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

Top-Line Results to be Reported in the First Quarter of 2016

NEW YORK, Dec. 8, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) ("Tonix"), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, today announced it has completed patient randomization in its Phase 2 proof-of-concept (POC) clinical study of TNX-201 (dexisometheptene mucate) in episodic tension-type headache.

"TNX-201, representing a new class of analgesics, could offer advantages over currently-approved products for episodic tension-type headache. All of the existing prescription medications contain barbiturates, which are not recommended for extended use due to their potential for tolerance, dependence, and addiction," said Seth Lederman, M.D., Tonix's president and CEO. "Our current proof-of-concept study is designed to evaluate the activity of TNX-201 using several different efficacy measures, as well as safety and tolerability," added Dr. Lederman. "We expect to report top-line results of this study in the first quarter of 2016."

The Phase 2 POC study is 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 for the treatment of a single tension-type headache. Approximately 150 headache events will be investigated. This study will assess the efficacy of TNX-201 on headache pain according to a variety of measures, including: the proportion of patients reported to be pain-free at several 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 use rescue medication during the 24-hour post-dose period; and the change from baseline pain severity at several time intervals. The performance of TNX-201 across these measures will guide Tonix's selection of appropriate and U.S. Food and Drug Administration (FDA)-accepted efficacy endpoints for future clinical trials.

Episodic tension-type headache affects approximately 75 million people in the U.S. and is estimated to be three times as prevalent as migraine. Approximately 21 million prescriptions are filled for acute treatment of non-migraine headache each year, including approximately 3.5 million prescriptions for butalbital combination products, the only prescription products approved for episodic tension-type headache.

To learn more about Tonix's Phase 2 POC study with TNX-201 in episodic tension-type headache, please visit www.clinicaltrials.gov (NCT02423408).

About Episodic Tension-Type Headache

Episodic tension-type headache is the most common type of headache. Patients with episodic tension-type headache experience a mild to moderate band of pain, tightness or pressure around the forehead or back of the head or neck, as if one's head was being 'squeezed in a vice.' The pain may last from 30 minutes to several days and often occurs in the middle of the day. The pain may render a sufferer unable to attend activities, force them to stay home from work, or impair their ability to function at work. It is estimated that 22 to 28 million Americans suffer from frequent episodic tension-type headache, defined as one to 14 headaches per month, many of whom do not obtain adequate relief from over-the-counter analgesics. However, all of the prescription options approved by the FDA for tension-type headache contain barbiturates, which can be habit forming and are not recommended for prolonged use.

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, 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. Studies have shown that TNX-201 significantly increases the pain threshold in several animal models 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 dedicated to the invention and development of novel pharmaceutical products that it believes will have broad societal impact, since they address medical conditions that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's Tonmya™ (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is currently being evaluated in the Tonix-sponsored Phase 3 AFFIRM study in fibromyalgia, for which Tonix expects to report top-line data in the third quarter of 2016. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in PTSD, for which Tonix expects to report top-line data in the second quarter of 2016. Tonix expects to report top-line data from its Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache in the first quarter of 2016. This press release and further information about Tonix can be found at www.tonixpharma.com.

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

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" 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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