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Tonix Pharmaceuticals Receives FDA Clearance to Initiate a Pharmacokinetic Study of TNX-102 For Fibromyalgia

NEW YORK-- Tonix Pharmaceuticals Holding Corp. (OTCBB:TNXP) (“TONIX” or the “Company”), a specialty pharmaceutical company developing therapies for challenging disorders of the central nervous system (“CNS”), including fibromyalgia syndrome (“FM”) and post-traumatic stress disorder (“PTSD”), will initiate a comparative pharmacokinetic (“PK”) and bioavailability (“BA”) study of TNX-102, a novel dosage oral formulation of cyclobenzaprine for the treatment of FM, following the U.S. Food and Drug Administration (“FDA”) clearance of the Company’s initial Investigational New Drug Application. TONIX also received clearance from Health Canada, which issued a No Objection Letter to the Company’s Clinical Trial Application.

This comparative PK/BA study is expected to enroll approximately 30 healthy adult volunteers to participate in a single-dose, open-label, randomized three-way-crossover study. The study will compare a TNX-102 candidate gelcap containing a very low dose (2.4 milligrams) of cyclobenzaprine to a currently available, immediate-release, 5 milligram cyclobenzaprine tablet. In addition, the effect of food on the PK of TNX-102 will be investigated in subjects who are either fasting or fed with a high-fat, high-caloric breakfast. The study will measure each subject’s circulating blood levels of cyclobenzaprine over time in each condition. A leading global clinical research organization based in Canada will be conducting the study in Quebec City, Quebec, Canada. TONIX anticipates the clinical portion of the study will be completed by year-end, and that analysis of the subjects’ blood samples will be completed in early 2012.

Seth Lederman, M.D., Chairman and President of TONIX said, “The objective of this PK study is to compare the PK profile of our proprietary gelcap formulation, TNX-102, to a conventional immediate-release formulation. Immediate release cyclobenzaprine results in relatively steady blood levels over the course of the day, which is ideal for the treatment of muscle spasm, its approved indication. TNX-102 is specifically formulated to work at night after bedtime administration. If this study validates our hypothesis, we will proceed with the first of our two pivotal clinical trials. Our successful Phase 2a proof-of-concept study, which used an immediate release capsule formulation of very low dose cyclobenzaprine, showed FM patients benefitted from bedtime very low dose cyclobenzaprine and that improvements were correlated with increased nights of restorative sleep. Our goal is to develop a bedtime cyclobenzaprine treatment with more predictable beneficial effects and possibly reduced next day drowsiness.”

The results of the Phase 2a study were recently published in the electronic edition of the Journal of Rheumatology and can be accessed at

<http://jrheum.org/content/early/2011/08/30/jrheum.110194.full.pdf+html>.

About TNX-102

TNX-102 is a bedtime gelcap 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 formulation of TNX-102 administered at bedtime will provide more predictable beneficial effects with less likelihood of next-day drowsiness 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 Pharmaceuticals

TONIX Pharmaceuticals is developing new therapies 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 reformulates approved pharmaceutical active ingredients to design products with optimal safety, efficacy and predictability. Its most advanced product candidates, TNX-102 for FM and TNX-105 for PTSD, are novel dosage formulation 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.

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 Current Report on Form 8-K filed with the SEC on October 14, 2011 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.

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