June 3, 2024

Tonix Pharmaceuticals Presented New Data on Tonmya™ Suggesting Activity for Improvement in Fibromyalgia-Associated Depression Severity in an Oral Presentation at ASCP Annual Meeting

Tonmya treatment was associated with improvement in depressive symptoms as measured by the Beck Depression Inventory-II

In addition, post-hoc analyses showed improvement in depression, anxiety, memory and energy items on the Fibromyalgia Impact Questionnaire-Revised

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

CHATHAM, N.J., June 03, 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, presented new data from the Phase 3 RESILIENT trial of Tonmya (TNX-102 SL, cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia in an oral presentation at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting on May 29, 2024 in Miami Beach, Fla. A copy of the presentation is available under the Scientific Presentations tab of the Tonix website atwww.tonixpharma.com.

In the oral presentation titled, *"Effects of Bedtime TNX-102 SL (Sublingual Cyclobenzaprine HCl) on Mood and Anxiety Symptoms in Fibromyalgia: Results of the Phase 3 RESILIENT Trial,"* Seth Lederman, MD, Chief Executive Officer, presented new data suggesting activity for improvement in depressive symptoms with Tonmya.

Depression was frequent among patients enrolled in the RESILIENT trial: ~47% reported experiencing depression within the past 6 months upon fibromyalgia diagnosis and ~25% of the intent-to-treat (ITT) population had experienced a lifetime major depressive episode (MDE). The effect of Tonmya on depressive symptoms was studied using the Beck Depression Inventory-II (BDI-II). Patients started with a baseline mean (standard deviation) for placebo of 10.0 (6.72) and Tonmya of 9.6 (6.32). The BDI-II score separated at Week 2 with a nominal p-value of <0.01. By Week 14, the total BDI-II score in the TNX-102 SL group improved over placebo with a nominal p-value of 0.005 and an effect size of 0.27.

Dr. Lederman said, "Although pain is the prototypic symptom in fibromyalgia and the validated FDA endpoint for the approval of a new drug, depression severity is also a prominent factor in the quality of life for fibromyalgia sufferers. In one study, depressive

symptoms had a higher correlation with impaired quality of life than any other symptom, including pain frequency and intensity.[2] The improvement in depression observed in the Phase 3 RESILIENT was particularly striking since the mean entry score of 10 reflects mild depression. Others have struggled to show benefits of traditional antidepressants in mild depression and consequently many antidepressants have been studied in moderate or severely depressed patients and the benefits of such drugs for patients with mild depression have been inferred."

Dr. Lederman continued, "In addition to the BDI-II score, in *post hoc* analyses several individual items on the Fibromyalgia Impact Questionnaire-Revised (FIQR) also improved in the Tonmya-treated group, including : depression ($p < 0.001$), anxiety ($p = 0.001$), sensitivity ($p = 0.020$), memory problems ($p = 0.001$) and energy ($p < 0.001$), for which these p-values were not corrected for multiplicity. Together these findings indicate that Tonmya has broad-spectrum activity against fibromyalgia symptoms and may improve fibromyalgia at the syndromal level."

In the RESILIENT trial, as previously reported, Tonmya improved overall daily pain (p=0.00005), the pre-specified primary endpoint, making it the second Phase 3 study of Tonmya in the management of fibromyalgia to reach statistical significance on the pre-specified primary endpoint. Tonmya also demonstrated statistically significant and clinically meaningful results in all six pre-specified key secondary endpoints including those related to improving sleep quality, reducing fatigue, and improving patient global ratings and overall fibromyalgia symptoms and function."

In the RESILIENT trial, there were no new safety signals, low rates of systemic adverse events, and a favorable tolerability profile.

Tonix remains on track to submit an 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.

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.

[2]Offenbaecher M, et al. Pain is not the major determinant of quality of life in fibromyalgia. Rheumatology International 2021; 41:1995–2006

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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