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Tonix Pharmaceuticals Initiates Phase 2 Clinical Study of TNX-201 in Episodic Tension-Type Headache

– Frequent episodic tension-type headache estimated to afflict 75 million Americans –

– Top-line results expected 4Q 2015 –

NEW YORK, June 16, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) ("Tonix"), a clinical-stage company developing next-generation medicines for fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache, today announced that it has begun randomizing patients into a Phase 2 clinical study of TNX-201 (dexisometheptene mucate) in episodic tension-type headache. The study is expected to enroll approximately 200 patients at nine clinical centers in the United States. Tonix plans to report top-line results from this study in the fourth quarter of 2015.

This randomized, double-blind, placebo-controlled, proof-of-concept (POC) Phase 2 study will evaluate the efficacy and safety of a single 140 mg dose of TNX-201 versus placebo for the treatment of a single tension-type headache. In addition to the primary efficacy endpoint of pain-free at two hours post-dose as recommended by the U.S. Food and Drug Administration (FDA) for a prospective confirmatory tension headache study, this POC Phase 2 study will also assess efficacy according to a variety of measures, including: the proportion of patients reported to be pain-free at several other post-dose time intervals as assessed on a four-point Numeric Rating Scale (NRS), Visual Analog Scale (VAS), and binary questionnaire for self-reporting pain; the proportion of patients who utilize rescue medication during the 24-hour post-dose period; and the change from baseline pain severity at several time intervals. This study is adequately designed to establish efficacy and safety evidence to support a future confirmatory study. In addition, this POC Phase 2 study may reveal efficacy endpoints that are more relevant to episodic tension-type headache than pain-free at two hours. To learn more, please visit www.clinicaltrials.gov (NCT02423408).

"Approximately 75 million people in the U.S. suffer from frequent episodic tension-type headache, a condition that is estimated to be three times as prevalent as migraine. We believe TNX-201 may offer differentiation from currently-approved drugs for episodic tension-type headache, all of which contain barbiturates," stated Seth Lederman, M.D., chairman and CEO of Tonix. "If approved by the FDA, TNX-201 may become the only non-narcotic prescription medicine for episodic tension-type headache and the first new prescription pharmaceutical approved for this indication in more than 40 years. We look forward to reporting top-line results from our Phase 2 study in episodic tension-type headache in the fourth quarter of this year."

In a Phase 1 single ascending dose safety, tolerability, and pharmacokinetic study, TNX-201

was well-tolerated at all doses tested and no subject discontinued due to treatment-emergent adverse events. Dose-dependent pharmacokinetic behavior was observed, with no evidence of isomer interconversion.

About Episodic Tension-Type Headache

Episodic tension-type headache is the most common type of headache. It is estimated that approximately 30% of U.S. adults experience frequent episodic tension-type headaches (one to 15 headaches per month over a three-month period). Tension-type headache pain is often described as a constant pressure on both sides of the head, and typically lasts for several hours. All of the FDA-approved prescription options for tension-type headache contain barbiturates.

About TNX-201

The active ingredient in TNX-201 is dexisometheptene mucate, the (R) isomer of isometheptene mucate. Racemic isometheptene mucate, a mixture of both the (R) and (S) isomers, is an active ingredient that had been widely used as a single-agent prescription medicine and as a component of combination drug products (e.g. Midrin®) for many decades in the U.S. for various indications including tension-type headache. Isometheptene mucate was introduced as a pharmaceutical prior to 1962, and no products containing isometheptene mucate are currently approved by the FDA for any indication. TNX-201 is being developed for the treatment of episodic tension-type headache to conform to modern FDA standards as a new chemical entity. Non-clinical studies of isometheptene isomers conducted under Tonix's direction have shown that TNX-201 potently and selectively binds to receptors in the central nervous system known as imidazoline type-1 (I1) receptors, where it acts as a receptor agonist. Studies have also shown that TNX-201 significantly increases the pain threshold in standard animal models of acute pain response as compared to vehicle control.

About Tonix Pharmaceuticals Holding Corp.

Tonix is dedicated to the development of next-generation medicines for common yet challenging disorders of the central nervous system, characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. Tonix's TNX-102 SL is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia and in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 POC study of TNX-201 for episodic tension-type headache was initiated in the second quarter of 2015. This press release and further information about Tonix can be found at www.tonixpharma.com.

TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved for any indications.

Cautionary Note on Forward Looking Statements

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 possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development 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 February 27, 2015 and future periodic reports filed with the Securities and Exchange Commission. All of Tonix'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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