July 8, 2024

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

Tonmya is a potential new first-line, centrally acting non-opioid analgesic for the management of fibromyalgia

Approximately 10 million adults in the U.S. are affected by fibromyalgia, predominantly women

NDA submission target confirmed for second half 2024, with potential for FDA approval in second half 2025

CHATHAM, N.J., July 08, 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) meeting with the U.S. Food and Drug Administration (FDA) for Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia. At the meeting, the Company and the FDA agreed that the proposed data package is sufficient to support the NDA submission. The Company reaffirmed its guidance to submit the NDA for Tonmya to the FDA in the second half of 2024 which would allow for a potential FDA approval in the second half of 2025.

“We are delighted with the results of this critical milestone meeting with the FDA to discuss our NDA, and we are appreciative of the FDA’s guidance throughout this process. We believe Tonmya has the potential to greatly benefit fibromyalgia patients, many of whom remain dissatisfied with the current treatment options, and many of whom turn to addictive, detrimental opioids as off-label treatments,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “The positive results from this pre-NDA meeting underscore the completeness of our data package in support of registration of Tonmya for the management of fibromyalgia.”

On June 20, 2024, Tonix announced receipt of formal minutes of a pre-NDA Type-B Chemistry, Manufacturing, and Controls (CMC) meeting confirming alignment with the FDA on key CMC topics to support the NDA submission. Today’s announcement confirms alignment with the nonclinical, clinical pharmacology and clinical features of the NDA submission, following completion of Tonix’s second and final pre-NDA meeting.

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, 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. According to the recent report from the U.S. National Academies of Sciences, fibromyalgia is a diagnosable condition that may also occur in the context of Long COVID.[1]

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

Tonmya is a centrally acting, non-opioid, non-addictive, bedtime investigational drug. 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. 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 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 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.

*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.

[1]U.S. National Academies of Sciences, Engineering, and Medicine. 2024.*A Long COVID Definition: A chronic, systemic disease state with profound consequences.* Washington, DC: The National Academies Press. https://doi.org/10.17226/27768. http://www.nationalacademies.org/long-covid-definition.

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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