May 30, 2017

Tonix Pharmaceuticals Presented Retrospective Analyses of Treatment Response and Remission to TNX-102 SL in a Phase 2 Military-Related PTSD Study

Highlights of these Important Findings from AtEase Presented in Pipeline Presentation at the 2017 American Society of Clinical Psychopharmacology Annual Meeting

NEW YORK, May 30, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, presented an oral pipeline presentation on May 30, 2017 entitled “Low-Dose Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD: Retrospective Analyses of the Mediators and Moderators of Treatment Response” at the 2017 American Society of Clinical Psychopharmacology Annual Meeting in Miami Beach. The presentation can be found on the Scientific Presentations page on Tonix’s website. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication. The U.S. Food and Drug Administration (FDA) has recently granted Breakthrough Therapy designation to TNX-102 SL for posttraumatic stress disorder (PTSD).

A mediator variable specifies how a particular effect or relationship between two other variables occurs. Sleep quality was a potential mediator of treatment response because improvements in sleep quality measured at week 4 by the PROMIS Sleep Disturbance scale in patients receiving TNX-102 SL 5.6 mg correlated with reduction in PTSD severity measured by change from baseline in the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) score at week 12. Baseline PTSD severity threshold was a potential moderator of treatment response. A retrospective analysis of the Phase 2 AtEase* data indicated a study entry CAPS-5 severity score of ≥33 is more aligned with the entry criteria of previous PTSD pharmacotherapy registration trials using prior CAPS versions. In the AtEase baseline CAPS-5 ≥33 subgroup, the effect size of TNX-102 SL 5.6 mg is approximately 0.5 on total CAPS-5 and also approximately 0.5 on cluster B (intrusion) and cluster E (arousal and reactivity) scores. The effect of TNX-102 SL was studied on remission, which was defined by CAPS-5 < 11 at week 12, and sustained remission, which was CAPS-5 < 11 at both weeks 8 and 12. TNX-102 SL 5.6 mg showed a statistically significant increase in sustained remission relative to placebo. TNX-102 SL was well-tolerated with a high completion rate in AtEase. Non-dose related tongue numbness was commonly reported in participants receiving TNX-102 SL 2.8 mg or 5.6 mg, which was generally transient and never rated as severe. There were no adverse event-related discontinuations in the TNX-102 SL 5.6 mg

group. No clinically significant changes in weight or vital signs over the 12 weeks of study were observed.

Seth Lederman, M.D., president and chief executive officer of Tonix, commented, “We continue to work with the FDA to accelerate the development and registration of TNX-102 SL for PTSD. Our Phase 3 HONOR study is currently enrolling participants with military-related PTSD. A planned unblinded interim analysis on 50% of the randomized participants (N=275) is on track for the first half of 2018.”

**AtEase is a Phase 2 multicenter, 12-week, double-blind placebo-controlled study conducted at 24 U.S. sites in men and women ages 18-65 years. Inclusions: PTSD DSM-5 Criterion A trauma(s) incurred during military service since 2001; screening and baseline CAPS-5 score ≥29; free of antidepressants ≥2 months from baseline; free of or washed off from other psychotropics; not participating in trauma-focused psychotherapy within a month from baseline. Exclusions: serious suicide risk; substance/alcohol use disorders within 6 months; lifetime bipolar I or II, psychotic, obsessive-compulsive, or antisocial personality disorders. Participants were randomized in 2:2:1 ratio to placebo, TNX-102 SL 2.8 mg or TNX-102 SL 5.6 mg. Primary analysis: comparison of mean change from baseline at Week 12 in CAPS-5 score between TNX-102 SL 2.8 mg and placebo.*

About TNX-102 SL and the Phase 3 HONOR Study

TNX-102 SL is a patented sublingual transmucosal 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, TNX-102 SL 5.6 mg 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 TNX-102 SL in military-related PTSD in the United States, the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of TNX-102 SL 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial, is targeting enrollment of up to approximately 550 participants across approximately 35 clinical sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent Cross-disciplinary Breakthrough meeting, the FDA confirmed that a single-study new drug application (NDA) approval could be possible if the topline data from the HONOR study are statistically very persuasive. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540. The U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique TNX-102 SL formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix’s proprietary TNX-102 SL composition. This patent is expected to provide TNX-102 SL, upon NDA approval, with U.S. market exclusivity until 2034.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address major public health challenges. In addition to TNX-102 SL for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage,

designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, to be developed as a potential smallpox-preventing vaccine.

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, substantial competition; 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, and future periodic reports filed with the SEC on or after the date hereof. 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 hereof.

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