May 22, 2017

Tonix Pharmaceuticals Presented Analyses of Potential Moderators of Treatment Response to U.S. FDA-Designated Breakthrough Therapy for PTSD, TNX-102 SL, in Phase 2 AtEase Study in Military-Related PTSD

Additional Important Findings Presented in Poster Session at the 72nd Annual Scientific Convention of the Society of Biological Psychiatry

NEW YORK, May 22, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, presented a poster on May 20, 2017, entitled "Phase 2 Multisite Double-Blind Placebo-Controlled Trial of TNX-102 SL in Military-Related Posttraumatic Stress Disorder: Mediators and Moderators of Treatment Response" (Poster No. 3001130) at the 72nd Annual Scientific Convention of the Society of Biological Psychiatry in San Diego. The poster can be found on the Scientific Presentations page on Tonix's website. A moderator is a characteristic of study participants that is associated with a treatment response.

Baseline posttraumatic stress disorder (PTSD) severity threshold and combat trauma-related PTSD were two potential moderators of treatment response that were further examined. A retrospective analysis of the Phase 2 AtEase* data indicated a study entry Clinician-Administered PTSD Scale for DSM-5 (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 CAPS-5 ≥33 subset, 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. Another potential moderator of treatment response was combat trauma, and the subgroup of AtEase with PTSD from combat-type traumas had statistically significant effects of TNX-102 SL 5.6 on CAPS-5 total severity and cluster B and cluster E, and on overall functional improvement by Sheehan Disability Scale total score, work and social items. TNX-102 SL was well-tolerated with a high completion rate in AtEase. There were no adverse event-related discontinuations; non-dose related tongue numbness was common, generally transient, and never rated as severe. 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 U.S. Food and Drug Administration (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 approximately 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.*

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

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 with U.S. market exclusivity until 2034 upon NDA approval.

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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