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Tonix Pharmaceuticals Reports Results from U.S. FDA Initial Cross-Disciplinary Breakthrough Meeting on TNX-102 SL for Posttraumatic Stress Disorder

Registration of TNX-102 SL Could be Solely Supported by the Phase 3 HONOR Study if Topline Data are Statistically Persuasive

NEW YORK, April 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 today the receipt of official minutes from its Initial Cross-Disciplinary Breakthrough Meeting held with the U.S. Food and Drug Administration (FDA) on March 9, 2017. Upon being awarded Breakthrough Therapy designation in December 2016, Tonix was invited to meet with the FDA to evaluate the feasibility of accelerating the development and registration of TNX-102 SL* for the treatment of posttraumatic stress disorder (PTSD).

Seth Lederman, M.D., president and chief executive officer of Tonix, stated, “The FDA’s consideration of a single-study New Drug Application (NDA) and continued support of the Phase 3 HONOR study are critical to accelerating the availability of a potentially improved treatment option for PTSD patients, especially those patients with military-related PTSD. The FDA’s standard of evidence for drug approval typically requires two positive Phase 3 trials; however, following our Initial Cross-Disciplinary Breakthrough Meeting in March, the FDA confirmed a single-study NDA approval could be possible based on statistically persuasive topline data from the ongoing HONOR study. Additionally, due to the lack of evidence of potential abuse in clinical studies of TNX-102 SL, the FDA agreed that studies in assessing abuse potential of TNX-102 SL are not required to support the TNX-102 SL NDA.”

About the HONOR Study

HONOR is a 12-week Phase 3 randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) versus placebo, in participants with military-related PTSD. The two-arm, adaptive design trial will enroll up to 550 participants across approximately 35 U.S. sites. The study will have one unblinded interim analysis (IA) by an independent data monitoring committee when the study has results from approximately 50% of efficacy-evaluable participants, or approximately 275 participants, which is projected to occur in the first half of 2018. If the IA results require continued enrollment, topline results from the 550-participants trial are expected to be available in the second half of 2018. Additional details of the HONOR study are available at www.thehonorstudy.com, or http://bit.ly/2lrMZ1H.

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

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. The Protectic™ protective eutectic and Angstro-Technology™ formulation are essential elements of the proprietary TNX-102 SL composition for which a Notice of Allowance has been issued by the U.S. Patent and Trademark Office. Other development efforts include TNX-601 (tianeptine 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 horsepox virus.

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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