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Tonix Pharmaceuticals Reports That Sublingual Formulation of Fibromyalgia Drug Reduces Production of a Psychoactive Metabolite, Improving Suitability for Long-Term, Chronic Treatment

Results Further Support the Development of Sublingual TNX-102 to Treat Fibromyalgia by Improving 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, today reports that its new sublingual (under-the-tongue) formulation of its fibromyalgia (FM) drug TNX-102 reduces the production of a problematic metabolite, according to data from a recently-completed clinical trial.

TNX-102 is the Company's low dose form of cyclobenzaprine. Cyclobenzaprine is a drug originally approved by the Food and Drug Administration for short term treatment of acute muscle spasm several decades ago and it is currently one of the most widely prescribed off-label medications for FM. TONIX has shown that low dose cyclobenzaprine given before bedtime is effective to reduce the pain suffered by FM patients and to improve the quality of sleep. Yet when given as an oral pill on a chronic daily regimen, cyclobenzaprine can lose its effectiveness over time.

Tonix's research sheds light on a potential cause of this problem. Tonix has discovered that a significant amount of cyclobenzaprine from oral tablets is converted into a metabolite called norcyclobenzaprine, which builds up in the body with daily dosing. Although norcyclobenzaprine had been described previously in cases of overdose, Tonix has found that the levels of norcyclobenzaprine are significant even at low doses and that norcyclobenzaprine is a psychoactive substance. Norcyclobenzaprine has a similar effect on the brain as cyclobenzaprine, so the accumulation of the metabolite over time is expected to interfere with the beneficial effects of bedtime cyclobenzaprine. Norcyclobenzaprine makes it impossible to use currently available cyclobenzaprine tablets in a chronic bedtime dosing regimen to achieve beneficial effects on the sleeping brain and still have the drug largely cleared by the next morning.

TONIX's new sublingual formulation of cyclobenzaprine (TNX-102 SL) can significantly reduce this problem, according to the Company's pharmacokinetic study. The study showed

that levels of the norcyclobenzaprine metabolite can be reduced by using a sublingual formulation compared to oral cyclobenzaprine tablets. As a result, TNX-102 SL is a significant advance over oral tablets and is suitable for long-term treatment.

“The study shows that bedtime TNX-102 SL should offer a substantial improvement over off-label oral tablets in the treatment of fibromyalgia,” said Seth Lederman, M.D., Chief Executive Officer of TONIX. “That’s why we believe our drug has the potential to be a game-changing medication in relieving pain and other symptoms of fibromyalgia, even though the oral tablet version of cyclobenzaprine is already available.”

“Delivering the drug under the tongue gets it into the bloodstream faster, and changes the way the drug is metabolized,” Lederman explained. “As a result, the production of the psychoactive, persistent metabolite, norcyclobenzaprine, is decreased. We look forward to commencing a pivotal trial of TNX-102 SL in fibromyalgia in the first quarter of 2013. We believe the drug will help people afflicted with fibromyalgia get the relief they need, by improving sleep quality.”

The new results reported by TONIX today come from a study designed to confirm in humans the results obtained in animals which demonstrate that the Company’s TNX-102 SL (2.4 mg) tablet provides faster delivery and more efficient absorption of cyclobenzaprine as compared to the currently available oral (5 mg or 10 mg) pills that deliver cyclobenzaprine to the stomach. In those studies, TONIX discovered that cyclobenzaprine given in a novel sublingual formulation is absorbed with a profile comparable to 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.

About Fibromyalgia

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*.

About TNX-102

TNX-102 is a bedtime medicine containing very low dose cyclobenzaprine (2.4 mg). In a randomized, double-blind, placebo-controlled eight-week Phase 2 study in FM patients, TONIX demonstrated that treatment with TNX-102 led to significant improvements in pain and other core symptoms. TONIX is optimizing TNX-102 for faster and more efficient absorption relative to currently marketed cyclobenzaprine products. TONIX believes its TNX-102 SL formulation 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 (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 post- traumatic stress disorder, 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.

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.