August 29, 2024

Tonix Pharmaceuticals Presented Data from Two Posters on TNX-102 SL for Reduction of Acute Stress Reaction and Prevention of PTSD and One Poster for Wound Healing at the 2024 Military Health System Research Symposium (MHSRS)

Investigator-initiated Phase 2 trial to evaluate TNX-102 SL's potential to reduce severity of acute stress reaction (ASR) and frequency of acute stress disorder (ASD) and posttraumatic stress disorder (PTSD) expected to begin third quarter 2024

Currently, no medication approved at or near point-of-care to treat patients suffering from traumatic events and support their long-term health

CHATHAM, N.J., Aug. 29, 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 clinical data on? acute stress reaction and prevention of PTSD data of TNX-102 SL in two poster presentations and presented preclinical data demonstrating automated high-throughput assay enabling screening for therapeutics to accelerate wound healing in a third poster presentation at the 2024 Military Health System Research Symposium (MHSRS), held August 26-29, 2024, in Kissimmee, Fla. Copies of the Company's posters, titled:

"*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*";

"*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*";

"*Integrating Automated High-Throughput Scratch Assay and Cell Painting for Comprehensive Analysis of Cell Migration and Wound Healing"*, are available under the Scientific Presentations tab of the Tonix website atwww.tonixpharma.com.

TNX-102 SL is being evaluated for the reduction in severity of acute stress reaction (ASR) and the frequency of acute stress disorder (ASD) and posttraumatic stress disorder (PTSD) when administered within 24 hours of trauma event. In two double-blind, randomized clinical trials of military-related PTSD, TNX-102 SL showed effects on sleep and PTSD symptoms in

two and four weeks of treatment[1]. Supportive data on the effects of TNX-102 SL on reducing PTSD symptoms suggest early intervention immediately after trauma using TNX-102 SL has the potential to reduce ASR/ASD symptoms which are similar to those of PTSD[2,3]. TNX-102 SL has been well-tolerated with no recognized liability for tolerance or abuse. Data from these trials support testing of TNX-102 SL within 24 hours of index trauma for effects on acute stress reaction (ASR) symptoms and the incidence of PTSD. In the U.S. Department of Defense-funded Optimizing Acute Stress Reaction Interventions (OASIS) trial conducted by the University of North Carolina under an investigator-initiated investigational new drug (IND) application, 14 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 results may ultimately provide military personnel with a new treatment option that, when administered in the early aftermath of a traumatic event to individuals with ASR symptoms, improves warfighter function.

“In previous trials, TNX-102 SL has been shown to improve sleep quality in PTSD and increased activity on sleep and stress-related symptoms in the first several weeks of treatment after a trauma event”, said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Since sleep disturbance plays a critical role in the development and maintenance of PTSD, sleep improvements may reorient the trajectory of posttraumatic pathology from acute trauma towards early recovery. The OASIS study is driven by the observation that the symptoms of ASR and PTSD are similar and by the hypothesis that TNX-102 SL’s effect on sleep quality may reduce ASR symptoms, potentially providing military personnel, veterans, and civilians with a new treatment option that, when administered in the early aftermath of a traumatic event, improves recovery, job performance, and quality of life.”

The investigator-initiated OASIS trial will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients presenting to the emergency department (ED) after a motor vehicle collision. The trial plans to enroll approximately 180 trauma survivors at ED study sites around the U.S. Participants will be randomized in the ED to receive a two-week course of either TNX-102 SL 5.6 mg or placebo. The first participant for the OASIS trial is expected to enroll in the third quarter of 2024.

The OASIS trial will build upon a foundation of knowledge and infrastructure developed through the UNC-led, $40 million AURORA initiative. AURORA is a major national research initiative to improve the understanding, prevention and recovery of individuals who experience a traumatic event. AURORA is supported by funding from the National Institutes of Health (NIH), leading brain health nonprofit One Mind, private foundations, and partnerships with leading tech companies, such as Mindstrong Health and Verily Life Sciences, the healthcare arm of Alphabet, the parent company of Google.

Acute and chronic stress disorders can affect both civilian and military populations. According to the National Center for PTSD, in the U.S. about 60% of men and 50% of women experience at least one trauma in their lives.[4] In the U.S. alone, one-third of ED visits (40-50 million patients per year) involve evaluation after trauma exposures, and in a 2014 study involving 3,157 US veterans, 87% reported exposure to at least one potentially traumatic event during their service.[5] Moreover, as many as 500,000 U.S. troops who

served in wars between 2001 and 2015 were diagnosed with PTSD.[6]

The third poster, titled "*Integrating Automated High-Throughput Scratch Assay and Cell Painting for Comprehensive Analysis of Cell Migration and Wound Healing*", demonstrated optimization of a highly efficient scratch-wound assay development method. The scratch-wound assay, commonly used to study wound healing, has limitations that the study addresses by introducing an automated miniaturized high-throughput wound healing assay, enabling mass screening and identification of novel therapies for wound-healing. The screening technology was merged with cell-painting to allow discovery of morphological characteristics to identify mechanism of action of drugs for wound healing.

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 Manufacutring 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.

This press release and further information about Tonix can be found at www.tonixpharma.com.

1. *TNX-102 SL (cyclobenzaprine HCl sublingual tablets) has not been approved for any*

indication; (Tonmya™ is conditionally approved by FDA for the management of fibromyalgia)

2. *Sullivan GM, et al. Randomized clinical trial of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related PTSD and the role of sleep quality in treatment response. Psychiatry Res. 2021 Jul;301:113974.*
3. *Parmenter ME, et al. A phase 3, randomized, placebo-controlled, trial to evaluate the efficacy and safety of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related posttraumatic stress disorder. Psychiatry Res. 2024 (In Press). https://doi.org/10.1016/j.psychres.2024.115764*
4. *Goldstein RB, et al. Soc Psychiatry Psychiatr Epidemiol. 2016. 51(8):1137-48*
5. *Wisco BE, et al. J Clin Psychiatry. 2014. 75(12):1338-46*
6. *Thompson M. Time. 2015;185(12):40-3*

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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