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Tonix Pharmaceuticals' Bedtime Very Low Dose Cyclobenzaprine Study Featured in Journal of Rheumatology

-Phase 2a Study Results Demonstrate Improvement in Core Fibromyalgia Symptoms Including Pain, Tenderness, Fatigue and Depression-

-Correlation Between Improved Restorative Sleep and Drug Efficacy Among Treatment Group Subjects-

New York, NY – September 7, 2011 – TONIX Pharmaceuticals, Inc. a specialty pharmaceutical company developing therapies for challenging disorders of the central nervous system ("CNS"), including fibromyalgia syndrome ("FM") and post-traumatic stress disorder, announces the publication of data in the peer-reviewed journal, *The Journal of Rheumatology*, demonstrating an improvement in core symptoms associated with FM.

The article, entitled "Effects of Bedtime Very Low Dose (VLD) Cyclobenzaprine (CBP) on Symptoms and Sleep Physiology in Patients with Fibromyalgia Syndrome (FM): A Double-blind, Randomized, Placebo-controlled Study," is authored by Dr. Harvey Moldofsky, Dr. Herbert Harris, Terence Kwong, W. Tad Archambault, Ph.D. and Dr. Seth Lederman. It appears in the current online edition of the Journal, and can be accessed at the following link:

http://jrheum.org/content/early/2011/08/30/jrheum.110194.full.pdf+html ; the article will be available in print in the November edition of the Journal.

The article discusses the results of a Phase 2a study of bedtime very low dose cyclobenzaprine for the treatment of FM. Bedtime very low dose cyclobenzaprine is the core technology underlying TNX-102, TONIX Pharmaceuticals' novel formulation of cyclobenzaprine for the treatment of FM. This study was a randomized, double-blind placebo-controlled, dose-escalating parallel-design study of 36 patients with FM and disturbed sleep. It was designed to investigate the effects of VLD CBP dosed at bedtime on FM symptoms, including pain, tenderness, fatigue, mood [Hospital Anxiety and Depression Scale ("HAD")] and EEG sleep physiology over eight weeks. The researchers also hoped to identify parameters that might be useful markers of drug effects.

Key eight week data from the 36 subjects in the Phase 2a study include:

- Musculoskeletal pain decreased 26.1% from baseline (p=0.01). Relative to placebo, the decrease was 18.2%, (p=0.04);

- Tenderness improved 30.1% from baseline (p=0.01). Relative to placebo, the decrease was 16.7% (p=0.03);
- HAD Depression decreased 22.2% from baseline (p=0.02). Relative to placebo, the decrease was 38.5% (p=0.02); and
- Fatigue decreased 14.0% from baseline (p=0.04). Relative to placebo, the decrease was 12.4% (p=0.13).

The rationale for the study was that VLD CBP dosed at bedtime might improve FM symptoms and also have a more acceptable side-effect profile than higher doses of CBP administered during daytime. The study showed that bedtime VLD CBP was well-tolerated, with no serious adverse events or discontinuations due to adverse events. The safety profile of VLD CBP compared favorably to that of placebo, and the types of treatment-emergent adverse events observed were relatively consistent with those reported in the Flexeril® (immediate release CBP) product label. This study showed bedtime treatment with VLD CBP improved core FM symptoms of pain, tenderness, fatigue, and depressed mood.

The Phase 2a study also found that analysis of cyclical alternating pattern ("CAP") in sleep EEG revealed that significantly more subjects in the VLD CBP treatment group than the placebo group had increased nights of restorative sleep, which correlated with a reduction in fatigue and improved total HAD and HAD depression scores. CAP rate levels are computer-analyzed rates that are not subject to inter-rater or inter-laboratory variability, unlike older methods of analyzing sleep EEG data. Therefore, CAP rates provide more accurate measurements of the α-EEG sleep abnormality in FM patients.

Professor Harvey Moldofsky, M.D., President and Medical Director of the Sleep Disorders Clinic of the Center for Sleep and Chronobiology, the Wilson Sleep Disorders Clinic and President of the Toronto Psychiatric Research Foundation, and lead author of the article said, "This study demonstrates the ability of bedtime VLD CBP to improve the core fibromyalgia symptoms of chronic widespread pain, unrefreshing sleep and fatigue as well as depressed mood. Further studies will elucidate the extent to which CBP's inhibition of 5HT2a receptors relates to effects on FM symptoms and sleep physiology."

The authors conclude, "Although the mechanism by which bedtime VLD CBP acts remains unclear, this study demonstrates the potential for bedtime VLD CBP to relieve pain, reduce fatigue, decrease tenderness, improve mood and improve sleep quality in patients with FM. The CAP rate may provide a novel biomarker for assessing treatment effects on non-restorative sleep and associated subjective somatic and mood symptoms in FM. Bedtime VLD CBP may have an advantage of decreased drowsiness relative to higher daytime doses. In theory, VLD CBP may have other advantages, since it is expected to have less potential for drug interaction or overdose, and may result in increased adherence as a result of once-daily dosing."

Seth Lederman, M.D., Chairman and President of TONIX, said, "We are pleased to have the results of our Phase 2a study, accepted for publication by *The Journal of Rheumatology*, which is a prestigious peer reviewed journal, and is a leading journal for FM clinical research. This study provides objective data supporting our novel approach to treating FM with VLD CBP. We believe that TNX-102 represents an exciting and meaningful new potential treatment option for FM patients and we look forward to continued validation of our lead product candidate in additional studies as TONIX advances its clinical development program. "

About Fibromyalgia Syndrome
Fibromyalgia Syndrome (FM) is a central nervous system (CNS) condition characterized by diffuse musculoskeletal pain, increased pain sensitivity, fatigue and disturbed sleep. According to the National Institutes of Health, scientists estimate that FM affects 5 million Americans age 18 or older. There are currently three drugs approved for the indication of FM: Lyrica®, an analgesic; Cymbalta® an antidepressant and Savella®, whose active ingredient is marketed as an antidepressant in Europe. No medicine from the "muscle relaxant" category has been approved for FM. Lyrica, Cymbalta and Savella are all daytime treatments; and no bedtime medication has been approved for this indication.

About TONIX Pharmaceuticals, Inc.

TONIX Pharmaceuticals is developing new therapies for challenging disorders of the central nervous system (CNS). The Company targets conditions characterized by significant unmet medical need, inadequate existing treatment options, and high dissatisfaction among both patients and physicians. TONIX re-engineers known pharmaceutical agents to design drugs with optimal safety, efficacy and predictability. Its most advanced product candidates, TNX-102 for FM and TNX-105 for post-traumatic stress disorder (PTSD), are novel dosage oral 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 CNS conditions, please visit www.tonixpharma.com.