May 31, 2018

Tonix Pharmaceuticals Presented New Data Related to Suicidal Ideation and Behaviors in Military-Related PTSD from the Phase 2 AtEase Study at the American Society of Clinical Psychopharmacology

Clinical Benefit of Tonmya, an FDA-Designated Breakthrough Therapy for PTSD, was Evidenced in AtEase

NEW YORK, May 31, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), presented data from the Phase 2 AtEase study of Tonmya®* (cyclobenzaprine HCl sublingual tablets) for the treatment posttraumatic stress disorder (PTSD). The presentation focused on the rationale for including suicidal individuals in the clinical trial of a treatment for PTSD.

"There are several examples in major psychiatric disorders in which pharmacological treatment of the underlying disorder may decrease suicidal behaviors," said Gregory Sullivan, M.D., Chief Medical Officer of Tonix. "Individuals with military-related PTSD have an elevated risk for suicidal behaviors, and it was hypothesized that addressing underlying PTSD with Tonmya might have an impact on reducing suicidal behaviors. Suicidal individuals were included in the AtEase study as it provided for a more representative sample of the condition for evaluating the efficacy Tonmya 2.8 mg and 5.6 mg as a potential treatment for military-related PTSD."

"Taken nightly at bedtime and absorbed by a sublingual (transmucosal) route, Tonmya is believed to reduce PTSD symptoms through improvement in sleep quality, potentially also addressing suicidal behaviors via upstream effects on sleep improvement," Dr. Sullivan continued "While rates of suicidal ideation and behaviors were not high enough to allow meaningful statistical analyses in AtEase, these data, combined with other datasets acquired by similar methodology, may provide important new information and insights leading to better prediction of, and interventions to prevent, suicides in PTSD."

As has been previously disclosed, a retrospective analysis of Tonmya 5.6 mg in the more severe PTSD subpopulation (Clinician-Administered PTSD Scale score of ≥ 33 at baseline) resulted in significantly reduced reckless or self-destructive behaviors at Week 12, potentially fulfilling a critical need in the military and veteran populations with PTSD who have elevated rates of suicidal and high-risk life-threatening behaviors. Local administration site reactions, i.e., transient mild tongue/mouth numbness, were reported more frequently in Tonmya patients in the AtEase study.

These results were presented on May 30, 2018 at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting being held in Miami Beach, Fl. The presentation entitled, *Including Suicidal Individuals in Treatment Trials: Treatment of Military-Related PTSD with TNX-102 SL, a Novel Sublingual Formulation of Cyclobenzaprine Hypothesized to Address PTSD through Improvement in Sleep Quality,* will be made available on the Company's website (www.tonixpharma.com/research-development/scientific-presentations).

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD which has been designated as a Breakthrough Therapy in December 2016. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

About Tonmya and the Phase 3 HONOR Study

Tonmya is a sublingual transmucosal tablet formulation of cyclobenzaprine that is in Phase 3 development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets) was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the U.S., the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants in approximately 40 U.S. sites. Results from an interim analysis, based on approximately the first 50% of randomized participants, are anticipated in the third quarter of 2018. In a Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that (i) a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive, and (ii) an additional abuse assessment study is not required for the NDA filing. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under an effective IND. TNX-102 SL is cleared to enter a Phase 2, potential pivotal efficacy study in agitation in Alzheimer's disease. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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 failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, 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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