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Tonix Pharmaceuticals to Present Positive Results from Phase 2 AtEase Study of TNX-102 SL in Post-Traumatic Stress Disorder at the ASCP 2016 Annual Meeting

NEW YORK, May 26, 2016 (GLOBE NEWSWIRE) -- [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced that it will present positive data from the Phase 2 dose-finding clinical study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related PTSD (AtEase Study). Data will be featured in oral and poster presentations at the [American Society of Clinical Psychopharmacology Annual Meeting](#) (ASCP, formerly NCDEU) being held May 30 – June 3, 2016 in Scottsdale, Arizona.

Tonix's abstract entitled, "*A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL*) for the Treatment of Military-Related PTSD*," will be presented by Gregory Sullivan, M.D., Tonix's chief medical officer on Tuesday, May 31 at 2:00 p.m. MST. Dr. Sullivan also will present Tonix's trial data in a poster presentation during Poster Session I, being held on Wednesday, June 1 from 11:15 a.m. – 2:00 p.m. MST.

The AtEase clinical study was a randomized, placebo-controlled study of 231 patients with PTSD at 24 U.S. clinical sites. A bedtime sublingual dose of 2.8 mg TNX-102 SL (n=90) or 5.6 mg TNX-102 SL (n=49) was compared to placebo (n=92) for the treatment of military-related PTSD. The retention rates were 79% on TNX-102 SL 2.8 mg, 84% on TNX-102 SL 5.6 mg, and 73% on placebo. The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with TNX-102 SL 2.8 mg and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the gold standard in research for measuring the symptom severity of PTSD.

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

About the American Society of Clinical Psychopharmacology 2016 Annual Meeting

The ASCP 2016 Annual Meeting will include representatives from academia, the National Institutes of Health (NIH), Food and Drug Administration (FDA), European regulatory agencies and industry to discuss key aspects of neuropsychiatric drug development, including the impact of diagnostic changes and personalized interventions based on biomarkers or genetic information. A Steering Committee chaired by Drs. Hussein Manji and Michael Thase, with representation of the sectors that are part of the ASCP community, led

the direction of the meeting. Representatives from the FDA, EMA, NIMH, NIDA, NIAAA, the pharmaceutical industry and academia comprise the 2016 Steering Committee. A Program Committee under the leadership of Drs. Holly Swartz and Alan Gelenberg were responsible for review of all program submissions.

About Post-Traumatic Stress Disorder

[PTSD](#) can develop from witnessing or experiencing a traumatic event or ordeal in which there was the severe threat or actual occurrence of grave physical harm. PTSD affects approximately 8.4 million Americans in any year and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of intrusive memories, flashbacks, and nightmares. PTSD is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and is sometimes associated with clinical depression, substance use disorders, and unpredictable violent or suicidal behaviors. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. It is estimated that 20 percent of the over 2.5 million US military personnel returning from tours of duty in the recent conflicts in Iraq and Afghanistan suffer from PTSD¹.

¹Source: Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD. Cumulative from 1st Qtr FY 2002 through 1st Qtr FY 2014.

About TNX-102 SL

[TNX-102 SL](#) is designed to deliver cyclobenzaprine to the bloodstream rapidly via sublingual (under the tongue) absorption and to bypass first-pass hepatic metabolism. 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 hyperarousal. Tonix is developing TNX-102 SL 2.8 mg for daily bedtime administration for the treatment of fibromyalgia and TNX-102 SL 5.6 mg for daily bedtime administration for the treatment of PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. 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.

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, 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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