March 6, 2024

Tonix Pharmaceuticals Selects EVERSANA® to Support Launch Strategy and Commercialization Planning of Tonmya™ for the Management of Fibromyalgia

Tonmya is a potential new first-line, centrally acting non-opioid analgesic for the management of fibromyalgia, supported by statistically significant results from two Phase 3 trials

New Drug Application (NDA) submission to the FDA planned for the second half of 2024

CHATHAM, N.J., March 06, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, announced today that EVERSANA®, a leading provider of commercialization services to the global life sciences industry, has been selected to support the launch strategy and commercial planning of Tonmya (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablets) in the U.S. Specifically, EVERSANA will work with Tonix to assess the fibromyalgia landscape and help plan an efficient go-to-market strategy.

“EVERSANA shares our commitment to delivering novel therapeutics to patients in need,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “We are excited to further refine our business strategy for the anticipated launch of Tonmya in 2025. It has been over a decade since patients suffering with fibromyalgia have been provided a new therapeutic option.”

“Today’s dynamic market requires experts that can help customers navigate the complexities of launch and commercial planning,” said Jim Lang, CEO, EVERSANA. “Together, we look forward to bringing a new treatment option to market for the millions of Americans suffering from this chronic disorder.”

Tonmya is a centrally acting, non-opioid medication. As previously announced, Tonix’s second positive Phase 3 study, RESILIENT, 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 (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 to the U.S. Food and Drug Administration 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.

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, a second positive 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 key secondary endpoints related to improving sleep quality, reducing fatigue and improving overall fibromyalgia symptoms and function. RELIEF, the first positive 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.

About EVERSANA®

EVERSANA is a leading independent provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 650 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences solutions for a healthier world. To learn more about EVERSANA, visit eversana.com or connect through LinkedIn and X.

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 Tonmya, a product candidate for which two positive 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 with 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.

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, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, 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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Source: Tonix Pharmaceuticals Holding Corp.