

May 24, 2017



# **Tonix Pharmaceuticals to Present Additional Clinical Results of Military-Related PTSD Study at the 2017 American Society of Clinical Psychopharmacology Annual Meeting**

## **Important Retrospective Analyses from Phase 2 Study of US FDA-Designated Breakthrough Therapy TNX-102 SL in PTSD will be Highlighted**

NEW YORK, May 24, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced upcoming presentations of additional analyses of data from its Phase 2 study in military-related posttraumatic stress disorder, or PTSD. Details of the additional analyses will be featured in oral and poster presentations by Gregory Sullivan, M.D., Tonix's chief medical officer, at the Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP) to be held May 29 – June 2, 2017, at the Loews Miami Beach Hotel in Miami Beach, FL. Information on the presentations is as follows:

### **Oral presentation**

**Title:** Low-Dose Bedtime Sublingual Cyclobenzaprine (TNX-102 SL<sup>\*</sup>) for the Treatment of Military-Related PTSD: Retrospective Analyses of the Mediators and Moderators of Treatment Response

**Date:** Tuesday, May 30, 2017

**Time:** 2:10 p.m. EDT

**Location:** Salon 3 – Americana Ballroom, Loews Miami Beach Hotel, Miami Beach, FL

### **Poster presentation**

**Title:** Low-Dose Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD: Retrospective Analyses of the Mediators and Moderators of Treatment Response (Poster Board T9)

**Date:** Thursday, June 1, 2017

**Time:** 12:30 – 2:00 p.m. EDT

**Location:** Salon 4 – Americana Ballroom, Loews Miami Beach Hotel, Miami Beach, FL

*<sup>\*</sup>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 transmucosal formulation of cyclobenzaprine that is in Phase 3 development. 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 a Phase 2 study, TNX-102 SL 5.6 mg was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of TNX-102 SL in military-related PTSD in the United States, the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of TNX-102 SL 5.6 mg. This two-arm, adaptive-design trial is targeting enrollment of 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 participants. In a recent Cross-disciplinary Breakthrough meeting, the FDA confirmed that a single-study new drug application (NDA) approval could be possible if the topline data from the HONOR study are statistically very persuasive. Additional details of the HONOR study are available at [www.thehonorstudy.com](http://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 TNX-102 SL formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary TNX-102 SL composition. This patent is expected to provide TNX-102 SL with U.S. market exclusivity until 2034 upon NDA approval.

### **About Tonix Pharmaceuticals Holding Corp.**

Tonix is developing innovative pharmaceutical products to address major public health challenges. In addition to TNX-102 SL for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage, designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, as a potential smallpox-preventing vaccine.

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, 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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