May 30, 2024

Tonix Pharmaceuticals Announces Two Poster Presentations of TNX-102 SL (Sublingual Cyclobenzaprine HCl) at the ASCP Annual Meeting

In the Phase 2 PREVAIL trial in fibromyalgia-type Long COVID, bedtime TNX-102 SL resulted in a signal in fatigue, sleep and cognitive function

Phase 2, investigator-initiated OASIS trial is designed to examine the safety and efficacy of TNX-102 SL in treating Acute Stress Disorder (ASD) after motor vehicle collision

First patient in OASIS expected to enroll in second quarter 2024

CHATHAM, N.J., May 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 two poster presentations at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting being held May 28-31, 2024 in Miami Beach, Fla. Copies of the presentations are available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com.

In the poster presentation titled, "*Effect of Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) on Pain, Sleep, Fatigue, and Cognition in Fibromyalgia-Type Long COVID: Results of a Double-Blind Randomized Proof-of-Concept Phase 2 Study*," TNX-102 SL showed a robust effect size of 0.5 in improving fatigue and showed consistent activity across secondary measures of sleep quality, cognitive function, disability and Patient Global Impression of Change, but did not meet the primary endpoint of multi-site pain reduction at Week 14. Prior to the trial, Tonix had pre-specified that any effect size greater than 0.2 would be considered of interest for further study and, even given a substantial placebo response in pain magnitude measurements, key endpoints such as sleep quality diary (ES = 0.23), PROMIS Sleep Disturbance (ES = 0.32), PROMIS Fatigue (ES = 0.50), PROMIS Cognitive Function (ES = 0.21), the Insomnia Severity Index (ES = 0.24) and the Sheehan Disability Scale (ES = 0.26) all matched the criterion for further evaluation. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies and no new safety signals observed.

"These results further support the growing evidence that for most Long COVID patients, symptoms are at least partly driven by central nervous system mechanisms rather than persistent exposure to the SARS-CoV-2 virus," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "While Tonix is preparing for submission of a New Drug Application (NDA) for TNX-102 SL for the management of fibromyalgia (branded "Tonmya"), we believe that these results demonstrate it may also be effective in managing pain and

aiding in sleep quality for patients with fibromyalgia-type Long COVID, further indicating that for many patients Long COVID should be viewed in the context of a chronic overlapping pain condition like fibromyalgia or chronic fatigue syndrome/myalgic encephalomyelitis framework."

In the poster presentation titled, *"Optimizing Acute Stress Reaction (ASR) Interventions with TNX-102 SL* (Sublingual Cyclobenzaprine HCl) – The OASIS Trial: Sustaining Civilian Performance Post-Trauma by Reduction of ASR and Prevention of ASD/PTSD*," TNX-102 SL will be evaluated for the reduction in severity of acute stress reaction (ASR) and the frequency of acute stress disorder (ASD) and posttraumatic stress disorder (PTSD) in civilians after a motor vehicle collision. To reduce the persistence of ASR symptoms and the rate and severity of ASD and PTSD, it may be critical to intervene in the immediate aftermath of trauma. Currently, there are no medications available at or near the point of care to treat patients suffering from acute trauma and support long-term health. Previous trials of TNX-102 SL showed that it reduced military PTSD symptoms in as early as two weeks with favorable tolerability. The first participant for the OASIS trial is expected to enroll in the second quarter of 2024.

"Previous trials of TNX-102 SL in PTSD suggested activity on sleep and stress related symptoms in the first several weeks of treatment,"[1,2] said Dr. Lederman. "The study is motivated 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, possibly 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."

TNX-102 SL is a centrally acting, non-opioid medication, and, under the trade name Tonmya™, Tonix remains on track to submit an NDA to the U.S. Food and Drug Administration (FDA) in the second half of 2024 for the management of fibromyalgia. Tonix has scheduled a Type B pre-NDA meeting with FDA for the second quarter of 2024.

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[1], 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 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.

[1]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.

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

1. *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.*
2. *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*

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

investor.relations@tonixpharma.com
(862) 904-8182

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

Media Contact

Katie Dodge
LaVoieHealthScience
kdodge@lavoiehealthscience.com
(978) 360-3151

Source: Tonix Pharmaceuticals Holding Corp.