January 15, 2015

Tonix Pharmaceuticals Commences Phase 2 Trial of TNX-102 SL in Post-Traumatic Stress Disorder

NEW YORK, Jan. 15, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) announced today that the first participant in the AtEase study, sponsored by Tonix to evaluate TNX-102 SL for post-traumatic stress disorder (PTSD), has received study medication.

The AtEase study is a Phase 2 randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of TNX-102 SL in people with military-related PTSD and related conditions. The three-arm trial is expected to enroll approximately 220 participants, who will be randomized to receive two tablets of study medication to be taken sublingually at bedtime daily for 12 weeks. In the two active arms, participants will receive either one 2.8 mg TNX-102 SL tablet and one placebo tablet or 5.6 mg of TNX-102 SL (2 x 2.8 mg tablets). In the placebo comparator arm, participants will receive two placebo tablets. The primary endpoint of the trial is the week eight mean change from baseline in the total CAPS-5 (Clinician-Administered PTSD Scale) score in participants who received 2.8 mg of TNX-102 SL as compared to those who received placebo only. The safety of TNX-102 SL also will be evaluated. The trial is expected to be conducted at approximately 25 U.S. sites. To learn more about the AtEase study, please visit www.ateasestudy.com.

"Enrollment of the first participant in the AtEase study represents the culmination of a comprehensive preparatory process in which we engaged a number of experts in the PTSD field. This is an important event for Tonix and for the estimated eight million U.S. adults suffering from PTSD, a serious illness with limited treatment options, since there has been no new treatment in PTSD in a decade," said Seth Lederman, M.D., Tonix's president and chief executive officer. "A growing body of evidence suggests a link between poor sleep quality and PTSD symptoms. We expect that TNX-102 SL can improve several sleep quality measurements with a safety profile similar to placebo, as previously demonstrated in our Phase 2b BESTFIT study in fibromyalgia. In the BESTFIT study, administration site conditions, e.g., tongue numbness, was the most frequent adverse event reported in subjects who received TNX-102 SL.

About Post-Traumatic Stress Disorder

Post-traumatic stress disorder is common among armed forces veterans and other military personnel, and also occurs in the non-military population. PTSD can arise from witnessing or experiencing traumatic events, and is linked to impulsive violent or reckless behaviors as well as suicide. An estimated 3.5% of American adults, or approximately 8.5 million individuals, suffer from PTSD each year, and only about half of these are receiving some

form of treatment.

About Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals is a clinical-stage company developing first-in-class medicines for common disorders of the central nervous system, including fibromyalgia, PTSD, and episodic tension-type headache. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. Tonix's lead candidate, TNX-102 SL, is intended to be a first-line treatment for fibromyalgia and for PTSD. A Phase 2b trial of TNX-102 SL in fibromyalgia (BESTFIT) has been completed, and Tonix will initiate a Phase 3 program in the second quarter of 2015 to support product registration in the U.S. A Phase 2 trial of TNX-201 for episodic tension-type headache will begin in the second quarter of 2015. To learn more, please visit 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" 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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 filed with the SEC on March 28, 2014 and future periodic reports filed with the Securities and Exchange Commission. All of the Company'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.