March 18, 2025

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results and Operational Highlights

August 15, 2025, is the FDA PDUFA goal date for TNX-102 SL for the management of fibromyalgia; If approved, TNX-102 SL would become the first new drug for treating fibromyalgia in more than 15 years

Company expects to have sufficient cash to fund planned operations beyond the FDA PDUFA goal date and anticipated fourth quarter 2025 launch of TNX-102 SL for fibromyalgia; $98.8 million in cash as of December 31, 2024

Announced positive topline results from Phase 1 study of TNX-1500, a next generation anti-CD40L mAb candidate for prevention of kidney transplant rejection and treatment of autoimmune diseases

Received government grant for potential mpox vaccine, TNX-801, which has demonstrated single-dose immune protection against a monkeypox challenge in non-human primates

Received first payments from U.S. Department of Defense (DoD) contract for up to $34 million over five years to develop a broad-spectrum antiviral drug program

CHATHAM, N.J., March 18, 2025 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced financial results for the fourth quarter and full year ended December 31, 2024, and provided an overview of recent operational highlights.

“With commercial preparations underway, we believe we are well positioned to launch TNX-102 SL for the management of fibromyalgia in the fourth quarter of this year if approved by the U.S. Food and Drug Administration,” said Seth Lederman, M.D., Chief Executive Officer of Tonix. “We believe that TNX-102 SL has the potential to be the first in a new class of non-opioid analgesic medicines for the management of fibromyalgia, and the first new drug for treating fibromyalgia in more than 15 years.”

Fibromyalgia is a debilitating chronic pain condition affecting over 10 million adults in the United States, most of whom are women. Data from our pivotal Phase 3 trials indicate that TNX-102 SL can provide fibromyalgia patients with significant reduction in pain. TNX-102 SL was generally well tolerated and has no known addictive properties.

Dr. Lederman continued, “Tonix is debt free and expects to have sufficient cash to fund operations through the PDUFA target date of August 15, 2025, and the anticipated

commercial launch of TNX-102 SL in the fourth quarter of this year. We continue to meaningfully add to our commercial team and are engaged in pre-launch activities. We look forward to continuing discussions with the FDA throughout the review period in advance of the PDUFA goal date to bring patients a potential new treatment option."

"Beyond TNX-102 SL for fibromyalgia, we are encouraged by the continued development of our pipeline in a capital efficient manner. Positive results from a Phase 1 study evaluating the tolerability and pharmacokinetics of TNX-1500, a next generation anti-CD40L mAb for prevention of kidney transplant rejection, support advancing to a planned Phase 2 trial in kidney transplant recipients with monthly dosing. In addition, we continue to advance TNX-801 vaccine for preventing mpox and smallpox towards the clinic. With the ongoing global mpox epidemic continuing to spread, TNX-801's ability to protect animals from lethal challenge with Clade Ia monkeypox virus and its tolerability in immune-compromised animals is encouraging and further supports testing in humans. We look forward to providing additional updates to each of these promising programs in 2025."

Key Product Candidates* -- Recent Highlights

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): 5.6 mg, once-daily at bedtime small molecule for the management of fibromyalgia (FM) – a centrally-acting, non-opioid analgesic.

- In December 2024, the Company announced U.S. Food and Drug Administration (FDA) acceptance of its New Drug Application (NDA) for TNX-102 SL for fibromyalgia, with a Prescription Drug User Fee Act (PDUFA) goal date of August 15, 2025. The NDA was based upon two Phase 3 studies of TNX-102 SL in fibromyalgia that showed statically significant reduction in the chronic, widespread pain associated with fibromyalgia. It was well tolerated and has no known addictive properties. If approved by the FDA, TNX-102 SL would be the first member of a new class of tertiary amine tricyclic (TAT) non-opioid analgesic drugs for fibromyalgia and the first new drug available for treating fibromyalgia in more than 15 years. Fibromyalgia affects more than 10 million adults in the U.S., most of whom are women.

- In March 2025, Tonix presented data and analyses of TNX-102 SL treatment and effects on fibromyalgia at the 7th International Congress on Controversies in Fibromyalgia, held in Vienna, Austria, in an oral presentation titled, "*Transmucosal Sublingual Cyclobenzaprine (TNX-102 SL) Treatment of Fibromyalgia at Bedtime to Target Non-Restorative Sleep Showed Durable Pain Reduction in Two Double-Blind Randomized Phase 3 Studies.*" TNX-102 SL, a sublingual formulation of cyclobenzaprine designed for transmucosal delivery and durable activity, has demonstrated statistically significant, durable activity (three months) in reducing fibromyalgia pain in two double-blind randomized Phase 3 studies.

- In November 2024, at the American College of Rheumatology (ACR) Convergence 2024 Annual Meeting, Tonix announced additional data and analyses of TNX-102 SL for the management of fibromyalgia. TNX-102 SL had met the pre-specified primary endpoint in the Phase 3 RESILIENT study, significantly reducing daily pain compared to placebo (p-value=0.00005) in participants with fibromyalgia with statistically significant improvement in all six pre-specified key secondary endpoints, including

those related to improving sleep quality, reducing fatigue, and improving patient global ratings and overall fibromyalgia symptoms and function. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies and no new safety signals were observed.

- In September 2024, at the 11th Global Conference on Pharmaceutics and Novel Drug Delivery Systems (PDDS 2024), the Company announced data highlighting the proprietary formulation technology and pharmacokinetic properties of TNX-102 SL, including composition and methods patents based on the proprietary eutectic formulation of TNX-102 SL that are expected to provide market exclusivity until at least 2034 in the U.S., EU, Japan, China and other jurisdictions. The eutectic protects cyclobenzaprine HCl from interacting with the basifying agent that is also part of the formulation and required for efficient transmucosal absorption. The formulation of TNX-102 SL was designed specifically for sublingual administration and transmucosal absorption for bedtime dosing to target disturbed sleep, relieve pain and other fibromyalgia symptoms, while reducing the risk of daytime somnolence.

TNX-102 SL for the treatment of acute stress reaction (ASR) and acute stress disorder (ASD), and prophylaxis against development of posttraumatic stress disorder (PTSD)

- The DoD-funded Optimizing Acute Stress Reaction Interventions (OASIS) trial will be conducted by the University of North Carolina under an investigator-initiated investigational new drug (IND) application. The OASIS trial will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients in the emergency department (ED) after a motor vehicle collision. Fourteen days of bedtime TNX-102 SL will be dosed and tested in the immediate aftermath of motor vehicle collision. The study will test the potential for TNX-102 SL to target trauma-related sleep disturbance and its ability to facilitate recovery from ASR and to prevent PTSD. The program has the potential to provide military personnel with a new treatment option that improves warfighter performance and resilience when administered in the early aftermath of a traumatic event, The study is expected to be initiated in the first half of 2025.

TNX-1300 (recombinant double mutant cocaine esterase): biologic for cocaine intoxication

- The National Institutes of Health (NIH)'s National Institute of Drug Abuse (NIDA) previously awarded Tonix a Cooperative Agreement grant for approximately $5 million to support development of TNX-1300.

- TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

The Phase 2 CATALYST study of TNX-1300 for the treatment of cocaine intoxication began enrolling in August 2024. CATALYST is a Phase 2 single-blind, placebo-controlled, proof-of-concept study in patients presenting to the emergency department. Because of the challenges of recruiting eligible patients into this study, we are not guiding to a timeline for completion of enrollment or topline data.

Immunology Pipeline

TNX-1500 (anti-CD40L Fc-modified humanized monoclonal antibody): third generation anti-

CD40L monoclonal antibody for prophylaxis for organ transplant rejection and treatment of autoimmune disorders.

- In February 2025, Tonix announced positive topline results from its Phase 1, single ascending dose (SAD) first-in-human trial of TNX-1500 in healthy participants. The objectives of the Phase 1 trial were to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of intravenous TNX-1500, as well as to support dosing in a planned Phase 2 trial in kidney transplant recipients, pending alignment with the FDA. All objectives were met and support proceeding to a Phase 2 trial. TNX-1500 blocked the primary and secondary antibody responses to a test antigen at the 10 mg/kg and 30 mg/kg i.v. doses, showed mean half-life of 34-38 days for the 10 mg/kg and 30 mg/kg doses (supporting monthly dosing for future efficacy trials) and was generally well-tolerated with a favorable safety profile.

- The first proposed indication for TNX-1500 is prophylaxis of organ rejection in adult patients receiving a kidney transplant; but multiple additional indications are possible, including the treatment of autoimmune diseases. Preclinical studies have shown that TNX-1500 maintains the activity of first-generation monoclonal antibodies (mAbs), yet with reduced risk of thrombotic complications. Pharmacokinetic data support a monthly *i.v.* dosing regimen. This analysis together with TNX-1500's activity and tolerability in animals, suggests that the protein engineering of TNX-1500's Fc region has achieved its design goals.

Infectious Disease Pipeline

TNX-801 (recombinant horsepox virus, minimally replicative live vaccine): potential vaccine to protect against mpox and smallpox.

- In March 2025, Tonix announced it was awarded a grant from the Medical CBRN Defense Consortium (MCDC) to support the development of TNX-801. The grant will allow Tonix to develop a commercialization plan for TNX-801.
- In November 2024, Tonix announced that it has entered into a sponsored research agreement with the Kenya Medical Research Institute (KEMRI) to design, plan and seek regulatory approval for a Phase I clinical study in Kenya to test the safety, tolerability, and immunogenicity of TNX-801 (horsepox, live virus) as a vaccine to prevent mpox and smallpox. Tonix is expected to be the sponsor and KEMRI is expected to lead the execution of the proposed clinical trial.

- In November 2024, the Company announced the publication of a peer-reviewed paper highlighting the tolerability of TNX-801 in immune-compromised animals. The publication describes data in which TNX-801 was compared with older vaccinia vaccine strains used in the eradication of smallpox for tolerability in both *in vitro* and *in vivo* models. Together, TNX-801 was shown to be greater than 10- to 1,000-fold less virulent (or more attenuated) compared to the older vaccinia smallpox vaccines. Previously, single-dose vaccination with TNX-801 was shown to protect animals from a lethal challenge with Clade Ia monkeypox.

- In September 2024, at the DoD's MHSRS conference and in October 2024 at the World Vaccine Congress in Barcelona, Spain, Tonix presented new data on potential

mpox vaccine, TNX-801, demonstrating tolerability and no evidence of spreading to blood or tissues, even at high doses, in immunocompromised animals. TNX-801 is a minimally replicative live-virus vaccine based on synthesized horsepox that has been shown to provide single-dose immune protection against a monkeypox challenge. After a single-dose vaccination, TNX-801 prevented clinical disease and lesions, and also decreased shedding in the mouth and lungs of non-human primates after a lethal challenge with Clade Ia monkeypox. These findings are consistent with TNX-801 inducing mucosal immunity and suggest TNX-801 has the ability to block forward transmission.

- In September 2024, the Company announced that the World Health Organization's (WHO) preferred target product profile (TPP) aligns with the characteristics of TNX-801. Key elements of the WHO draft TPP include single-dose, durable protection, administration without special equipment, and stability at ambient temperature. Other potential beneficial characteristics include the ability to limit forward transmission, use in case-contact vaccination strategies and suitability for use in immunocompromised individuals. In August 2024, the WHO determined that the upsurge of mpox in a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC), the second such declaration in the past two years in response to transmission of the virus. Mpox cases of the new Clade Ib mpox have since also been detected in many countries outside of Africa including at least three cases in the U.S.

Corporate and Partnerships – Recent Highlights

- In February 2025, the Company announced the promotion of Siobhan Fogarty to Chief Technical Officer from Executive Vice President, Product Development. Ms. Fogarty originally joined Tonix in 2016 and has over 25 years of experience in pharmaceutical and biotech product development, manufacturing and quality, for both small and large molecules, at notable pharmaceutical and biotech companies.
- In January 2025, Tonix announced the appointment of Gary Ainsworth as its new Vice President, Market Access. With over two decades of industry and market access experience, Mr. Ainsworth offers a significant track record of success building market access functions, developing launch-ready access and reimbursement strategies and payer-focused resources, including those for fibromyalgia and migraine treatment options.
- In December 2024, the Company announced the expansion of its leadership team with the appointment of two strategic hires: Bradley Raudabaugh, MBA, joined Tonix as Vice President, Marketing, and Errol Gould, Ph.D., joined the company as Vice President, Medical Affairs. Mr. Raudabaugh brings over 25 years of marketing, sales and product planning experience to Tonix and Dr. Gould offers over 25 years of experience in R&D and medical affairs across a wide range of therapeutic areas, including fibromyalgia.
- In October 2024, the Company announced the receipt of the first contract payment from the previously awarded contract by the U.S. Department of Defense (DoD) for accelerated development of broad-spectrum antivirals with the Defense Threat Reduction Agency (DTRA). The contract, awarded in July 2024, has the potential for up to $34 million over five years with an objective to develop small molecule broad-

spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix's program is focusing on optimization and development of its TNX-4200 program, to develop an orally available CD45 antagonist, with broad-spectrum efficacy against a range of viral families through preclinical evaluation. The program is expected to establish physicochemical properties, pharmacokinetics, and safety attributes to support an IND submission and to fund a first-in-human Phase 1 clinical study.

- In October 2024, the Company announced it entered into an artificial intelligence and machine learning drug discovery collaboration with X-Chem, Inc., a leader in small molecule drug discovery, to accelerate the development of small molecules as orally available host-targeted broad-spectrum medical countermeasures. Tonix's TNX-4200 antiviral program focuses on the development of oral CD45 phosphatase inhibitors, with broad-spectrum activity against a range of viral families.
- In September 2024, Tonix announced the appointment of Thomas Englese as its new Executive Vice President, Commercial Operations. Mr. Englese brings significant leadership to Tonix across several functions, including commercial operations, sales and marketing, and launching and managing major brands through all stages of commercialization.

Marketed Products – Recent Highlights

- In September 2024, Tonix announced that the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 12,097,183 to the Company, claiming use of a pre-filled autoinjector comprising a composition of Zembrace® SymTouch® for treating migraines via subcutaneous administration. This patent, excluding possible patent term extensions, is expected to fortify protection and market exclusivity into 2036.
- Tonix announced that the USPTO issued U.S. Patent No. 12,090,139 to the Company, claiming a pharmaceutical composition, a method of treating migraine via intranasal administration, and an intranasal delivery system for Tosymra®. This patent is expected to fortify protection and market exclusivity into 2030.

In September 2024, Tonix Medicines launched a national educational campaign focusing on the link between migraine, gastroparesis, and the need for non-oral acute migraine therapies. Tonix Medicines is the only manufacturer with both a branded injectable and nasal spray indicated for the acute treatment of migraine with or without aura in adults.

Financial - Recent Highlight

Tonix had approximately $98.8 million of cash and cash equivalents as of December 31, 2024, compared to approximately $24.9 million as of December 31, 2023. Net cash used in operations was approximately $60.9 million for the full year ended December 31, 2024, compared to $102.0 million for the same period in 2023. Net cash used in investing activities for the full year ended December 31, 2024, was approximately $0.1 million compared to $29.1 million for the same period in 2023.

Following the repayment of a mortgage (Loan and Guaranty Agreement) with JGB Capital and related parties in February 2025, the Company is now debt-free.

Tonix continues to expect that its cash resources at December 31, 2024, and the net proceeds of approximately $46.3 million raised from the sale of common stock under an at-the-market (ATM) facility in the first quarter of 2025, will be sufficient to fund its planned operations into the first quarter of 2026, beyond the August 15, 2025 PDUFA goal date assigned by the FDA for a decision on marketing authorization for TNX-102 SL for management of fibromyalgia.

Subsequent to December 31, 2024, the Company repurchased 250,000 of its shares of common stock outstanding under the 2024 share repurchase program.

Fourth Quarter 2024 Financial Results

Net product revenue for the fourth quarter 2024 was approximately $2.6 million, compared to $3.8 million for the same period in 2023, and consisted of combined net sales of Zembrace® SymTouch® and Tosymra®. Cost of Sales for the fourth quarter 2024 was approximately $1.2 million, compared to $2.4 million for the same period in 2023.

R&D expenses for the fourth quarter 2024 were approximately $8.3 million, compared to $17.1 million for the same period in 2023. This decrease is predominantly due to decreased clinical expenses resulting from fewer clinical trials and pipeline prioritization efforts.

SG&A expenses for the fourth quarter 2024 were $15.6 million, compared to $11.6 million for the same period in 2023. The increase was primarily due to an increase in financial reporting expenses, sales and marketing, and professional fees associated with TNX-102 SL's NDA submission.

Net loss available to common stockholders was $22.1 million, or $9.77 per basic and diluted share, for the fourth quarter 2024, compared to net loss available to common stockholders of $27.3 million, or $2,179.83 per basic and diluted share, for the same period in 2023. The basic and diluted weighted average common shares outstanding for the fourth quarter 2024 was 2,263,535 compared to 12,534 shares for the same period in 2023.

Full Year 2024 Financial Results

Net product revenue for the full year 2024 was approximately $10.1 million. Cost of sales for the full year 2024 was approximately $7.8 million.

R&D expenses for the full year 2024 were approximately $40.0 million, compared to $86.7 million in 2023. This decrease is predominantly due to fewer clinical trials and from pipeline prioritization efforts, which further decreased non-clinical, manufacturing, employee-related and professional expenses as well.

SG&A expenses for the full year 2024 were $40.1 million, compared to $34.8 million in 2023. The increase was primarily due to an increase in financial reporting expenses, sales and marketing expenses associated with the Company's recently acquired marketed products, and professional fees associated with TNX-102 SL's NDA submission.

Net loss available to common stockholders was $130.0 million, or $176.60 per basic and diluted share, for the full year 2024, compared to net loss available to common stockholders of $116.7 million, or $14,720.25 per basic and diluted share, in 2023. The basic and diluted

weighted average common shares outstanding for the full year 2024 was 736,339 compared to 7,925 shares for 2023.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to advance TNX-102 SL, a product candidate for the management of fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia and for which a PDUFA (Prescription Drug User Fee act) goal date of August 15, 2025 has been assigned for a decision on marketing authorization. The FDA has also granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also 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 CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the National Institute on Drug Abuse. 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 Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

* 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Year Ended December 31,		Three Months Ended December 31,	
	2024	**2023**	**2024**	**2023**
REVENUE:				
Product revenue, net	$ 10,094	$ 7,768	$ 2,582	$ 3,779
COSTS AND EXPENSES:				
Cost of revenue	7,765	4,741	1,183	2,367
Research and development	39,972	86,655	8,297	17,120
Selling, general and administrative	40,101	34,752	15,582	11,621
Asset impairment charges	58,957	—	—	—
	146,795	126,148	25,062	31,108
Operating loss	(136,701)	(118,380)	(22,480)	(27,329)
Grant income	2,594	—	926	—
Gain on change in fair value of warrant liabilities	6,150	—	—	—
Other (expense) income, net	(2,079)	1,722	(554)	7
Net loss	(130,036)	(116,658)	(22,108)	(27,322)

Net loss available to common stockholders	$ (130,036)	$ (116,658)	$ (22,108)	$ (27,322)
Net loss per common share, basic and diluted	$ (176.60)	$ (14,720.25)	$ (9.77)	$ (2,179.83)
Weighted average common shares outstanding, basic and diluted	736,339	7,925	2,263,535	12,534

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands)
(Unaudited)[1]

	December 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 98,776	$ 24,948
Accounts Receivable, net	3,683	-
Inventory	8,408	13,639
Prepaid expenses and other	8,135	9,181
Total current assets	119,002	47,768
Other non-current assets	43,888	106,689
Total assets	$ 162,890	$ 154,457
Liabilities and stockholders' equity		
Total liabilities	$ 23,332	$ 48,932
Stockholders' equity	139,558	105,525
Total liabilities and stockholders' equity	$ 162,890	$ 154,457

[1]The condensed consolidated balance sheets for the years ended December 31, 2024 and 2023 has been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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Indication and Usage

Zembrace® SymTouch® (sumatriptan succinate) injection (Zembrace) and Tosymra® (sumatriptan) nasal spray are prescription medicines used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace and Tosymra are not used to prevent migraines. It is not known if Zembrace or Tosymra are safe and effective in children under 18 years of age.

Important Safety Information

Zembrace and Tosymra 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 and Tosymra are 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 or 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

- 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, or dihydroergotamine. Ask your provider for a list of these medicines if you are not sure.
- 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 or Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace and 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.

Zembrace and 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 Zembrace or 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.
- 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 and Tosymra include: pain and redness at injection site (Zembrace only); 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; application site (nasal) reactions (Tosymra only) and throat irritation (Tosymra only).

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 and Tosymra. For more information, ask your provider.

This is the most important information to know about Zembrace and Tosymra but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. You can also visit https://www.tonixpharma.com or call 1-888-869-7633.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Source: Tonix Pharmaceuticals Holding Corp.