

Tonix Pharmaceuticals Announces Oral Presentation and Three Poster Presentations at the 2024 Military Health System Research Symposium (MHSRS)

Oral presentation highlights TNX-102 SL (sublingual cyclobenzaprine HCl) treatment in Phase 3 RESILIENT study demonstrating statistically significant improvement in fibromyalgia nociplastic pain and in all six key secondary endpoints, including sleep quality

Posters highlighting other TNX-102 SL programs in clinical development, including acute stress disorder

Poster demonstrating automated high-throughput assay enabling screening for therapeutics to accelerate wound healing

CHATHAM, N.J., Aug. 21, 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 that representatives of the Company will deliver an oral presentation and present three posters at the 2024 Military Health System Research Symposium (MHSRS), being held August 26-29, 2024, in Kissimmee, Fla. Details on the presentations can be found below.

Copies of the Company's oral presentation and posters 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 MHSRS website <u>here</u>.

Oral Presentation

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

Session: Assuaging Agony: Novel Pain Therapeutics

Title: Efficacy and Safety of Bedtime TNX-102 SL (Sublingual Cyclobenzaprine HCI)

for the Management of Fibromyalgia: Results from the Confirmatory Phase 3

Randomized, Double-Blind, Placebo-Controlled RESILIENT Trial

Date/Time: Tuesday, August 27, 2024, 1:00 p.m. – 3:00 p.m. ET

Poster Presentations

Presenter: Megan Parmenter, Ph.D., Massachusetts General Hospital

Title: Two Clinical Trials of Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) in

Military-Related Posttraumatic Stress Disorder (PTSD) Provide Rationale to Study TNX-102 SL in the Aftermath of Trauma to Reduce Acute Stress

Disorder (ASD) and Prevent PTSD

Date/Time: Tuesday, August 27, 2024, 3:00 p.m. – 5:00 p.m. ET

Presenter: Sina Bavari, Ph.D., EVP, Infectious Disease Research and Development,

Tonix Pharmaceuticals

Title: Integrating Automated High-Throughput Scratch Assay and Cell Painting for

Comprehensive Analysis of Cell Migration and Wound Healing

Date/Time: Wednesday, August 28, 2024, 1:00 p.m. - 3:00 p.m. ET

Presenter: Samuel McLean, M.D., Professor of Psychiatry and Emergency Medicine at

the UNC School of Medicine

Title: Development of the AURORA Platform Trial Network to Test Interventions to

Reduce Acute Stress Reaction Symptoms, and Illustration of Use Testing

Sublingual Cyclobenzaprine TNX-102 SL

Date/Time: Tuesday, August 27, 2024, 3:30 p.m. – 5:30 p.m. ET.

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 recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to \$34 million over five years in an Other Transaction Agreement (OTA) to develop TNX-4200 small molecule broad-spectrum antiviral agents 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. The company's Good Manufacturing Practice (GMP)-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801 and the GMP suites are ready to be reactivated in case of a national or international emergency. 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 TNX-102 SL, 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 TNX-102 SL 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® 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.

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.

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.

Investor Contact

Jessica Morris Tonix Pharmaceuticals <u>investor.relations@tonixpharma.com</u> (862) 904-8182

Peter Vozzo ICR Westwicke peter.vozzo@westwicke.com (443) 213-0505

Media Contact

Ray Jordan Putnam Insights ray@putnaminsights.com (949) 245-5432



Source: Tonix Pharmaceuticals Holding Corp.