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Tonix Pharmaceuticals Announces Outcome of Interim Analysis for Phase 3 RECOVERY Study of Tonmya® (TNX-102 SL) in PTSD

RECOVERY Study has Stopped Enrollment Due to Inadequate Separation from Placebo at Week-12 Based on Interim Analysis Results of the First 50% of Enrolled Participants

Company Plans to Unblind and Report Top Line Results in the Second Quarter After Currently Enrolled Study Participants Have Completed

Company is Currently Enrolling a Phase 3 Study of TNX-102 SL in Fibromyalgia Syndrome and Expects Interim Results in the Third Quarter

NEW YORK, Feb. 05, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today that the Company has decided to stop enrollment in the Phase 3 RECOVERY study of Tonmya# or TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the treatment of posttraumatic stress disorder (PTSD) following an unblinded, pre-specified interim analysis by the Independent Data Monitoring Committee (IDMC). Based on interim analysis results of the first 50% of enrolled participants, the IDMC recommended stopping the trial for futility as Tonmya is unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms, as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with Tonmya and those receiving placebo. Preliminary blinded safety data from these participants did not reveal any serious and/or unexpected adverse events and the decision to discontinue enrolling in the study is not related to safety. The Company intends to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data to determine the next steps in this program, with the topline results expected to be reported in the second quarter of 2020. The Company is reallocating resources from the PTSD program to the Phase 3 fibromyalgia study of TNX-102 SL 5.6 mg that is currently enrolling and from which interim results are expected in the third quarter.

“We are disappointed for patients suffering from PTSD that the interim analysis did not detect a signal that would warrant continued enrollment in this Phase 3 study.” commented Seth Lederman, M.D., President and Chief Executive Officer. “These results underscore the difficulty in treating PTSD.”

** TNX-102 SL is an investigational new drug and has not been approved for any indication.*

[#] *Tonmya is the FDA conditionally accepted proprietary name for TNX-102 SL for the treatment of PTSD*

About the Phase 3 RECOVERY Study

The RECOVERY study is a double-blind, randomized, placebo-controlled, adaptive design study evaluating the efficacy and safety of Tonmya 5.6 mg over 12 weeks of treatment for civilian and military-related PTSD. The study is designed to enroll approximately 250 participants across approximately 30 clinical sites in the U.S. An interim analysis was conducted by an unblinded IDMC for potential sample size re-estimation after half the target population was enrolled and evaluable. Enrollment is restricted to individuals with PTSD who experienced an index trauma within nine years of screening. The primary efficacy endpoint will be the mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with Tonmya and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. Earlier versions of the CAPS were used to support the approval of the two currently marketed PTSD treatments.

About Posttraumatic Stress Disorder (PTSD)

PTSD can develop from witnessing or experiencing a traumatic event in which there was the severe threat of, or actual occurrence of, grave physical harm or death. PTSD affects approximately 12 million Americans and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of intrusive memories, flashbacks, and nightmares. PTSD typically is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and sometimes is associated with clinical depression and suicidal thinking. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable violent or suicidal behaviors.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat pain, addiction and psychiatric conditions. Tonix's lead product candidate, TNX-102 SL*, is in Phase 3 development as a bedtime treatment for fibromyalgia. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya**) in PTSD will stop enrolling and topline data are expected in the second quarter of 2020. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. The Company has started enrollment in the Phase 3 RELIEF trial in fibromyalgia and expects data from an interim analysis in the second half of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation and the development for AUD is in the pre-Investigational New Drug (IND) application stage. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for PTSD, as well as for depression. The first efficacy study will be performed outside the U.S. TNX-1600 (a triple reuptake inhibitor) is a third product candidate being developed for PTSD, as a daytime treatment. Tonix's programs for

treating addiction conditions also include TNX-1300*** (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. TNX-801 (live horsepox virus vaccine for percutaneous administration) and TNX-1200 (live vaccinia virus vaccine for percutaneous administration) are vaccines to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.

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; 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, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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