

# Tonix Pharmaceuticals Announces Poster Presentation at the IASP 2024 World Congress on Pain

Presentation to highlight statistically significant Phase 3 results of Tonmya™ for the management of fibromyalgia, including improvement in pain and sleep quality

Tonix granted FDA Fast Track Designation for Tonmya™; NDA submission on track for the second half of 2024

CHATHAM, N.J., July 30, 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, today announced a poster presentation at the International Association for the Study of Pain (IASP) 2024 World Congress on Pain, being held August 5-9, 2024 in Amsterdam, Netherlands. Details on the presentation can be found below.

A copy of the Company's poster presentations will be available under the <u>Scientific</u> <u>Presentations</u> tab of the Tonix website at <u>www.tonixpharma.com</u> following the conference. Additional meeting information can be found on the IASP website <u>here</u>.

### **Poster Presentation Details**

Presenter: Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals

Title: Targeting Fibromyalgia Non-Restorative Sleep with Bedtime TNX-102 SL

(Sublingual Cyclobenzaprine HCI): Results of the Positive Phase 3 RESILIENT

Trial Consistent with Syndromic Improvement

Abstract: #WE685

Date/Time: Wednesday, August 7, 2024, 3:15 p.m. CEST

# 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\*, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has granted Fast Track designation to Tonmya for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction. Tonix's CNS portfolio includes TNX-1300 (cocaine

esterase), a biologic designed to treat cocaine intoxication that has Breakthrough Therapy designation. 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 <sup>®</sup> SymTouch <sup>®</sup> (sumatriptan injection) 3 mg and Tosymra <sup>®</sup> (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

\*Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

\*\*Tonix's product development candidates are investigational new drugs or biologics and have 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 <a href="https://www.tonixpharma.com">www.tonixpharma.com</a>.

## **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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Source: Tonix Pharmaceuticals Holding Corp.