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Tonix Pharmaceuticals and U.S. Department of Defense Military Developer in Partnership to Expand Efforts to Examine TNX-102 SL for Post-Traumatic Stress Disorder

NEW YORK, Dec. 7, 2015 (GLOBE NEWSWIRE) --Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) ("Tonix"), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, announced today the signing of a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Materiel Development Activity (USAMMDA) to explore expansion and potential development of Tonix's investigational new drug, TNX-102 SL (cyclobenzaprine HCl sublingual tablets), for the treatment of military-related PTSD. USAMMDA is the Department of Defense's (DoD) advanced development activity for products designed to protect and preserve the lives of Warfighters. USAMMDA develops new drugs, vaccines and medical support equipment that enhance readiness, and ensures the provision of the highest quality medical care to the DoD.

TNX-102 SL is a small, rapidly dissolving tablet containing very low dose cyclobenzaprine in a eutectic formulation for sublingual (under the tongue) administration and rapid absorption into the blood stream. It is designed for use at bedtime to improve sleep quality and to have a tolerability profile that supports chronic treatment.

About Post-Traumatic Stress Disorder

PTSD can arise from witnessing or experiencing traumatic events, and is linked to negative behavioral outcomes such as suicide. An estimated 3.5% of American adults, or approximately 8.5 million individuals, suffer from PTSD each year, and only about half of these are receiving some form of treatment. The prevalence rate of PTSD in the military population is higher than that among civilians.

About Tonix Pharmaceuticals Holding Corp.

Tonix is dedicated to the invention and development of novel pharmaceutical products that it believes will have broad societal impact, since they address medical conditions that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's Tonmya™ (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is currently being evaluated in the Tonix-sponsored Phase 3 AFFIRM study in fibromyalgia, for which Tonix expects to report top-line data in the third quarter of 2016. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2

AtEase study in PTSD, for which Tonix expects to report top-line data in the second quarter of 2016. Tonix expects to report top-line data from its Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache in the first quarter of 2016. This press release and further information about Tonix can be found at www.tonixpharma.com.

Tonmya, TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved for any indications.

Safe Harbor / 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" 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 possible 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, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and November 6, 2015, respectively, 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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