

TONIX Pharmaceuticals Announces Poster Presentation at the 2012 American College of Rheumatology Annual Scientific Meeting

Published Abstract Describes Metabolism and Receptor Interactions of Bedtime Cyclobenzaprine Treatment for Fibromyalgia

NEW YORK, NY -- (MARKETWIRE) -- 09/19/12 -- Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing non-addictive treatments for chronic pain syndromes, today announced the online publication of the abstract of preclinical and human pharmacokinetic data related to the Company's fibromyalgia and post-traumatic stress disorder programs that it will present at the 2012 American College of Rheumatology (ACR) / Association of Rheumatology Health Professionals Annual Scientific Meeting to be held from November 10-14, 2012 at the Walter E. Washington Convention Center in Washington, D.C. The abstract can be accessed at http://www.acrannualmeeting.org/ by members of the ACR or by individuals registered to attend the meeting.

The presentation details are as follows:

- Abstract Title: Cyclobenzaprine (CBP) and Its Major Metabolite Norcyclobenzaprine (nCBP) are Potent Antagonists of Human Serotonin Receptor 2a (5-HT2a), Histamine Receptor H1 and Alpha-Adrenergic Receptors: Mechanistic and Safety Implications for Treating Fibromyalgia Syndrome by Improving Sleep Quality
- Date: Monday, November 12, 2012 from 9:00 a.m. to 6:00 p.m.
- Location: Poster Hall (Hall B)
- Session: Fibromyalgia and Soft Tissue Disorders
- Presented by: Bruce Daugherty, Ph.D., Senior Director of Drug Development, TONIX
- Abstract: #960

The abstract presents data showing blood levels of a metabolite, norcyclobenzaprine (nCBP), were unexpectedly high and persistent in healthy volunteers who ingested a 5 mg tablet of cyclobenzaprine (CBP). A single oral dose of 5 mg CBP exhibits a maximum blood level, or C_{max} of 4.12 ng/ml, and a blood half-life, or $T_{1/2}$ of 31 hours, similar to previously reported results. However, nCBP was produced by the liver and appeared in the blood with a C_{max} of 1.27 ng/ml and a $T_{1/2}$ of 73 hours. Previously, plasma nCBP had only been detected in cases of overdose.

The abstract also showed that that CBP and nCBP are both active at blocking certain central

nervous system receptors, which include the serotonin 5-HT2A receptor, the histamine H1 receptor and the adrenergic alpha 1A receptor.

Dr. Daugherty, the lead author of the study commented, "CBP is metabolized to nCBP, which persists in plasma at biologically relevant concentrations after oral CBP in healthy subjects. Antagonists of 5HT2a and H-1 are known to have effects on sleep and sleep maintenance. Adrenergic antagonists may have effects on autonomic dysfunction. The accumulation of biologically active nCBP without N⁺-glucuronidation may affect responses to CBP therapy in a chronic bedtime dosing regimen."

About Fibromyalgia

Fibromyalgia ("FM") is a common and complex central nervous system condition characterized by chronic diffuse musculoskeletal pain, increased pain sensitivity at multiple tender points, fatigue, abnormal pain processing, and disturbed sleep, and often features psychological stress. Despite the fact that most FM patients suffer from poor sleep, there are no medications indicated for FM that work by improving sleep quality. Research has shown that the restorative sleep of FM patients is disrupted by alarm signals called CAP A2 and A3. In a Phase 2a trial, TONIX demonstrated that bedtime administration of very low dose cyclobenzaprine improves core FM symptoms including pain, tenderness, fatigue, and depression, and also demonstrated that improvements in key symptoms correlate with increased nights of restorative sleep. These results were published in the December 2011 issue of the *Journal of Rheumatology*.

About TNX-102 SL

TNX-102 SL is a novel sublingual formulation of cyclobenzaprine for bedtime use. TONIX designed TNX-102 SL to provide faster and more efficient absorption of cyclobenzaprine, relative to currently marketed products approved for other indications. TONIX believes TNX-102 SL administered at bedtime will provide more targeted sleep quality effects with less likelihood of side effects than commercially-available cyclobenzaprine preparations.

About TONIX

TONIX is developing innovative prescription medications 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's core technology improves the quality of sleep in patients with chronic pain syndromes. TONIX's lead product is designed to be a fundamental advance in sleep hygiene and pain management and to be safer and more effective than currently available treatments. Its most advanced product candidate, TNX-102 SL for FM and post-traumatic stress disorder, is a novel dosage formulation of cyclobenzaprine, the active ingredient in two U.S. FDA-approved muscle relaxants. To learn more about the Company, 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 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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