March 10, 2026

# Tonix Pharmaceuticals Presented Post Hoc Analyses of Phase 3 Data on TONMYATM at the 8th International Congress on Controversies in Fibromyalgia

*Company launched TONMYA, approved by the FDA as a treatment for fibromyalgia, in November 2025*

*In post hoc analysis of the pivotal RESILIENT study, TONMYA produced rapid pain relief as early as Day 2 of treatment, with durable pain reduction and significant improvements in all key secondary endpoints as compared to placebo*

*In pooled post hoc analysis of the pivotal RELIEF and RELISIENT studies, TONMYA showed favorable benefit-risk profile using number needed to treat, number needed to harm, and likelihood to be helped or harmed*

BERKELEY HEIGHTS, N.J., March 10, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial biotechnology company, announced two oral presentations on TONMYA™, which was investigated as TNX-102 SL (cyclobenzaprine HCl sublingual tablets) at the 8th International Congress on Controversies in Fibromyalgia held on March 9-10, 2026, in Krakow, Poland.

"Phase 3 *post hoc* analyses reinforce the potential of TONMYA to provide a benefit to the approximately 10 million adults in the U.S. living with fibromyalgia," said Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals. "In a *post hoc* analysis of RESILIENT, the data show rapid and early onset of pain relief. In a *post hoc* analysis of two pivotal studies, TONMYA showed a favorable benefit-risk profile that suggests treatment benefit is nearly four times more likely than discontinuation of treatment due to an adverse event. Together, these findings underscore TONMYA's profile as a differentiated, generally well tolerated, and effective medicine that may address the unmet medical needs of those with fibromyalgia. TONMYA is the first medication approved for fibromyalgia in over 15 years."

*Oral Presentation One: "Cyclobenzaprine HCl Sublingual Tablets (CBP SL) Provide Rapid Pain Relief in Adults with Fibromyalgia"*

In the RESILIENT trial, a 14-week, randomized, placebo-controlled Phase 3 study evaluating 457 adults with fibromyalgia as defined by 2016 American College of Rheumatology (ACR) criteria, a *post hoc* mixed-model repeated-measures analysis demonstrated that TONMYA

produced a rapid reduction in pain, with improvements versus placebo observed as early as Day 2 of treatment and statistically significant pain relief at each week over Weeks 1–14. The primary endpoint, change from baseline to Week 14 in weekly average daily numeric rating scale (NRS) pain scores, was met with high statistical significance ($p<0.001$), with a least-squares mean treatment difference of -0.65. All key secondary endpoints were also statistically significant in favor of TONMYA.

TONMYA was generally well tolerated, with 6.1% of participants discontinuing due to adverse events versus 3.5% with placebo. The most common treatment-emergent adverse events were oral cavity reactions, including oral hypoesthesia (23.8%) and abnormal product taste (11.7%), which were typically mild, transient, and self-limited.

*Oral Presentation Two: "Cyclobenzaprine HCl Sublingual Tablets for the Treatment of Fibromyalgia: Number Needed to Treat and Number Needed to Harm"*

The data from a pooled post hoc analysis of 959 participants (783 completed the studies) from the RELIEF and RESILIENT Phase 3 trials was utilized to further clarify the benefit-risk profile of TONMYA using number needed to treat (NNT), number needed to harm (NNH), and likelihood to be helped or harmed (LHH). The NNT for achieving a clinically meaningful ≥30% pain reduction over placebo at Week 14 was 7 (95% confidence interval (CI): 5–12) while the NNH for discontinuation due to an adverse event was 26 (95% CI: 14–110). Based on these values, the LHH was 3.7, indicating that TONMYA provides a nearly four-fold greater likelihood of clinical benefit than adverse event-related discontinuation.

The pooled safety data were consistent with the known profile of TONMYA, with no new or unexpected safety signals. The most common treatment-emergent adverse events were oral cavity reactions that were typically mild, transient, and self-limited.

Copies of the Company's presentations are available under the Scientific Presentations tab on 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 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 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 multifunctional agent with potent binding and antagonist activities at the 5-HT2A serotonergic, α1-adrenergic, H1-histaminergic, and M1-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 2.8mg), the Company's recently approved flagship medicine, is the first new treatment for fibromyalgia in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® SymTouch® and Tosymra®. Tonix is maximizing the science behind TONMYA in Phase 2 clinical trials to evaluate its potential in major depressive disorder and acute stress disorder. In addition, the company's CNS portfolio includes TNX-2900, which is Phase 2 ready for the treatment of Prader-Willi syndrome, a rare disease. Tonix is also advancing a pipeline of immunology programs, including monoclonal antibody TNX-4800 for Lyme disease prophylaxis and TNX-1500, a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. 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.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines.

**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. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially as a result of a number of factors, including the ability of the Company to satisfy the conditions to the closing of the offering and the timing thereof, as well as those described in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on March 18, 2025, 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.

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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](www.fda.gov/medwatch).**

Source: Tonix Pharmaceuticals Holding Corp.