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Tonix Pharmaceuticals Announces Positive Pre-NDA CMC Meeting with FDA for Tonmya™ for the Management of Fibromyalgia

Company aligned with FDA on key CMC topics

Tonix also has completed the second and final pre-New Drug Application (NDA) meeting and discussed nonclinical, clinical pharmacology and clinical matters with the FDA, formal minutes pending

On track to submit NDA to the FDA in the second half of 2024

CHATHAM, N.J., June 20, 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 receipt of the formal minutes from a recent pre-New Drug Application (NDA) Type-B Chemistry, Manufacturing, and Controls (CMC) meeting with the U.S. Food and Drug Administration (FDA) for Tonmya™ for the management of fibromyalgia. The purpose of the meeting was to seek alignment and agreement with the FDA on key CMC topics to support a planned NDA submission for Tonmya for the management of fibromyalgia. Based on formal written feedback, the Company believes it is aligned with the FDA on key topics, including proposed drug substance and drug product commercial specifications, shelf life assignment, manufacturing and commercial drug packaging.

In addition, the Company has completed the second and final pre-NDA meeting for Tonmya with the FDA and discussed nonclinical, clinical pharmacology and clinical matters. The Company awaits formal minutes after which it expects to announce the results of that meeting. The Company remains on track to submit the NDA for Tonmya for the management of fibromyalgia to the FDA in the second half of 2024.

"We remain encouraged and excited about the prospect of bringing the first new treatment to market for fibromyalgia patients in over a decade, and this encouraging meeting with the FDA is an important milestone as we head into the final stages of completion of the NDA package," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "During the pre-NDA CMC meeting, the FDA affirmed alignment with Tonix on CMC content and commercial strategy for Tonmya, and we are very appreciative of the FDA's guidance as we prepare for our NDA submission. We are currently actively preparing a dual manufacturing launch strategy with global contract development and manufacturing organization (CDMO) Almac Pharma Services and another CDMO."

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 6 million to 12 million adults in the U.S., the majority of whom are women. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled. Physicians and patients report common dissatisfaction with currently marketed products.

About Tonmya* (also known as TNX-102 SL)

Tonmya is a centrally acting, non-opioid, non-addictive, bedtime medication. The tablet is a patented sublingual formulation of cyclobenzaprine hydrochloride developed for the management of fibromyalgia. In December 2023, the company announced highly statistically significant and clinically meaningful topline results in RESILIENT, the second pivotal Phase 3 clinical trial of Tonmya for the management of fibromyalgia. In the study, Tonmya met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo ($p=0.00005$) in participants with fibromyalgia. Statistically significant and clinically meaningful results were also seen in all six key secondary endpoints related to improving sleep quality, reducing fatigue and improving overall fibromyalgia symptoms and function. RELIEF, the first statistically significant Phase 3 trial of Tonmya in fibromyalgia, was completed in December 2020. It met its pre-specified primary endpoint of daily pain reduction compared to placebo ($p=0.010$) and showed activity in key secondary endpoints.

*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 Pharmaceuticals Holding Corp.*

Tonix is a 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 Tonmya¹, 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 FDA Breakthrough Therapy designation that is in Phase 2 development and is supported by a grant from the National Institute of Drug Abuse. 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.

¹Tonmya™ 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.

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.

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