

June 15, 2017



## **Tonix Pharmaceuticals Participated in the "Pathophysiology of Posttraumatic Stress Disorder: Rethinking Drug Targets" Summit Sponsored by U.S. Department of Defense**

NEW YORK, June 15, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced today its participation and a poster presentation at the "Pathophysiology of Post-Traumatic Stress Disorder: Rethinking Drug Targets" summit sponsored by the Department of Defense. Tonix's participation at the Summit does not constitute endorsement of company or product by the U.S. Army. At the summit, Seth Lederman, M.D., president and chief executive officer of Tonix, presented a poster entitled, "Phase 2 Multicenter Double-Blind Placebo-Controlled Trial of TNX-102 SL (cyclobenzaprine sublingual tablets) in Military-Related Posttraumatic Stress Disorder (PTSD): Analysis of CAPS-5 Thresholds for Baseline Severity and Week 12 Remission in the mITT Population and Combat PTSD Subset" on June 13, 2017. The poster can be found on the Scientific Presentations page on [Tonix's website](#). TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication. Based on the Phase 2 study results, the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to TNX-102 SL for the treatment of PTSD.

The summit, an invitation-only meeting held June 13-14, 2017, at the National Conservation Training Center in West Virginia, assembled experts from government, industry and academia, included presentations and working group sessions focused on current prospects for drug treatment of PTSD. The summit was the first of its kind and was motivated by the need for more effective and safe pharmacological therapies for PTSD among the military population. The summit was co-hosted by the U.S. Army Medical Materiel Development Activity (USAMMDA) Neurotrauma and Psychological Health Project Management Office and the Joint Program Committee/Military Operational Medicine Research Program (MOMRP). Additional information about the summit can be found at [https://www.army.mil/article/184816/dod\\_sponsored\\_summit\\_pursues\\_hope\\_for\\_ptsd\\_patient](https://www.army.mil/article/184816/dod_sponsored_summit_pursues_hope_for_ptsd_patient):

"We are pleased that the Department of Defense recognized PTSD with this summit, which included industry, academia, and government groups that are involved in developing new pharmacological therapies to address the serious issue of PTSD," further commented Dr. Lederman. "The summit assembled the relevant groups with development focus on PTSD. We are proud that TNX-102 SL is the only FDA-designated Breakthrough Therapy for

PTSD. Based on the publicly available information from other PTSD development programs, TNX-102 SL is the only drug currently in Phase 3 development. Furthermore, TNX-102 SL for the treatment of PTSD is the only industry-sponsored clinical research that has successfully studied U.S. veterans with military-related PTSD in an adequate well-controlled multi-center study. We are encouraged by our Phase 2 clinical results. We believe TNX-102 SL is a promising new pharmacological therapy to treat the overall PTSD symptoms by a unique mechanism of addressing the sleep disturbances that are thought to be fundamental to the pathophysiology of the disorder and facilitating sleep-dependent memory processing, which are thought to be important in extinction and recovery. We are pleased that the summit recognized chronobiology and sleep disturbance as potentially important drug targets, because it is a validation of our work on these targets over the past several years. With interim results from our currently-enrolling Phase 3 HONOR study expected in the first half of next year, and topline results from the full study expected in the second half of next year, we are on track to accelerate the development and approval of TNX-102 SL for PTSD.”

Dr. Lederman added, “We were also pleased that the mechanism and potential of TNX-601 (tianeptine oxalate), our pre-IND (Investigational New Drug) drug candidate, that modulates the glutamatergic pathway for the daytime treatment of PTSD, was identified in this summit as one of the potential drug candidate targeting the excitatory and inhibitory pathways.”

### **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 in participants with military-related PTSD. 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 randomized 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, upon NDA approval, with U.S. market exclusivity until 2034.

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

Tonix is developing innovative pharmaceutical products to address major public health challenges. Tonix has two programs focusing on PTSD: TNX-102 SL and TNX-601. PTSD is

a serious condition characterized by chronic disability, inadequate treatment options and overall high utilization of healthcare services creating significant economic burden. TNX-102 SL has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. TNX-601 (tianeptine oxalate) is in the pre-IND stage of development for the daytime treatment of PTSD. TNX-801, a live synthetic version of horsepox virus, is a potential smallpox-preventing vaccine that is at the pre-IND application stage as well.

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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