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Tonix Pharmaceuticals to Present New Clinical Results from Retrospective Analysis of Phase 2 AtEase Study in Military-Related PTSD

New Results to be Presented in Poster Session at International Society for Traumatic Stress Studies 32nd Annual Meeting

NEW YORK, Nov. 10, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for posttraumatic stress disorder (PTSD), will announce new results today from a retrospective analysis of the data from the AtEase study, a 12-week, randomized, double-blind, placebo-controlled Phase 2 clinical study evaluating TNX-102 SL*, 5.6 mg, in military-related PTSD.

The retrospective analysis focused on patients whose total CAPS-5 entry score was greater than or equal to 33. The analysis revealed that at the 5.6 mg dose, TNX-102 SL had a significant improvement (p=0.012) in reckless or self-destructive behavior, which can include dangerous driving, high-risk thrill-seeking, excessive alcohol or drug use, injurious behaviors to self or others, or suicidal behaviors.

Gregory Sullivan, M.D., chief medical officer of Tonix, will present these findings at the International Society for Traumatic Stress Studies 32nd Annual Meeting today, November 10, 2016, in Dallas, Texas in a poster session. The poster showcasing this new data can be found on Tonix's website on the Scientific Presentations page.

Dr. Sullivan commented, "Not only did the retrospective analysis support the viability of TNX-102 SL, 5.6 mg, as a potential treatment for military-related PTSD, it also demonstrated that Tonix's lead compound could potentially fulfill a critical need in the military and veteran populations with PTSD who have elevated rates of suicidal behaviors, as well as vehicular and other accidents resulting from high-risk behaviors." Dr. Sullivan continued, "The most common side effect in AtEase was transient tongue numbness at the site of administration in about 38% of those on TNX-102 SL. Systemic side effects that were elevated over those seen with placebo were somnolence, headache, and sedation at rates of 12-16% in the TNX-102 SL, 5.6 mg, group."

Seth Lederman, M.D., president and chief executive officer of Tonix, added, "These findings further validate our focus on PTSD and our commitment to the patients who await a new therapeutic option. The anticipated commencement of the Phase 3 HONOR study in the first quarter of 2017 provides an opportunity for patients with military-related PTSD to take part in a milestone study."

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an Investigational New Drug and has not been approved for any indication.*

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, with its lead program focusing on posttraumatic stress disorder. This disorder is a serious condition characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. 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, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, 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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