

June 17, 2024



# **Tonix Pharmaceuticals Presented Poster of Tonmya™ for the Management of Fibromyalgia at the Annual European Congress of Rheumatology (EULAR) 2024**

*Treatment with Tonmya™ (TNX-102 SL, sublingual cyclobenzaprine HCl) in Phase 3 RESILIENT study significantly reduced daily pain and demonstrated broad fibromyalgia symptom improvement, as demonstrated by significant improvement on the primary pain endpoint and on all six key secondary endpoints*

*RESILIENT was the second Phase 3 study to reach statistical significance on the primary endpoint*

*New Drug Application (NDA) submission to the FDA on track for the second half of 2024*

CHATHAM, N.J., June 17, 2024 (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, presented data from a poster presentation at the Annual European Congress of Rheumatology (EULAR) 2024, held June 12-15, 2024 at the Messe Wien Congress Center in Vienna, Austria. A copy of the Company's poster presentation is available under the [Scientific Presentations](#) tab of the Tonix website at [www.tonixpharma.com](http://www.tonixpharma.com).

In the poster presentation titled, "*Targeting Non-Restorative Sleep in Fibromyalgia with Bedtime TNX-102 SL (Sublingual Cyclobenzaprine HCl) Significantly Improves Pain in RESILIENT, a Confirmatory Phase 3 Randomized Clinical Trial*", Tonmya met the pre-specified primary endpoint in the Phase 3 RESILIENT trial, significantly reducing daily pain compared to placebo (p-value=0.00005) in participants with fibromyalgia while also demonstrating broad syndromal improvement. Tonmya demonstrated 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. Tonmya was well tolerated with an adverse event (AE) profile comparable to prior studies and no new safety signals observed.

In pre-specified exploratory analyses, Tonmya treatment also improved depressive symptoms measured by the Beck Depression Inventory and improved female sexual function by the Changes in Sexual Function Questionnaire in the RESILIENT trial.

"People suffering with fibromyalgia tend to struggle with daily activities, have impaired quality of life and are frequently disabled", said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We believe the activity of Tonmya on pain, sleep quality, fatigue

cognitive dysfunction, and depression are indicative of the broad-spectrum activity of Tonmya, suggesting Tonmya treats fibromyalgia at a syndromal level. We are excited by the prospect of offering this patient population its potential first new therapy option in more than a decade.”

Tonix remains on track to submit an NDA to the U.S. Food and Drug Administration (FDA) in the second half of 2024 for Tonmya for the management of fibromyalgia.

### **Tonix Pharmaceuticals Holding Corp.\***

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix’s development portfolio is focused on central nervous system (CNS) disorders. Tonix’s priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for Tonmya<sup>1</sup>, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction as well as fibromyalgia-type Long COVID. Tonix’s CNS portfolio includes TNX-1300 (cocaine esterase), a biologic designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation and is in Phase 2 development supported by a grant from the National Institute of Drug Abuse. Tonix’s immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a 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 also has product candidates in development in the areas of rare disease and infectious disease. 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 and have not been approved for any indication.

<sup>1</sup>Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://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.

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