September 8, 2025

Tonix Pharmaceuticals Presents Clinical Data on Tonmya™ for the Treatment of Fibromyalgia at PAINWEEK 2025

Tonmya was approved by FDA on August 15, 2025 for the treatment of fibromyalgia and is the first new FDA approved treatment for fibromyalgia in over 15 years

Two pivotal Phase 3 studies demonstrated Tonmya significantly reduced fibromyalgia pain compared to placebo

Tonmya showed consistent improvements across core fibromyalgia symptoms, including widespread pain, sleep disturbance and fatigue

Tonmya was well tolerated, supporting its potential as a long-term treatment option for fibromyalgia

Tonmya is expected to be commercially available in the fourth quarter

CHATHAM, N.J., Sept. 08, 2025 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully-integrated biotechnology company with marketed products and a pipeline of development candidates, presented four posters at the PAINWEEK conference 2025, held September 2-5, 2025, in Las Vegas, Nevada entitled:

- *"TNX-102 SL, Cyclobenzaprine HCl Sublingual Tablets, Demonstrates Pain Reduction and Favorable Tolerability in Participants With Fibromyalgia"*
- *"Sublingual Cyclobenzaprine (TNX-102 SL) for Fibromyalgia: Efficacy and Safety in Two Randomized, Placebo-Controlled Trials"*
- *"Steady-state Pharmacokinetic Properties of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL): Comparison to Simulations of Oral immediate-release CBP"*
- *"Randomized, Double-Blind, Placebo-Controlled Confirmatory Phase 3 Trial of Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) in Fibromyalgia"*

"Fibromyalgia is a chronic and debilitating condition marked by widespread pain, poor sleep, and fatigue and cognitive dysfunction," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "The data presented at PAINWEEK show that Tonmya significantly improved pain with a favorable tolerability profile, offering patients and physicians a new, non-opioid treatment option. Now that Tonmya has been approved by FDA, we believe we are well-positioned to execute the launch and remain on track to deliver this drug to patients next quarter."

The posters included data from two pivotal Phase 3 trials: RELIEF, a 14-week randomized,

double-blind, placebo-controlled study of TNX-102 SL 5.6 mg (now Tonmya™), and RESILIENT, a confirmatory trial evaluating efficacy and safety. Across both studies, Tonmya significantly reduced fibromyalgia pain and demonstrated a favorable tolerability profile. By pharmacologically targeting nonrestorative sleep through antagonism of receptors that regulate sleep architecture, Tonmya engages a central mechanism believed to drive the persistence of fibromyalgia symptoms. The availability of a safe and well-tolerated treatment may also support earlier diagnosis and intervention, ultimately improving patient outcomes. Together, these findings suggest Tonmya has the potential to improve a broad spectrum of fibromyalgia symptoms.

Copies of the posters are available under theScientific Presentations tab of the Tonix website at www.tonixpharma.com.

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 10 million adults in the U.S., approximately 80% of whom are women. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep (waking up tired and unrefreshed), 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. Patients with fibromyalgia have double the medical costs compared to the general population in the U.S.

About Tonmya™ (cyclobenzaprine HCl sublingual tablets)
Tonmya, which was investigated as TNX-102 SL, is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride, which provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. As a tertiary amine tricyclic (TAT) and multifunctional agent with potent binding and antagonist activities at the 5-HT2A serotonergic, α1-adrenergic, H1-histaminergic, and M1-muscarinic receptors, Tonmya is now approved as a once-daily bedtime treatment for fibromyalgia in adults. 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. 10357465 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 composition. These patents are expected to provide Tonmya with U.S. market exclusivity until 2034. Pending patent applications related to method of use could extend exclusivity until 2044.

About the Phase 3 Clinical Trials: RELIEF, RALLY and RESILIENT
The RELIEF and RESILIENT studies were double-blind, randomized, placebo-controlled trials designed to evaluate the efficacy and safety of Tonmya™ (cyclobenzaprine hydrochloride sublingual tablets) for the treatment of fibromyalgia. RELIEF and RESILIENT were two-arm trials that enrolled 503 and 457 adults with fibromyalgia across 40 and 33 United States sites, respectively. In both trials, the first two weeks of treatment consisted of a run-in period in which participants started on Tonmya 2.8 mg (1 tablet) or placebo. Thereafter, all participants increased their dose to Tonmya 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks. The primary endpoint across both trials was

the daily diary pain intensity score change (Tonmya 5.6 mg vs. placebo) from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores). Additional details on RELIEF (NCT04172831) and RESILIENT (NCT05273749) are available on clinicaltrials.gov.

RALLY was a replicate Phase 3 trial to RELIEF and RESILIENT that demonstrated greater but non-significant treatment effect with Tonmya compared to placebo and demonstrated consistent safety. Results of this trial may not have been generalizable due to the presence of factors outside the conduct of the study. Additional details are available on clinicaltrials.gov (NCT04508621).

Tonix Pharmaceuticals Holding Corp.*

Tonix Pharmaceuticals is a fully-integrated biotechnology company with marketed products and a pipeline of development candidates. Tonix recently received FDA approval for Tonmya™, a first-in-class, non-opioid analgesic medicine for the treatment of fibromyalgia, a chronic pain condition that affects millions of adults. This marks the first approval for a new prescription medicine for fibromyalgia in more than 15 years. Tonix also markets two treatments for acute migraine in adults. Tonix's development portfolio is focused on central nervous system (CNS) disorders, immunology, immuno-oncology and infectious diseases. TNX-102 SL is being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix's infectious disease portfolio includes TNX-801, a vaccine in development for mpox and smallpox, as well as TNX-4200 for which Tonix has a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years. TNX-4200 is a small molecule broad-spectrum antiviral agent targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, Md.

* 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.

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements
Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to 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. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2025, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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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.

Source: Tonix Pharmaceuticals Holding Corp.