July 25, 2024

Tonix Pharmaceuticals Granted Fast Track Designation by FDA for Tonmya™ for Fibromyalgia

Fast Track is designed to expedite FDA review of important new drugs to treat serious conditions and fill an unmet medical need

Fast Track designation for Tonmya recognizes fibromyalgia as a serious condition impacting more than 10 million U.S. adults

NDA submission on track for second half 2024

Tonmya has the potential to be the first new drug for treating fibromyalgia in more than 15 years

CHATHAM, N.J., July 25, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia. Tonmya is a non-opioid, centrally-acting analgesic drug under development for treating fibromyalgia, which is a common chronic pain condition affecting mostly women. The designation validates that fibromyalgia is a serious condition and that Tonmya has the potential to address this unmet medical need. Tonix previously announced alignment with the FDA regarding the content of its proposed NDA submission, following completion of the Company's pre-NDA meetings. The Company reaffirms its guidance to submit the NDA for Tonmya to the FDA in the second half of 2024.

"The FDA's decision to grant Tonmya Fast Track designation supports our goal of bringing this well tolerated, non-opioid analgesic treatment option to the market in 2025," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "The designation underscores the importance of addressing the unmet needs of fibromyalgia patients, who report dissatisfaction with current treatment options. If approved by the FDA, we expect Tonmya to become the first new pharmacotherapy for fibromyalgia in over 15 years. The NDA being prepared supports Tonmya's potential position as a first line therapy for fibromyalgia, indicated for long-term daily use at bedtime."

The FDA's Fast Track process is designed to facilitate development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially bring important new medicines to patients sooner. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development. Tonix plans to request Priority Review designation, and if

granted, FDA may accelerate the review of the NDA. For more information on Fast Track designation, please visit the FDA's website at www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

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

Tonmya is a centrally acting, non-opioid, analgesic investigational drug for bedtime use. 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 (all $p\leq0.001$). 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. In both pivotal studies, the most common treatment-emergent adverse event was tongue or mouth numbness at the administration site, which was temporally-related to dosing, self-limited, never rated as severe, and rarely led to study discontinuation (one participant in each study). Tonix has announced the results of two positive pre-NDA meetings and alignment with FDA on nonclinical, clinical pharmacology, clinical and CMC features of the NDA submission.

About Fibromyalgia

Fibromyalgia is a common 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, non-restorative sleep, fatigue, and brain fog (or cognitive dysfunction). Other associated symptoms include mood disturbances, including anxiety and depression, headaches, and abdominal pain or cramps. 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.

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, 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. 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.

*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'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.

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