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Tonix Pharmaceuticals Announces Successful End-of-Phase 2 Meeting with FDA for TNX-102 SL in Post-Traumatic Stress Disorder

Regulatory Acceptance of Phase 3 Program and Product Registration Plan

Dosing in First Phase 3 Trial Expected to Commence in the First Quarter of 2017

NEW YORK, Aug. 29, 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 has received the final meeting minutes from the U.S. Food and Drug Administration (FDA) from an End-of-Phase 2/Pre-Phase 3 meeting. These minutes confirmed the FDA's acceptance of Tonix's proposed Phase 3 studies and the planned New Drug Application (NDA) data package to support the registration of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD.

As discussed at the End-of-Phase 2/Pre-Phase 3 meeting, and reflected in the final minutes, the FDA indicated that positive results from two adequate, well-controlled Phase 3 efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would provide substantial evidence of efficacy and safety to support the registration of TNX-102 SL, 5.6 mg, for the treatment of PTSD. Since Tonix is also developing TNX-102 SL for potential use in fibromyalgia, the FDA has agreed that the same chemistry, manufacturing and controls (CMC) and nonclinical studies proposal it previously accepted for the fibromyalgia NDA will be applicable for the PTSD NDA. Tonix expects that the first Phase 3 study will be in military-related PTSD patients and the second Phase 3 study will be in predominantly civilian PTSD patients.

Seth Lederman, M.D., president and chief executive officer of Tonix, said, "We are pleased by the FDA's response to our completed Phase 2 AtEase study results and encouraged by its agreement on the design of the two Phase 3 studies and our proposed NDA plan. Considering the FDA's concurrence that the primary endpoint used in the AtEase study will be the same primary endpoint for both upcoming Phase 3 trials, we remain confident in achieving this important milestone. The promising data from the AtEase study supports the potential for TNX-102 SL to be an effective treatment for this large and growing patient population. Importantly, we believe the urgent medical need to treat military-related PTSD also creates the possibility for a Breakthrough Therapy Designation."

Tonix plans to commence a randomized, double-blind Phase 3 clinical study of TNX-102 SL, 5.6 mg, in military-related PTSD in the first quarter of 2017 and to commence a randomized,

double-blind Phase 3 clinical study of TNX-102 SL in predominantly civilian PTSD later in 2017. Tonix expects each of the studies to be conducted in 400 to 500 patients at approximately 35 U.S. centers. In both studies, patients will take either TNX-102 SL, 5.6 mg (2x 2.8 mg), or placebo, daily at bedtime for 12 weeks. Similar to the Phase 2 AtEase study in military-related PTSD, the primary efficacy endpoint of these two Phase 3 studies will be 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.

Following the completion of the 12-week double-blind randomized portion of these studies, patients may be eligible to enroll in open-label extension studies of TNX-102 SL, 5.6 mg. Tonix expects the planned open-label extension studies to provide sufficient long-term safety exposure data to support the TNX-102 SL NDA for the treatment of PTSD.

The Phase 2 AtEase Study

The AtEase study was among the first to use the most recent version of the CAPS, named CAPS-5, as the primary endpoint. The entry criteria of the upcoming Phase 3 studies will use CAPS-5 baseline score of ≥33 as the entry criteria, which is higher than the ≥29 baseline threshold for AtEase. As recently presented at a poster at the Military Health System Research Symposium (MHSRS)(http://bit.ly/2bFo4mx), a retrospective analysis of the AtEase data using CAPS-5 ≥33 at entry appeared to discriminate patients more closely to the ≥50 standard in prior CAPS versions used in registration trials of the marketed products. Retrospective analysis of the AtEase data showed that among the CAPS-5 ≥33 subset of AtEase patients, TNX-102 SL, 5.6 mg (2 x 2.8 mg tablets), significantly improved CAPS-5 relative to placebo at all assessment time points: weeks 2, 4, 8 and 12 ($P<0.025$; mixed models repeated measures), and the effect size of TNX-102 SL, 5.6 mg, compared with placebo at Week 12 was 0.53. There were no drug-related serious adverse events. The most commonly reported adverse events were oral hypoaesthesia, 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.

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

About PTSD

PTSD affects approximately 8.5 million Americans and is a chronic and debilitating condition, in which patients experience nightmares and disturbed sleep, and which is associated with depression and suicide. Individuals who suffer from PTSD experience impaired social functioning, occupational disability, intense anxiety and avoidance, emotional numbness, intense guilt or worry, agitation and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable or violent behaviors, additional reasons that make it a critical public health concern. PTSD can develop from witnessing or experiencing a traumatic event in which there was the threat or actual occurrence of grave physical harm.

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 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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