December 8, 2016

Tonix Pharmaceuticals Presented New Clinical Results from Sub-Group Analysis of Phase 2 AtEase Study in Military-Related Posttraumatic Stress Disorder (PTSD)

Sub-Group Analysis of the Phase 2 AtEase Clinical Study Confirms TNX-102 SL's Potential Efficacy in Combat-Related PTSD Patients Who are the Most Difficult to Treat

New Results Presented in Poster Session at the American College of Neuropsychopharmacology (ACNP) Annual Meeting

NEW YORK, Dec. 08, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for PTSD, recently presented new results from a sub-group analysis of the data from the AtEase study, a 12-week, randomized, double-blind, placebo-controlled Phase 2 study evaluating TNX-102 SL*, 5.6 mg, in military-related PTSD.

The sub-group analysis focused on those patients whose index trauma in the AtEase study was directly related to combat. Patients were enrolled in the trial with military-related PTSD, which was defined by trauma during military service and included combat trauma, but also included non-combat trauma such as sex trauma. Combat-related PTSD represented the majority of index traumas in the AtEase study (85%; N=197). The combat-related PTSD sub-group was analyzed for those with baseline scores of the Clinician Administered PTSD Scale for the Diagnostic and Statistical Manual for Mental Illness, Edition 5, or CAPS-5, at baseline of ≥ 33, as well as for the whole population with entry CAPS-5 ≥ 29. The sub-group analysis confirmed that patients with combat-related PTSD and entry CAPS-5 ≥ 33, treated with TNX-102 SL, 5.6 mg, showed improvement on total CAPS-5 severity, in addition to certain items in CAPS-5 cluster scores, such as reckless and self-destructive behavior. Functional improvement by the Sheehan Disability Scale total score, work and social items was also observed in the sub-group with CAPS-5 ≥ 33, treated with TNX-102 SL, 5.6 mg.

Gregory Sullivan, M.D., chief medical officer of Tonix, presented these findings at the 55th Annual Meeting of the American College of Neuropsychopharmacology on December 7, 2016 in Hollywood, FL, in a poster session. The poster showcasing this new data, and titled "The AtEase Study: A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL* in the Treatment of Military-Related PTSD," can be found on Tonix's website on the Scientific Presentations page.

Dr. Sullivan commented, "The data from this sub-group analysis is very exciting and

reassuring since, typically, combat-related PTSD is the most difficult to treat, and TNX-102 SL can be an important treatment option for this group based on this sub-group analysis. The retrospective analysis of the CAPS-5 ≥ 33 subset is relevant to our Phase 3 plan, because CAPS-5 ≥ 33 will be the enrollment criteria for future registration studies."

Seth Lederman, M.D., president and chief executive officer of Tonix, added, "This combat-related PTSD sub-group analysis confirms that TNX-102 SL has the potential to improve the health and function of military veterans suffering from PTSD, including those whose trauma directly resulted from events experienced in the combat theater. We are committed to developing a treatment solution for military-related PTSD, and Tonix remains on target to initiate the first of the two 12-week, randomized, double-blind, placebo-controlled Phase 3 studies in military-related PTSD in the first quarter of 2017."

*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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Source: Tonix Pharmaceuticals Holding Corp.