-stage biotechnology company focused on central nervous system (CNS) and immunology treatments in areas of high unmet medical need. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8 mg), is the first new treatment for fibromyalgia in adults in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® Symtouch® (sumatriptan injection 3 mg) and Tosymra® (sumatriptan nasal spray 10 mg). Tonix is investigating TONMYA® in Phase 2 clinical trials to evaluate its potential in major depressive disorder and acute stress disorder/acute stress reaction. Tonix is also advancing a pipeline of immunology programs, including TNX-4800, a Phase 2 ready long-acting human anti-*Borrelia* OspA monoclonal antibody (mAb) for the prevention of Lyme disease in the U.S., and TNX-1500, a Phase 2 ready third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. In addition, the Company is progressing TNX-2900 (intranasal potentiated oxytocin), which is Phase 2 ready for the treatment of Prader-Willi syndrome, a rare disease. To learn more, visit www.tonixpharma.com and follow the Company on LinkedIn and X.

*Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

Forward Looking Statements
Certain statements in this press release are forward-looking within the meaning of the

Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statements that are predictive in nature. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to successfully launch and commercialize TONMYA® and any of our approved products; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. Tonix does not undertake an obligation to update or revise any forward-looking statement. All of Tonix’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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

Brian Korb
astr partners
(917) 653-5122
brian.korb@astrpartners.com

Media Contacts
Deborah Elson
Tonix Pharmaceuticals
deborah.elson@tonixpharma.com

Ray Jordan
Putnam Insights
ray@putnaminsights.com

INDICATION
TONMYA is indicated for the treatment of fibromyalgia in adults.

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.

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.

TONIX PHARMACEUTICALS

Source: Tonix Pharmaceuticals Holding Corp.