

August 15, 2016



Tonix Pharmaceuticals Presents Poster on the Development of TNX-102 SL for Post-Traumatic Stress Disorder (PTSD) at the 2016 Military Health System Research Symposium

NEW YORK, Aug. 15, 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 today that it will present efficacy and safety results of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), for the treatment of military-related PTSD, in a poster at the 2016 Military Health System Research Symposium being held August 15-18, 2016 in Kissimmee, FL.

Gregory M. Sullivan, M.D., chief medical officer of Tonix, will present the poster, titled, "*The AtEase Study: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD*" (Abstract ID: MHSRS-16-0816; Poster No.: 1133).

Event: 2016 Military Health System Research Symposium
Title: The AtEase Study: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD
Date: Tuesday, August 16, 2016
Time: 1:00 PM - 3:30 PM (Eastern Time)

Seth Lederman, M.D., president and chief executive officer of Tonix, said, "We are committed to developing TNX-102 SL for PTSD, a serious chronic illness, and are encouraged by the positive results from our Phase 2 AtEase study, as we plan for the next phase of development."

Pending the final meeting minutes from an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), a Phase 3 study of TNX-102 SL, 5.6 mg, in military-related PTSD is expected to be initiated in the first quarter of 2017. This trial will have a similar design to the Phase 2 AtEase study and is expected to enroll approximately 500 patients across approximately 35 clinical sites in the U.S.

TNX-102 SL is an investigational new drug and has not been approved for any indication.

About the AtEase Clinical Study

In the first quarter of 2015, Tonix initiated the AtEase study, a Phase 2 randomized, double-

blind, placebo-controlled, 12-week study of TNX-102 SL, in military-related PTSD. Patients were randomized in a 2:1:2 ratio to TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg (2 x 2.8 mg), or placebo sublingual tablets, administered at bedtime daily for 12 weeks. AtEase was conducted at 24 U.S. centers with 231 patients in the modified intent-to-treat population.

The primary efficacy endpoint of the study 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 and those receiving placebo. In May 2016, Tonix announced positive topline results from the Phase 2 AtEase study, which identified 5.6 mg as the effective and well-tolerated dose for further Phase 3 studies. The 2.8 mg dose showed a positive trend but was not statistically significant. There were no drug-related serious adverse events. The most commonly reported adverse events were oral hypoesthesia, somnolence, and dry mouth. AtEase was the first large, multicenter, adequate and well-controlled clinical trial of a pharmaceutical product that showed promising results with an investigational new drug product to treat military-related PTSD.

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 fibromyalgia and PTSD and is intended to provide broad spectrum improvement by targeting sleep quality and the stress response. 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. The FDA has provisionally accepted the trademark Tonmya® for TNX-102 SL for the treatment of fibromyalgia.

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.

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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