June 27, 2012

Tonix Pharmaceuticals Receives Health Canada Clearance to Study a Novel Treatment for Fibromyalgia

Non-Addictive Drug Formulation Targets Sleep Problems

NEW YORK--(BUSINESS WIRE)--Tonix Pharmaceuticals Holding Corp. (OTCBB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing therapies for challenging disorders of the central nervous system ("CNS") including fibromyalgia syndrome ("FM") and post-traumatic stress disorder ("PTSD"), announces that the Company will initiate a comparative study on a novel treatment for FM that targets sleep problems associated with chronic pain syndromes. TONIX's new approach is opiate-free and non-addictive.

Health Canada has provided TONIX with clearance for a comparative pharmacokinetic ("PK") and bioavailability ("BA") study of TNX-102, the Company's novel oral formulation of cyclobenzaprine for the treatment of FM. Health Canada has issued a No Objection Letter to TONIX's Clinical Trial Application. Cyclobenzaprine is the active ingredient in two U.S. FDA- and Health Canada-approved prescription muscle relaxants that are marketed by other companies.

Seth Lederman, M.D., Chairman and President of TONIX said, "FM patients are desperate to get a good night's sleep because many have learned that restorative sleep can improve their pain and fatigue. We have designed TNX-102 to work at night after bedtime administration. We expect the results of this PK study will corroborate studies done in animals, and we will use the findings to finalize our commercial formulation for pivotal clinical studies."

Dr. Lederman also said, "The objective of this study is to compare the PK profile of our proprietary TNX-102 formulation with the PK of a conventional immediate release formulation and the PK of an intravenous injection."

In addition, Dr. Lederman noted, "Immediate release cyclobenzaprine results in relatively steady blood levels over the course of the day, which is ideal for the treatment of muscle spasms, its approved indication. In our Phase 2a study, bedtime administration of very low dose cyclobenzaprine capsules improved core FM symptoms including pain, tenderness, fatigue and depression. This study also demonstrated that those improvements were correlated with increased nights of restorative sleep. Our goal is to develop a bedtime cyclobenzaprine treatment with more predictable beneficial effects and reduced next-day somnolence compared with the current doses and formulations of cyclobenzaprine."

The study will be conducted in Canada by a leading global clinical research organization. TONIX anticipates the clinical portion of the study to be completed by the end of July, with analysis of the subjects' blood samples to be completed before September 30, 2012.

TONIX's comparative PK/BA study is expected to enroll approximately 15 healthy adult volunteers to participate in a single-dose, open-label, randomized study. The three arms will compare a TNX-102 candidate tablet in a novel formulation containing a very low dose (2.4 mg) of cyclobenzaprine with a currently available, immediate release, 5 milligram cyclobenzaprine tablet and with intravenous cyclobenzaprine, which is considered a standard for BA studies. The study will measure each subject's circulating blood levels of cyclobenzaprine over time in each condition.

TONIX also plans to use new doses and formulations of cyclobenzaprine in a new treatment for PTSD, in addition to FM.

About TNX-102

TNX-102 is a bedtime medicine containing very low dose cyclobenzaprine (2.4 mg). TONIX is designing TNX-102 for faster and more efficient absorption relative to currently marketed cyclobenzaprine products. TONIX believes its formulation of TNX-102 administered at bedtime will provide more predictable beneficial effects with less likelihood of next-day drowsiness than commercially available cyclobenzaprine preparations. Previous studies of the mechanism by which cyclobenzaprine works have discovered that it acts selectively on serotonin receptor type 2a (5HT2a) and alpha-2 adrenergic receptors. Serotonin is thought to play a major role in the central inhibition of pain.

About TONIX

TONIX is developing innovative prescription medications for challenging disorders of the central nervous system. The Company targets conditions characterized by significant unmet medical need, inadequate existing treatment options, and high dissatisfaction among both patients and physicians. TONIX's core technology improves the quality of sleep in patients with chronic pain syndromes. TONIX's lead products are designed to be fundamental advances in sleep hygiene and pain management and to be safer and more effective than currently available treatments. TONIX's products are the result of a program to harvest advances in science and medicine to search for potential therapeutic solutions among known pharmaceutical agents. TONIX is developing new formulations that have been optimized for new therapeutic uses. Its most advanced product candidates, TNX-102 for FM and TNX-105 for PTSD, are novel dosage formulation of cyclobenzaprine, the active ingredient in two U.S. FDA-approved muscle relaxants. To learn more about the Company and its pipeline of treatments for CNS conditions, please visit www.tonixpharma.com.

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," "estimated" 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 ability to continue as a going concern; our need for additional financing; uncertainties of patent

protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 filed with the SEC on March 30, 2012 and future periodic reports filed with the Securities and Exchange Commission. All of the Company'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.