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TONIX Pharmaceuticals Reports Analysis of Phase 2a Study of Very Low Dosage Cyclobenzaprine in Fibromyalgia Syndrome (FMS)

- For the First Time, Correlation Demonstrated between Sleep Stability and Reductions of Fatigue in FMS -

- Results Presented at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) 2010 Annual Scientific Meeting -

New York, NY – November 9, 2010 – TONIX Pharmaceuticals (formerly known as Krele Pharmaceuticals), a specialty central nervous system (CNS) pharmaceutical company, announced today results of a new analysis of a Phase 2a study, which previously demonstrated reduced pain, fatigue and tenderness in patients with Fibromyalgia Syndrome (FMS) following bedtime administration of very low dosage (VLD) cyclobenzaprine (CBP). According to the analysis, VLD CBP treatment was associated with reductions in an objective measure of non-REM sleep instability, referred to as Cyclic Alternating Patterns (CAP) A2 & A3; these reductions were statistically significantly correlated with diminished pre-sleep/p.m. fatigue in FMS. The findings are the subject of a poster presentation at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) 2010 Annual Scientific Meeting.

Dr. Harvey Moldofsky, President and Medical Director, Centre for Sleep and Chronobiology, Toronto, Canada, and lead author of the study, commented, “Current treatments for FMS are inadequate, and there is substantial interest in the impact of improving sleep quality in these patients. Our analysis demonstrates improvements in FMS fatigue can be correlated with a therapeutic modality that normalizes nonrestorative sleep, and we believe this provides additional confirmation of the central importance of poor sleep quality in FMS.”

“Dr. Moldofsky’s latest contribution to understanding the relationship of fibromyalgia and non-restorative sleep is a significant advance because bedtime VLD cyclobenzaprine has subtle and specific effects on sleep, unlike agents that are potent sedatives. Further, VLD cyclobenzaprine is well-tolerated, and, in general, cyclobenzaprine has not been associated with tolerance or abuse at higher daily doses, as demonstrated in formulations currently on the market in the U.S.,” stated President Seth Lederman, M.D. “The more data we have, the firmer our belief that it would be critically important for fibromyalgia patients to receive the correct dose, formulation and treatment regimen of cyclobenzaprine for optimal treatment of

their condition. We therefore are advancing the development of VLD cyclobenzaprine toward submission of a New Drug Application, and research such as Dr. Moldofsky's is a critical step along this path."

TONIX also announced a separate poster presentation at the ACR/ARHP 2011 Annual Scientific Meeting. In preclinical research, VLD CBP showed potent antagonism of both the Serotonin Type 2a receptor (5-HT_{2a}) and α -2 adrenergic receptors. Functional antagonism of these receptors may underlie the ability of bedtime VLD CBP to improve sleep quality in FMS.

About the Phase 2a Study

The Phase 2a dose-escalating, double-blind, placebo-controlled, randomized trial enrolled 36 individuals with FMS in two sites in Canada. Polysomnography data were retrospectively analyzed, and responders had normalized CAP A2 + A3 after 2, 4 or 8 weeks of treatment relative to screening and baseline assessments. Reduction in p.m. fatigue in VLD CBP-treated subjects was significantly correlated with decreases in CAP A2 & A3 rates ($p = 0.0064$), whereas p.m. fatigue was neither decreased nor correlated with responder status in placebo-treated subjects. CAP A2 & A3 rates are objective measures of sleep instability detected via electroencephalogram (EEG).

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 very low dosage cyclobenzaprine, an active pharmaceutical ingredient used in higher doses in approved therapeutics in the U.S. 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.