May 31, 2016

Tonix Pharmaceuticals Presents Positive Results from Phase 2 AtEase Study of TNX-102 SL in Post-Traumatic Stress Disorder (PTSD) at the American Society of Clinical Psychopharmacology (ASCP) 2016 Annual Meeting

- *Study Successfully Identified Effective and Well-tolerated Dose for Registration Studies*
- *Phase 3 Clinical Program Planned*

NEW YORK, May 31, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and PTSD, today announced the presentation of positive results from its Phase 2 dose-finding clinical study (AtEase Study) of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related PTSD. Data are featured in oral and poster presentations on May 31 and June 1 at the American Society of Clinical Psychopharmacology Annual Meeting (ASCP, formerly NCDEU) in Scottsdale, Arizona. Tonix's abstract, titled, "*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,"* is being presented by Gregory Sullivan, M.D., Tonix's chief medical officer. The abstract and presentation materials are available on Tonix's website at www.tonixpharma.com.

"The data being presented by Dr. Sullivan confirm that the study was a success and that a 5.6 mg dose of TNX-102 SL was efficacious and well-tolerated in the treatment of military-related PTSD," commented Seth Lederman, M.D., president and chief executive officer of Tonix. "We are pleased to have successfully identified the 5.6 mg dose for our upcoming Phase 3 program for the treatment of PTSD."

The goal of the multicenter, 12-week, double-blind study was to evaluate the potential clinical benefit of TNX-102 SL in treating military-related PTSD at a dose of 2.8 mg or 5.6 mg in a randomized, placebo-controlled study of 231 patients with PTSD at 24 U.S. clinical sites. Patients were provided with a bedtime sublingual dose of 2.8 mg TNX-102 SL (n=90) or 5.6 mg TNX-102 SL (n=49), and were compared to placebo (n=92).

Adults meeting a DSM-5 diagnosis of PTSD as assessed by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) were recruited and randomized to TNX-102 SL 2.8 mg, 5.6 mg or placebo in a 2:1:2 ratio. Eligible participants were between 18 and 65 years old, had experienced DSM-5 PTSD Criterion A-qualifying trauma(s) during military service since 2001, had at least a moderate level of PTSD severity as indicated by a CAPS-5 score ≥ 29,

and were free of antidepressants for at least two months and free of or washed off other psychotropic medications. Exclusion criteria for the study included serious suicide risk, unstable medical illness, substance use disorders within the prior six months, and lifetime history of bipolar 1 or 2, psychotic disorders, obsessive compulsive disorder, or antisocial personality disorder. A dynamic randomization procedure was used to minimize trial-wide imbalances among the three treatment arms by site, sex and presence of current major depressive disorder. CAPS-5 raters were certified MA-level or above in mental health fields who underwent a rigorous training and certification process.

The primary efficacy analysis was the 12-week mean change from baseline in the CAPS-5 severity score between the TNX-102 SL 2.8 mg and placebo groups, and the TNX-102 SL 5.6 mg group also was compared with placebo. Key secondary endpoints were the Clinical Global Impression–Improvement (CGI-I) scale, and the Sheehan Disability Scale (SDS). Other secondary measures included the CAPS-5 Cluster scores and Montgomery-Asberg Depression Rating Scale.

Tonix's AtEase study successfully identified a dose-response relationship on multiple efficacy and safety measurements. On the Arousal and Reactivity CAPS-5 cluster, both dosage groups had a significantly greater mean change from baseline at several time points: at weeks 2, 8 and 12 for the TNX-102 SL 5.6 mg group, and at weeks 2, 4, and 8 for the TNX-102 SL 2.8 mg group. At week 12, the TNX-102 SL 5.6 mg group had significantly more responders (much improved or very much improved) on the CGI-I. TNX-102 SL 2.8 mg and 5.6 mg were well tolerated as evidenced by the high overall completion rate in the active treatment groups, which exceeded the completion rate in the placebo group.

There were four distinct serious adverse events (SAEs); three were in the placebo group, and one (proctitis/peri-rectal abscess), in the TNX-102 SL group, was reported to be unrelated to TNX-102 SL. The most common systemic adverse reactions included: (i) for the TNX-102 SL 5.6 mg group, somnolence (16%), dry mouth (16%), headache (12%), insomnia (6%) and sedation (12%); and (ii) for the 2.8 mg group, somnolence (12%), dry mouth (4%), headache (5%), insomnia (8%) and sedation (2%).

Dr. Lederman concluded, "We are grateful to the participants in the AtEase study and to their families. This is an important step in developing a promising treatment for those who suffer from PTSD. We are now making plans to meet with the Food and Drug Administration to discuss a registration program for PTSD, with an interest in conducting trials in military-related and civilian PTSD."

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

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 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 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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