NEW YORK, Dec. 02, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for posttraumatic stress disorder (PTSD), announced today that it will present efficacy and safety results from the Phase 2 AtEase clinical trial evaluating TNX-102 SL* for the treatment of military-related PTSD (“At Ease Study”) in a poster at the American College of Neuropsychopharmacology (ACNP) 55th Annual Meeting, being held December 4-8, 2016 in Hollywood, Florida.

Gregory Sullivan, M.D., chief medical officer of Tonix, will present the poster, titled, “The AtEase Study: A Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL in the Treatment of Military-Related PTSD” (Poster No.: W134; Abstract ID: 3005588). The poster focuses on the results of the TNX-102 SL, 5.6 mg dose, which will be the dose that is compared with placebo in the upcoming Phase 3 trial. Tonix recently held a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) based on positive data from its 12-week randomized, double-blind, placebo-controlled Phase 2 AtEase Study. Tonix intends to commence a 12-week Phase 3 study evaluating TNX-102 SL, 5.6 mg, in military-related PTSD in the first quarter of 2017, upon FDA acceptance of the protocol and proposed interim analysis plan.

*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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