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Tonix Pharmaceuticals Announces Issuance of U.S. Patent for TNX-102 SL Composition and Formulation: Designed for Transmucosal Absorption and Bedtime Daily Use

TNX-102 SL is an FDA-Designated Breakthrough Therapy for PTSD in Phase 3 Development

NEW YORK, May 02, 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 issuance of U.S. Patent No. 9,636,408 ('408 patent) by the U.S. Patent and Trademark Office. The patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride," claims the composition and manufacture of a unique formulation that characterizes TNX-102 SL*. The '408 patent is expected to provide Tonix with U.S. market exclusivity until 2034.

"The formulation of TNX-102 SL enables the transmucosal delivery of cyclobenzaprine that has been shown to be active in treating military-related posttraumatic stress disorder, or PTSD," commented Seth Lederman, M.D., president and chief executive officer of Tonix. "The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the '408 patent are important elements of our proprietary TNX-102 SL composition."

*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 for the treatment of PTSD and the HONOR study is a Phase 3 randomized, double-blind, placebo-controlled trial evaluating the efficacy of TNX-102 SL 5.6 mg in participants with military-related 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. Other development efforts include TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus and TNX-601 (tianeptine oxalate), a clinical candidate at the Pre-IND (Investigational New Drug) application stage. It is designed for daytime use for the treatment of PTSD.

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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