

May 11, 2017



Tonix Pharmaceuticals to Present PTSD Clinical Data at the Society of Biological Psychiatry 72nd Annual Scientific Convention

Additional Results to be Presented from Phase 2 Study of US FDA-Designated Breakthrough Therapy, TNX-102 SL, in PTSD

NEW YORK, May 11, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced it will present additional analyses of data from its Phase 2 study in military-related posttraumatic stress disorder, or PTSD, at the 72nd Annual Scientific Convention of the Society of Biological Psychiatry (SOBP) on May 20, 2017 in San Diego.

Gregory Sullivan, M.D., chief medical officer of Tonix, will present moderators and mediators analyses from Tonix's Phase 2 AtEase study of TNX-102 SL*. TNX-102 SL is the first PTSD drug candidate designated by the U.S. Food and Drug Administration (FDA) as a Breakthrough Therapy. A moderator is a characteristic of participants going into the study that is associated with a response to treatment, while a mediator is a clinical finding that the response to therapy may depend on, such as sleep quality. Details of the poster presentation follow.

Title: Phase 2 Multisite Double-Blind Placebo-Controlled Trial of TNX-102 SL in Military-Related Posttraumatic Stress Disorder: Mediators and Moderators of Treatment Response (Poster No. 3001130)

Date: Saturday, May 20, 2017

Time: 5-7 p.m. PDT

Location: Sapphire CP, Hilton San Diego Bayfront

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

About TNX-102 SL and the Phase 3 HONOR Study

TNX-102 SL is a patented** sublingual formulation of low dose cyclobenzaprine that is in Phase 3 development for PTSD. In a Phase 2 study, TNX-102 SL 5.6 mg was found to be effective in treating military-related PTSD, and FDA has awarded TNX-102 SL Breakthrough

Therapy designation. Tonix is currently conducting a Phase 3 HONOR study of TNX-102 SL in military-related PTSD in the United States. HONOR is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of TNX-102 SL 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting to enroll up to approximately 550 participants across approximately 35 clinical sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent Cross-disciplinary Breakthrough meeting, FDA confirmed that a single-study NDA approval could be possible if the topline data from HONOR is statistically very persuasive. Additional details of HONOR are available at www.thehonorstudy.com or <https://clinicaltrials.gov/ct2/show/NCT03062540>.

** The U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique formulation that characterizes TNX-102 SL. This patent is expected to provide Tonix with U.S. market exclusivity until 2034 upon NDA approval.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address public health challenges. TNX-102 SL is in Phase 3 development and has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. PTSD is a serious condition characterized by chronic disability, inadequate treatment options especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In addition to TNX-102 SL for PTSD, other development efforts include TNX-601 (tianepetine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage, designed for daytime use for the treatment of PTSD, and TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of HPXV.

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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