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Tonix Pharmaceuticals Reports Top Line Results From Phase 2 Proof-of-Concept Clinical Study of TNX-201 in Episodic Tension-Type Headache

NEW YORK, Feb. 16, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), today announced topline results of the Phase 2 proof-of-concept (POC) clinical study of TNX-201 (dexisometheptene mucate) in episodic tension-type headache (ETTH).

Based on preliminary analysis of the results from this exploratory study, Tonix has determined that the study did not achieve its primary efficacy endpoint of participants achieving headache pain-free status at two hours after dosing. The study also did not achieve two other primary endpoints, which were the proportion of participants with at least a 70% reduction in pain from baseline on the Visual Analog Scale (VAS) at two hours after dosing, and an increase of the mean change from baseline to two hours post-dose in the VAS score. The goal of this POC trial was to evaluate the potential clinical benefit of using TNX-201 to treat tension-type headache. A single 140 mg dose of TNX-201 was compared to placebo for the treatment of a single tension-type headache. A single 140 mg dose of TNX-201 proved to be safe and extremely well tolerated by all participants with ETTH. No serious adverse events were reported throughout the duration of the study. There were no treatment emergent adverse event categories reported by more than one participant (1.4%) in either treatment group during the double-blinded treatment period.

“We were interested in exploring the potential clinical benefit of TNX-201 as a new class of analgesic that might offer a non-addictive headache treatment option. Racemic isometheptene mucate previously had been used as a treatment for both tension-type headaches and migraine,” said Seth Lederman, M.D., Tonix’s president and CEO. “Given the current treatment landscape, we determined tension-type headache to be the most probable and feasible path to commercialization for TNX-201. We executed a well-designed and efficient POC study to determine whether our hypothesis had merit. Among other things, the data showed that TNX-201 did not demonstrate efficacy in patients with ETTH whether or not they had a history of migraine headaches. Although TNX-201 has proved to be safe and very well tolerated in the study, our review of the results supports discontinuing all work on this program.”

“These results are disappointing, but we designed the study to challenge our hypothesis rapidly and with minimal capital investment. We are satisfied that we achieved a definitive outcome,” continued Dr. Lederman. He concluded, “We are excited to continue the rigorous

execution of our registration-quality Phase 2 study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in post-traumatic stress disorder, as well as our flagship development program, a Phase 3 trial in fibromyalgia of TonmyaÔ (TNX-102 SL, cyclobenzaprine HCl sublingual tablets, 2.8 mg). We look forward to reporting data from these studies, planned for the second and third quarters this year, respectively."

The POC study of TNX-201 was a randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of a single 140 mg dose of TNX-201 versus placebo in 147 patients treating a single tension-type headache. The TNX-201 (n = 75) and placebo groups (n = 72) were similar in participant demographics. The patient self-reported outcome measures were collected on an electronic diary that was programmed to capture qualifying headache information. The primary efficacy endpoint of headache pain-free at two hours post-dose was assessed on a four-point Numeric Rating Scale (NRS), a Visual Analog Scale (VAS), and a binary questionnaire for self-report of pain. In addition to the primary efficacy endpoint of pain-free at two hours post-dose, this study assessed efficacy according to a variety of measures, including the proportion of participants reported to be pain-free at several other post-dose time intervals, the proportion of participants who utilized rescue medication during the 24-hour post-dose period, and the change from baseline pain severity at several time intervals.

The United States Food and Drug Administration (FDA) has conditionally accepted "Tonmya" as the proposed trade name of TNX-102 SL for fibromyalgia. TNX-201, Tonmya and TNX-102 SL are Investigational New Drugs and have not been approved by FDA for any indication.

About TNX-201

The active ingredient in TNX-201 is dexisometheptene mucate, the (R) isomer of isometheptene mucate. The dose of 140 mg TNX-201 is calculated as the free base, which is equivalent to approximately 244 mg of dexisometheptene mucate salt. Racemic isometheptene mucate, a mixture of both the (R) and (S) isomers, 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 currently are approved by the FDA for any indication. Studies in several animal models have shown that TNX-201 significantly increases the pain threshold of acute pain response, and 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.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder. 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.

Safe Harbor / 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, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on February 27, 2015 and November 6, 2015, respectively, 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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