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# **TONIX Pharmaceuticals Completes Pharmacokinetic Study on New Formulation of TNX-102 for Fibromyalgia**

## **Results Justify Further Development of TNX-102 as Potential Bedtime Treatment 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") completed a pharmacokinetic (PK) study of the first formulation of its lead drug, TNX-102, for the treatment of fibromyalgia syndrome ("FM"). The study results support further development of TNX-102 as a product that can potentially deliver benefits similar to those observed in FM patients treated with very low dose cyclobenzaprine in the Company's dose-escalating Phase 2a study. This research was published in the December 2011 edition of the Journal of Rheumatology and can be viewed by accessing the following link:

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

TONIX is developing new formulations of cyclobenzaprine that are designed for bedtime use. The Company is investigating different technologies to improve the absorption of cyclobenzaprine. The technology applied in this study involves a mixture of cyclobenzaprine and lipids that the Company obtained from Lipocine, Inc. and is designated TNX-102 2.4 mg promicellar gelatin capsules, or gelcaps.

The PK study was conducted on healthy subjects in Canada under a U.S. Investigational New Drug Application, or IND, and a Canadian Clinical Trial Application, or CTA. This cross-over randomized study assessed the blood levels of cyclobenzaprine in approximately 30 healthy adult volunteers after they ingested either a TNX-102 2.4 mg promicellar gelcap or a marketed, generic version of Flexeril® 5 mg immediate release cyclobenzaprine. Circulating blood levels of cyclobenzaprine after oral administration of the TNX-102 2.4 mg promicellar gelcap in a fed or fasting state were determined and compared to the blood levels resulting from oral administration of the currently marketed 5 mg immediate release tablet ("tablet") in a fasting state. The clinical portion of this study was completed at the end of 2011 and analyses of the data were completed during the first quarter of 2012.

Both TNX-102 2.4 mg promicellar gelcaps and the cyclobenzaprine 5 mg immediate release tablet were well-tolerated in this PK study. There were no serious and/or unexpected adverse events, which was consistent with TONIX's expectations and the marketing experience with cyclobenzaprine, a widely used treatment for muscle spasm.

The new formulation preserved fundamental properties of the tablet including the rate of absorption and elimination of cyclobenzaprine. Absorption was measured by the time to

peak plasma concentration, or  $T_{max}$ , and elimination was measured by the half-life, or  $T_{1/2}$ . The finding that the TNX-102 2.4 mg promicellar gelcap formulation did not change the  $T_{max}$ , or the  $T_{1/2}$  of cyclobenzaprine delivered by the 5 mg immediate release tablets suggests that the new formulation will maintain clinical effects of immediate release cyclobenzaprine such as the beneficial effects on FM patients observed in our dose-escalating Phase 2a study.

When compared to the generic cyclobenzaprine 5 mg immediate release tablet administered under fasting conditions, the TNX-102 2.4 mg promicellar gelcap has a lower extent and rate of absorption, as measured by the “area under the curve” or “AUC” of the time and concentration data and also by the maximum concentration or  $C_{max}$ . The finding demonstrates that TNX-102 2.4 mg promicellar gelcap is clearly differentiated and not bioequivalent to generic cyclobenzaprine 5 mg immediate release tablet, and suggests that a commercial product based on the new formulation would be protected from substitution by pharmacists with generic cyclobenzaprine.

No food effect was observed in the comparison of TNX-102 2.4 mg promicellar gelcaps between fed and fasting states, indicating this formulation provides dosing precision. TONIX plans to conduct at least one additional pharmacokinetic study before selecting a final formulation for clinical development that will be tested on FM patients. TONIX is on track to initiate a pivotal efficacy study with the final formulation of TNX-102 in the first quarter of 2013.

Seth Lederman, M.D., Chairman and President of TONIX said, “We are pleased to have completed the pharmacokinetic study on the first TNX-102 formulation, which represents an important milestone for our company. The results of this study provide us with valuable insights which will enable us to further advance our development programs targeting Fibromyalgia and other challenging disorders of the central nervous system. The core technology underlying TNX-102 improves the quality of sleep in patients with fibromyalgia and perhaps other chronic pain syndromes. We are developing TNX-102 to be a fundamental advance in sleep hygiene and pain management and to be safer and more effective than currently available treatments.”

## **About Fibromyalgia**

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**

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](http://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.*

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