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Tonix Pharmaceuticals Completes Enrollment in Phase 2 Clinical Trial of TNX-102 SL in Post-Traumatic Stress Disorder (PTSD)

Top-Line Results on Track to be Reported in the Second Quarter of 2016

NEW YORK, Dec. 23, 2015 (GLOBE NEWSWIRE) -- [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) ("Tonix"), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, announced today that it has completed enrollment in its Phase 2 AtEase clinical trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD.

"We are studying military-related PTSD in our AtEase trial because there is an urgent need to develop PTSD treatments for the veterans who have served our nation," said Seth Lederman, M.D., Tonix's president and CEO. "AtEase is potentially a landmark study in PTSD research, and we look forward to reporting top-line data from this trial in the second quarter of 2016," added Dr. Lederman.

The AtEase study is a randomized, double-blind, placebo-controlled, registration-quality Phase 2 clinical trial designed to evaluate the efficacy and safety of TNX-102 SL for the treatment of patients with military-related PTSD. Participants are treated with TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg, or inactive control, sublingually once daily at bedtime for 12 weeks. The primary endpoint of the study is the week 12 mean change from baseline score in the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) in participants who received TNX-102 SL 2.8 mg as compared to those who received inactive control. The AtEase study is being conducted at approximately 25 U.S. sites, and enrollment has exceeded the 240-patient goal.

About Post-Traumatic Stress Disorder

PTSD can arise from witnessing or experiencing traumatic events, and is linked to negative behavioral outcomes such 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. The prevalence rate of PTSD in the military population is higher than that among civilians.

About TNX-102 SL

[TNX-102 SL](#) is designed to deliver a low dose of cyclobenzaprine to the bloodstream via sublingual (under the tongue) absorption. As a multifunctional agent with antagonist

activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is under clinical development for the treatment of PTSD and is intended to provide broad spectrum improvement by targeting sleep and the stress response. Tonix is developing TNX-102 SL for daily bedtime administration for the treatment of fibromyalgia and PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache. These disorders are 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.

TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

Safe Harbor / 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 possible 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, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on February 27, 2015 and November 6, 2015, respectively, 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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