March 11, 2013

TONIX Completes Pre-Phase 3 Meeting With U.S. Food and Drug Administration for TNX-102 SL in Fibromyalgia

Regulatory Acceptance of Design of Registrational Clinical Studies; Dosing in First Safety and Efficacy Trial to Commence in the Third Quarter of 2013

NEW YORK, NY -- (MARKETWIRE) -- 03/11/13 -- Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) ("TONIX" or "the Company"), a specialty pharmaceutical company developing novel treatments for challenging disorders of the central nervous system, including fibromyalgia ("FM") and post-traumatic stress disorder ("PTSD"), announced that it recently held an End-of-Phase 2/Pre-Phase 3 meeting with the U.S. Food and Drug Administration ("FDA") to discuss its proposed New Drug Application ("NDA") plan for the Company's novel sublingual tablet formulation of cyclobenzaprine for bedtime use, TNX-102 SL, for the management of FM. Official FDA meeting minutes indicate FDA acceptance of the clinical program and provide clear direction to achieve a successful NDA filing of TNX-102 SL in FM.

The registrational clinical trials will consist of two randomized, double-blind, placebo-controlled 12-week safety and efficacy studies in FM patients who will take either a TNX-102 SL (cyclobenzaprine HCl 2.8 mg) tablet or placebo at bedtime. The primary endpoint of both trials will be the change in pain from baseline to Week 12 as measured by the Numeric Rating Scale. The Company plans to conduct these trials in sequence, and expects to begin dosing in the first trial in the third quarter of 2013. This trial will enroll 100 to 200 FM patients, and top-line data are anticipated to become available in the second half of 2014.

Following the completion of the double-blind randomized portion of these studies, patients may be eligible to enroll in open-label extension studies of TNX-102 SL. The FDA agreed that the safety database needed to support a 505(b)(2) NDA submission for TNX-102 SL would contain a total exposure of at least 300 FM patients, with at least 100 patients receiving TNX-102 SL for six months and at least 50 patients for one year.

Seth Lederman, M.D., Chief Executive Officer of TONIX, said, "We view our meeting with the FDA as a major milestone for TONIX. We are pleased to have concurrence from the FDA on the design and selection of efficacy endpoints of our registrational clinical studies in FM in addition to receiving clear guidance on the remaining requirements for the TNX-102 SL NDA program. We are also pleased with the FDA's requirements on chronic exposure, which are appropriately less than those typically needed for a new drug to be approved for a chronic use indication. We look forward to advancing TNX-102 SL towards a successful NDA filing."

About Tonix Pharmaceuticals Holding Corp.

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, which is believed to translate into reductions in pain and other symptoms. An Investigational New Drug Application ("IND") has been filed for the Company's lead product candidate, TNX-102 SL, a novel under-the-tongue tablet formulation of cyclobenzaprine, the active ingredient in two FDA-approved muscle relaxants. TONIX expects to begin a registrational clinical study of TNX-102 SL in FM in the third quarter of 2013. TONIX expects to file an IND for TNX-102 SL in PTSD in the third quarter of 2013, and to begin a Phase 2 trial in this indication in the fourth quarter of 2013. To learn more, 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.

Contact:
Tonix Pharmaceuticals Holding Corp.
Leland Gershell
Chief Financial Officer
(212) 980-9155 x104
leland.gershell@tonixpharma.com

Investor Relations:
Dian Griesel Inc.
Cheryl Schneider
(212) 825-3210
cschneider@dgicomm.com

Public Relations:

Dian Griesel Inc.
Susan Forman
(212) 825-3210
sforman@dgicomm.com