May 22, 2024

Tonix Pharmaceuticals to Deliver an Oral Presentation and Present Two Posters at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting

Oral Presentation of Tonmya™ (TNX-102 SL) for Fibromyalgia; NDA preparation in progress

Posters Highlighting Other TNX-102 SL Programs In Clinical Development; Long COVID and Acute Stress Disorder

CHATHAM, N.J., May 22, 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 the Company will deliver an oral presentation and present two posters at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting being held May 28-31, 2024 at the Loews Miami Beach Hotel in Miami Beach, Fla.

The oral presentation will detail findings of studies of Tonmya (TNX-102 SL, sublingual cyclobenzaprine HCl) in fibromyalgia. One poster will describe the Phase 2 proof of concept study of TNX-102 SL in fibromyalgia-type Long COVID. The second poster will describe the upcoming investigator-initiated Phase 2 trial of TNX-102 SL in treating acute stress disorder and preventing posttraumatic stress disorder after motor vehicle collision, which will be conducted by the University of North Carolina, the sponsor of the study.

TNX-102 SL is a centrally acting, non-opioid medication, which is trade named Tonmya™ for the management of fibromyalgia. As previously announced, the second statistically significant Phase 3 study of Tonmya, RESILIENT, met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo in participants with fibromyalgia (p=0.00005). Statistically significant and clinically meaningful results (p=0.001 or better) were also seen in all key secondary endpoints related to improving sleep quality, reducing fatigue, and improving overall fibromyalgia symptoms and function.

Tonix plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2024 for Tonmya for the management of fibromyalgia and has scheduled a Type B pre-NDA meeting with FDA for the second quarter of 2024.

Copies of the Company's presentation and posters will be available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com following the conference.

Additional meeting information can be found on the ASCP website here.

Oral Presentation Details

Presenter: Seth Lederman, M.D., Chief Executive Officer

Title: Effects of Bedtime TNX-102 SL (Sublingual Cyclobenzaprine (CBP) HCl) on Mood and Anxiety Symptoms in Fibromyalgia: Results of the Phase 3 RESILIENT Trial

Date/Time: May 29, 2024, 3:00 p.m. ET

Poster Presentation Details

Presenter: Herbert Harris, M.D., Ph.D., Executive Vice President, Translational Medicine

Title: 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

Date/Time: May 30, 2024, 12:30 p.m. ET

Presenter: David Hsu, Ph.D., Senior Scientist

Title: 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

Date/Time: May 30, 2024, 12:30 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'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.

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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