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# **Tonix Pharmaceuticals Reports Positive Preclinical Data on Sublingual TNX-102**

## **New Formulation of Very Low Dose Cyclobenzaprine for Bedtime Use Designed to Treat Fibromyalgia by Facilitating Restorative Sleep**

NEW YORK--(BUSINESS WIRE)--Tonix Pharmaceuticals Holding Corp. (OTCBB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing non-addictive treatments for chronic pain syndromes, including fibromyalgia ("FM"), today reported positive data from an animal pharmacokinetic ("PK") study of its novel sublingual ("SL") formulation of TNX-102, the Company's very low dose cyclobenzaprine.

"TONIX is developing TNX-102 as a therapy to help people afflicted with FM get the relief they need, by improving sleep quality," said Seth Lederman, M.D., Chief Executive Officer of TONIX. "With better sleep quality, patients report a reduction in their chronic pain. Sleep quantity and sleep quality are different. The clinical data support the idea that improving sleep quality leads to significant alleviation of FM symptoms. We believe that improving sleep quality allows the natural restorative properties of sleep to work on reducing pain. TONIX is pursuing this goal through our novel formulations of cyclobenzaprine."

FM 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. Research has shown that the restorative sleep of FM patients is disrupted by alarm signals called CAP A2 and A3. In a Phase 2a trial, TONIX demonstrated that bedtime administration of very low dose cyclobenzaprine improves core FM symptoms including pain, tenderness, fatigue, and depression, and also demonstrated that improvements in key symptoms correlate with increased nights of restorative sleep. These results were published in the December 2011 issue of the *Journal of Rheumatology*.

The new research reported by TONIX today demonstrates that the Company's SL TNX-102 (2.4 mg) tablet provides faster delivery and more efficient absorption of cyclobenzaprine as compared to the currently available pills that deliver cyclobenzaprine to the stomach. In fact, TONIX discovered that cyclobenzaprine given in a novel SL formulation is absorbed as well as intravenous cyclobenzaprine. Cyclobenzaprine is the active ingredient in two prescription muscle relaxants that have been approved by the U.S. Food and Drug Administration and are marketed by other companies.

The Company recently announced that it received clearance from Health Canada to initiate a pharmacokinetic/bioavailability study of an oral solution formulation of its SL TNX-102 tablet

in comparison to a marketed oral cyclobenzaprine tablet (5 mg) and to intravenous cyclobenzaprine (2.4 mg) in healthy adults in Canada. For more information about this trial, please visit <http://www.clinicaltrials.gov/ct2/show?term=tonix&rank=1>.

“We are pleased to announce the discovery that our SL TNX-102 formulation can deliver cyclobenzaprine rapidly and efficiently into the bloodstream and that it is also rapidly cleared. The existing literature taught away from this discovery and led scientists to believe that the cyclobenzaprine molecule itself had an inherently long plasma half-life that could not be shortened. We believe the improved pharmacokinetic profile of SL TNX-102 will enable it to provide several significant advantages over commercial oral formulations of cyclobenzaprine, including targeting the sleeping brain with greater dose intensity when taken at bedtime and lower rates of side-effects such as next-day grogginess or hangover. The PK profile of SL TNX-102 appears well suited to allow the natural restorative processes of sleep to relieve FM pain.” said Dr. Lederman. “We have filed with the U.S. Patent and Trademark Office for patents on SL TNX-102, which we believe is an important advance for FM patients that should ultimately reduce the use of addictive pain killers and sedatives,” continued Dr. Lederman. “We look forward to executing on our clinical study plan toward the commercialization of what we anticipate will be an effective, well-tolerated, and differentiated treatment option for FM. We remain on track to enroll patients into the first of two pivotal efficacy studies of TNX-102 in FM in the first quarter of 2013.”

TONIX also plans to explore the utility of proprietary, low dose formulations of cyclobenzaprine in a new treatment paradigm for post-traumatic stress disorder (“PTSD”).

### **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 SL formulation of TNX-102 administered at bedtime will provide more targeted sleep quality effects with less likelihood of side-effects 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 (5HT<sub>2a</sub>) 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 fibromyalgia and TNX-105 for PTSD, are novel dosage formulations 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 central nervous system conditions, please

visit [www.tonixpharma.com](http://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.*