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Tonix Pharmaceuticals Initiates Second Pivotal Phase 3 Clinical Study of TNX-102 SL in Fibromyalgia

First Pivotal Phase 3 Study of TNX-102 SL to Report Topline This Quarter

NEW YORK, July 26, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced today that the first patient has been randomized in RE-AFFIRM, the second Phase 3 clinical study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, in fibromyalgia.

Seth Lederman, M.D., president and chief executive officer of Tonix, said, “We have taken an important step forward in advancing the clinical development of a much-needed new therapy for the 5 to 15 million people in the U.S. suffering with fibromyalgia by initiating our second pivotal Phase 3 study of TNX-102 SL in fibromyalgia. This is a once-daily bedtime sublingual formulation designed to treat fibromyalgia by improving sleep quality, and given the results of our Phase 2b BESTFIT study, we believe TNX-201 SL could offer therapeutic benefits to patients with fibromyalgia across a broad spectrum of symptoms**.** It has the potential to capture an important share of the $1.2 billion market for approved fibromyalgia drugs. The clinical phase of AFFIRM, our first Phase 3 study of TNX-102 SL in fibromyalgia, is now complete and we anticipate announcing its topline data later this quarter.”

RE-AFFIRM is a randomized, double-blind, placebo-controlled study similar in design to the ongoing AFFIRM Phase 3 clinical trial of TNX-102 SL in fibromyalgia. The U.S. Food and Drug Administration (FDA) requires two well-documented registration-quality clinical studies to support marketing approval of a new drug. Like AFFIRM, RE-AFFIRM is expected to enroll approximately 500 fibromyalgia patients at approximately 35 clinical centers in the U.S. For information about RE-AFFIRM, please visit www.clinicaltrials.gov.

RE-AFFIRM will evaluate the efficacy of TNX-102 SL, taken daily at bedtime, in improving pain, sleep quality, and other clinical measures, as well as safety. As accepted by the FDA, the primary outcome assessment of the study will be a pain responder analysis, defined as the proportion of patients who report at least a 30 percent reduction in pain from baseline at the end of the 12-week treatment period. In Tonix’s Phase 2b BESTFIT trial of TNX-102 SL in fibromyalgia patients, the 30 percent responder analysis was a pre-specified secondary outcome measure and achieved a statistically significant p-value of 0.033.

TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

About Fibromyalgia

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

About TNX-102 SL

TNX-102 SL is designed to deliver cyclobenzaprine to the bloodstream rapidly via sublingual (under the tongue) absorption and to bypass first-pass hepatic metabolism. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is under clinical development for the treatment of fibromyalgia and PTSD and is intended to provide broad spectrum improvement by targeting sleep and the stress response. Tonix is developing TNX-102 SL 2.8 mg for daily bedtime administration for the treatment of fibromyalgia and TNX-102 SL 5.6 mg for daily bedtime administration for the treatment of PTSD. The FDA has provisionally accepted the trademark Tonmya® for TNX-102 SL for fibromyalgia.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

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," "expect," 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 for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. 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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