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Tonix Pharmaceuticals Secures Third Major Commercial Payer Agreement for TONMYA®, Expanding Total Coverage to Approximately 190 Million Covered Lives (61% of Total U.S. Lives)

New agreement adds approximately 24 million U.S. commercial lives

All three of the leading group purchasing organizations (GPOs) are now under contract

BERKELEY HEIGHTS, N.J., Nov. 23, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or "the Company"), a fully integrated, commercial-stage biopharmaceutical company, today announced a third commercial payer agreement with a leading GPO for TONMYA® (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia in adults. The agreement, effective immediately, adds approximately 24 million U.S. commercial lives, or 13% of the approximately 186 million U.S. commercial lives, with standard utilization management criteria.

With this agreement, commercial coverage for TONMYA now reaches approximately 85 million lives, or 46% of U.S. commercial lives. Total commercial and government payer coverage for TONMYA now reaches approximately 190 million covered lives, or 61% of the approximately 314 million covered lives in the U.S. Previously, Tonix announced commercial payer agreements with two leading GPOs, two major managed Medicare agreements, and Medicaid coverage in nearly all states.

"Signing agreements with all three leading GPOs strengthens the foundation of commercial access to TONMYA," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "TONMYA is a non-opioid analgesic designed for bedtime administration and long-term use. We are dedicated to translating broader coverage into access for the 10 million-plus people in the United States living with fibromyalgia who face significant unmet needs."

Thomas Englese, MBA, Chief Commercial Officer of Tonix Pharmaceuticals, added, "Our previously signed coverage agreements are contributing to net sales growth, and we expect additional impacts as additional downstream plans adopt TONMYA. We are encouraged by increasing approval rates for commercially insured patients as our agreements take effect. Also, our recently introduced third-party field access managers are now supporting prior authorization submissions. We are dedicated to helping eligible patients start TONMYA. Our approximately 150 sales representatives are committed to increasing awareness of TONMYA to prescribers."

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 more than 10 million adults in the U.S., predominantly 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 sublingual tablet formulation of cyclobenzaprine hydrochloride that 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 provides rapid transmucosal absorption of cyclobenzaprine and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypassing first-pass hepatic metabolism. TONMYA is a multifunctional agent with potent binding and antagonist activities at the 5-HT2A serotonergic, α1-adrenergic, H1-histaminergic, and M1-muscarinic receptors. TONMYA was investigated as TNX-102 SL. TNX-102 SL is also being developed to treat acute stress disorder (ASD)/acute stress reaction (ASR), 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.

Tonix Pharmaceuticals Holding Corp.
Tonix Pharmaceuticals* is a fully integrated, commercial-stage biopharmaceutical company focused on central nervous system (CNS) disorders, infectious diseases, and immunology conditions with high unmet medical needs. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8 mg), the Company's flagship internally conceived and developed medicine, is the first FDA-approved treatment for fibromyalgia 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 extending the science behind TONMYA in Phase 2 clinical studies to evaluate the potential of TNX-102 SL in major depressive disorder (Tonix-led study) and acute stress disorder/acute stress reaction (investigator-initiated study). Tonix is also advancing monoclonal antibody TNX-4800 (anti-OspA mAb) for Lyme disease prevention in the U.S. Within immunology, Tonix is developing TNX-1500 (anti-CD40L mAb), a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection (investigator-initiated study). To learn more, visit www.tonixpharma.com.

*Tonix's product development candidates, including TNX-102 SL for new, unapproved indications, are investigational new drugs or biologics. Their efficacy and safety for the indications being investigated have not been established, and they have not been approved for those indications.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. TONMYA is a registered trademark of Tonix Pharma Limited. All other marks are property of their respective owners.

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 expected impact of the Company's payer agreements, downstream plan engagement and expanded commercial efforts on access to TONMYA. 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; uncertainties of patent protection and litigation; 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 government or third-party payer 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. Investors should read the risk factors set forth 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 hereof.

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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 inhibitor 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 in pediatric patients.

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. For patients aged 65 years or older, the recommended dose is 2.8 mg administered sublingually once daily at bedtime.

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.