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TONIX Pharmaceuticals Presents Findings on the Effects of Bedtime Very Low Dose (VLD) Cyclobenzaprine (CBP) on Symptoms and Sleep Physiology in Patients with Fibromyalgia Syndrome

-Presented at the Associated Professional Sleep Societies, June 2011 25th Anniversary Meeting in Minneapolis, MN

New York, NY – June 16, 2011 – TONIX Pharmaceuticals, a specialty pharmaceutical company developing therapies for challenging disorders of the central nervous system, including Fibromyalgia Syndrome (FM) and Post-traumatic Stress Disorder (PTSD), presented sleep EEG (electroencephalogram) findings from a clinical study in which patients with FM were treated with very low dosage (VLD) cyclobenzaprine (CBP) at bedtime. The VLD CBP treated patients showed a decrease in pain, fatigue, tenderness and depressive symptoms and reported fewer of the side effects often associated with daytime CBP at higher doses. In the new findings, VLD CBP treatment improved sleep efficiency and increased the number of nights with reduced rates of EEG Cyclic Alternating Pattern (CAP) sleep types CAPA2 + CAPA3, which are associated with sleep instability and previously were shown to be elevated in FM patients. The findings were the subject of a poster presentation at the Associated Professional Sleep Societies 2011 Anniversary Meeting in Minneapolis, MN.

Dr. Harvey Moldofsky, President and Medical Director, Centre for Sleep and Chronobiology, Toronto, Canada, and lead author of the study, commented, "This study showed that a low dose of cyclobenzaprine taken at bedtime improves the widespread pain and tenderness in patients with fibromyalgia. It also provides a novel algorithm that identifies reductions in a specific EEG pattern of sleep instability that correlate with improvements in the nonrestorative sleep symptoms of fatigue and disturbed mood."

"These new findings suggest that our technology for bedtime treatment of fibromyalgia with very low dose cyclobenzaprine confers benefits that have been associated with restful or restorative sleep," stated President Seth Lederman, M.D., Chairman and President of TONIX.

About the Study

The study was a randomized, double-blind, placebo-controlled, dose-escalating parallel-design study in 36 patients with FM conducted at two Canadian sites. The study was

analyzed with regard to efficacy, safety and tolerability as well as EEG and other parameters assessed during sleep. VLD CBP treated subjects showed significant improvements over eight weeks in pain, fatigue, tenderness, the Hospital Anxiety and Depression Scale (HAD), and sleep efficiency. In addition, VLD CBP was well tolerated, with no adverse events or discontinuations due to adverse events. The sleep EEG data were analyzed for the types of CAP: CAPA1 (associated with sleep stability) and CAPA2 + CAPA3 (usually associated with sleep instability). VLD CBP treatment increased EEG sleep nights with normalized CAPA2+A3, or CAPA2+A3(Norm) $\leq 33\%$. Increased nights of CAPA2+A3(Norm) $\leq 33\%$ correlated with improvement in fatigue, total HAD score, HAD depression subscore, and self-rated and clinician-rated change in fatigue. In VLD CBP treated subjects, the correlation of increased nights of CAPA2+A3(Norm) $\leq 33\%$ with improvement with FM symptoms is consistent with the hypothesized effects of restorative sleep. The symptomatic benefit may relate to VLD CBP decreasing arousal or alarm signals during sleep. CAPA2+A3(Norm) rate may provide a novel biomarker for assessing treatment effects on nonrestorative sleep and associated subjective somatic and mood symptoms in FM. The full abstract can be found at www.sleepmeeting.org (# 0690).

About TONIX Pharmaceuticals

TONIX Pharmaceuticals is developing new treatments for challenging disorders of the central nervous system. The Company's most advanced program targets fibromyalgia syndrome based on bedtime treatment with very low dosage cyclobenzaprine. Cyclobenzaprine in higher doses is the active ingredient of U.S. FDA approved muscle relaxants. Based on this foundation, the Company is building a deep and diverse pipeline of high-value medications for other syndromes, disorders and diseases, including post-traumatic stress disorder. For more information, please visit www.tonixpharma.com.