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Tonix Pharmaceuticals Launches Phase 3 Clinical Study of TNX-102 SL in Fibromyalgia

AFFIRM Study to Enroll 500 Patients in Up to 35 U.S. Centers

NEW YORK, May 13, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) ("Tonix") announced today that it has begun a Phase 3 clinical study of TNX-102 SL (cyclobenzaprine HCl sublingual tablet, 2.8 mg) in fibromyalgia, having recently randomized the first patient. The study is expected to enroll approximately 500 patients with fibromyalgia at approximately 35 clinical centers in the U.S.

The randomized, double-blind, placebo-controlled "AFFIRM" study will evaluate the efficacy of TNX-102 SL taken daily at bedtime in improving pain, sleep quality, and other clinical measures, as well as the safety of TNX-102 SL. As accepted by the U.S. Food and Drug Administration ("FDA"), the primary outcome assessment for 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. Tonix expects to report top-line results from the AFFIRM study in the second half of 2016. To learn more, please visit www.clinicaltrials.gov (NCT02436096).

"Fibromyalgia is one of the most common chronic pain conditions, and yet despite approved medications, the majority of patients either do not respond to, or cannot tolerate, these products," said Daniel J. Clauw, M.D., professor of anesthesiology, medicine (rheumatology) and psychiatry and director of the Chronic Pain and Fatigue Research Center at the University of Michigan, and a consultant to Tonix. "The efficacy and tolerability profile of TNX-102 SL as demonstrated in prior clinical evaluations supports this candidate as a promising treatment for fibromyalgia."

"We are proud to be developing a new prescription medicine for people suffering from a condition that, despite its prevalence, remains inadequately addressed," said Seth Lederman, M.D., chairman and CEO of Tonix. "If approved, we believe TNX-102 SL would offer a clinical profile that would be highly differentiated from currently-marketed drug products, and would be the first medicine for fibromyalgia to target non-restorative sleep."

About Fibromyalgia

Fibromyalgia is a prevalent central nervous system disorder that is thought to result from amplified sensory and pain signaling. Common symptoms of fibromyalgia include chronic widespread pain, unrefreshing sleep (poor sleep quality), and fatigue. As a result of these symptoms, individuals suffering from fibromyalgia struggle with normal daily activities, have

impaired quality of life, and frequently are disabled. It is estimated that five to 15 million Americans are afflicted with fibromyagia.

About Tonix Pharmaceuticals

Tonix Pharmaceuticals 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 (PTSD). A Phase 2 proof-of-concept study of TNX-201 for episodic tension-type headache will begin in the second quarter of 2015. To learn more, please visit www.tonixpharma.com.

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 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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