Tonix Pharmaceuticals Initiates Enrollment in Phase 2b BESTFIT Trial of TNX-102 SL in Fibromyalgia Patients

NEW YORK, NY--(September 16, 2013) - Tonix Pharmaceuticals Holding Corp. (TNXP), a development stage specialty pharmaceutical company, today announced the start of its Phase 2b BESTFIT (BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy) trial of the Company's lead therapeutic candidate, TNX-102 SL 2.8 mg tablets, in patients with fibromyalgia.

BESTFIT is a randomized, double-blind trial of TNX-102 SL versus placebo in patients diagnosed with primary fibromyalgia. The trial is expected to enroll approximately 120 patients who will be randomized (1:1) to receive either TNX-102 SL or placebo tablets, taken sublingually at bedtime, daily for 12 weeks. The trial will be conducted at approximately 13-15 U.S. sites. The primary endpoint of the trial is change in pain intensity at week 12 from baseline, as evaluated by scoring on the 11-point Numeric Rating Scale. Safety and tolerability of TNX-102 SL taken at bedtime over 12 weeks will also be evaluated.

The Study Chair of the BESTFIT trial is Daniel J. Clauw, M.D., Professor of Anesthesiology, Medicine, and Psychiatry and Director of the Chronic Pain and Fatigue Research Center at the University of Michigan.

"Enrollment of the first patient in the BESTFIT trial of TNX-102 SL in fibromyalgia represents an important milestone in the clinical development of TNX-102 SL and for Tonix as a company. We look forward to completing this trial in time to report the top-line results in the second half of 2014," said Seth Lederman, M.D., Chief Executive Officer and President of Tonix. "We continue to pursue opportunities for TNX-102 SL in other indications, including post-traumatic stress disorder," he added.

About Tonix Pharmaceuticals Holding Corp.
Tonix is developing innovative prescription medications for challenging disorders of the central nervous system. The Company seeks to address conditions characterized by significant unmet medical need, inadequate existing treatment options, and high dissatisfaction among patients and physicians. Tonix's lead pharmaceutical candidate, TNX-102 SL, targets central pain.

Fibromyalgia is a central pain syndrome, and central pain is a component of post-traumatic stress disorder. Tonix applies its core technology toward the treatment of people suffering from central pain disorders by targeting their inability to obtain restorative sleep. 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," "estimate" 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 11, 2013 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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