

October 23, 2012



# **Tonix Pharmaceuticals Confirms Clinical Utility of TNX-102 Sublingual Tablet**

## **Study Demonstrated Desirable Pharmacokinetic Profile With Rapid Absorption Well-Suited for Bedtime Use**

NEW YORK, NY -- (MARKETWIRE) -- 10/23/12 -- Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing novel treatments for challenging disorders of the central nervous system, including fibromyalgia ("FM") and post-traumatic stress disorder ("PTSD"), today reported that it has completed the dosing and plasma analysis of a pharmacokinetic ("PK") study of its TNX-102 sublingual tablet ("TNX-102 SL"), a proprietary formulation of cyclobenzaprine ("CBP") for bedtime use.

This PK study of 24 healthy volunteers evaluated a single dose of one 2.4 mg tablet or two tablets (4.8 mg) of TNX-102 SL or the currently-marketed 5 mg CBP tablet. In comparison to oral administration of the 5 mg CBP tablet, both sublingual doses of TNX-102 SL demonstrated faster systemic absorption. After administration of TNX-102 SL, blood levels of CBP were significantly higher at 20, 30, 45 and 60 minutes relative to administration of the 5 mg CBP tablet. In the study, TNX-102 SL was generally well tolerated. There were no unexpected adverse events, with the exception of a mild, temporary numbness at the tongue experienced by less than one-third of the subjects that received TNX-102 SL tablets.

For more information about this trial, please visit:

<http://www.clinicaltrials.gov/ct2/show/NCT01689259?term=TONIX&rank=2>.

"TONIX is developing TNX-102 SL to help people afflicted with FM obtain pain relief by improving sleep quality," said Seth Lederman, M.D., Chief Executive Officer of TONIX. "We believe we have identified a greatly improved formulation to be studied as a bedtime therapy in pivotal trials for fibromyalgia."

Dr. Lederman continued, "We believe the improved PK profile of TNX-102 SL can potentially provide several clinically meaningful advantages over commercial oral formulations of CBP, including possibly faster onset of action, which is desirable for a bedtime medication. We also believe that our dose and dosing regimen will be associated with lower rates of side-effects such as next-day somnolence over commercial oral tablet

formulations of CBP. We look forward to executing on our clinical study plan of what we anticipate will be a much-needed treatment option for FM. We remain on track to enroll patients into the first of two pivotal efficacy studies of TNX-102 SL in FM in the first quarter of 2013."

### **About Fibromyalgia**

Fibromyalgia is a common and complex central nervous system condition characterized by chronic diffuse musculoskeletal pain, increased pain sensitivity at multiple tender points, fatigue, abnormal pain processing, and disturbed sleep, and often features psychological stress. Despite the fact that most FM patients suffer from poor sleep, there are no medications indicated for FM that work by improving sleep quality. It is estimated that five million people are suffering from FM in the US.

### **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, which is believed to translate into reductions in daytime pain. The Company's lead product candidate, TNX-102 SL, is a novel under-the-tongue tablet formulation of CBP, the active ingredient in two U.S. FDA-approved muscle relaxants, and is expected to enter a Phase 3 program in FM in early 2013. In a randomized, double-blind, placebo-controlled, eight-week Phase 2 trial, TONIX demonstrated that low-dose CBP given at bedtime resulted in a significant decrease in next-day pain and other core FM symptoms, as well as in a significant improvement in sleep quality. Legacy CBP products are widely used by FM patients, but are neither designed nor approved for this indication. TONIX also plans to explore the utility of TNX-102 SL in a new bedtime treatment paradigm for PTSD.

To learn more about the Company, please visit [www.tonixpharma.com](http://www.tonixpharma.com).

*TNX-102 SL is an Investigational New Drug ("IND"). A US IND has been filed with the Food and Drug Administration. 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.*

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