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Tonix Pharmaceuticals Announces Completion of Clinical Trial of Sublingual TNX-102

Results Support Development as a Bedtime Therapy for Fibromyalgia

NEW YORK--(BUSINESS WIRE)--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"), announces that the clinical portion of a human study of a solution version of TNX-102 2.4 mg sublingual tablets ("TNX-102 SL") has completed. TNX-102 is TONIX's very low dose form of cyclobenzaprine, which the Company is developing as a first-in-class medication for the management of FM.

This comparative pharmacokinetic ("PK") and bioavailability study was conducted in Canada by a leading global clinical research organization. The trial evaluated a solution formulation of the Company's TNX-102 SL tablet containing 2.4 mg of cyclobenzaprine, a control sublingual solution that was designed to simulate crushed immediate-release cyclobenzaprine tablets (2.4 mg), oral ingestion of an immediate-release cyclobenzaprine tablet (5 mg), and intravenous cyclobenzaprine (2.4 mg). The study enrolled 23 healthy adult volunteers and periodically measured circulating blood levels of cyclobenzaprine over six days after receiving study medication.

Seth Lederman, M.D., Chairman and President of TONIX said, "We designed TNX-102 SL to work overnight following bedtime administration, with the goal of improving the pain and other symptoms of FM by improving sleep quality. We view these results as highly encouraging. This was a stringent test of sublingual absorption of cyclobenzaprine, as patients receiving sublingual formulations were instructed to spit and rinse 90 seconds following administration. TNX-102 SL was well-tolerated, and no serious adverse events were reported. The PK results demonstrated that the solution formulation of TNX-102 SL delivered cyclobenzaprine to the systemic circulation more efficiently than the sublingual solution of a simulated crushed tablet and faster than the ingested tablet. We believe the kinetics of plasma cyclobenzaprine demonstrated by TNX-102 SL will translate to more rapid effects compared with current cyclobenzaprine products. We believe these improvements favor its advancement in the FM indication. The data also indicate that, in contrast to our proprietary formulation, sublingual absorption cannot be achieved by crushing currently-available cyclobenzaprine products. We are on track to commence a pivotal clinical trial of TNX-102 SL tablets for FM in the first quarter of 2013."

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. 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. 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

TONIX is developing innovative prescription medications for challenging disorders of the CNS. 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 products are designed to be fundamental advances in sleep hygiene and pain management and to be safer and more effective than currently available treatments. TONIX's products are the result of a program to harvest advances in science and medicine to search for potential therapeutic solutions among known pharmaceutical agents. TONIX is developing new formulations that have been optimized for new therapeutic uses. Its most advanced product candidates, TNX-102 for FM and TNX-105 for PTSD, are novel dosage formulations 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 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.