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Tonix Pharmaceuticals Announces Clinical Progress on Potential Treatment for Headache

TNX-201 to Enter Phase 2 Study for Episodic Tension-Type Headache Next Quarter

NEW YORK, Jan. 9, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) has completed a Phase 1 safety, tolerability, and pharmacokinetic study of TNX-201, which is being developed for episodic tension-type headache. In this single ascending dose, placebo-controlled trial, TNX-201 was well-tolerated at all doses studied, and showed a dose-related increase in pharmacokinetic parameters. A Phase 2, double-blind, randomized, multicenter, placebo-controlled study to evaluate the efficacy and safety of TNX-201 for the treatment of a single episodic tension-type headache will commence in the second quarter of 2015.

The active ingredient of TNX-201 is (R)-isometheptene mucate, the (R) isomer of isometheptene mucate. The Phase 1 study was an ascending dose tolerability study in 45 subjects divided into three cohorts receiving 35 mg, 70 mg and 140 mg TNX-201 capsules. Each cohort consisted of 15 subjects, who were randomly assigned in a 3:1:1 ratio to TNX-201, racemic isometheptene mucate (70 mg), or placebo, respectively. All treatments were well tolerated and no subject discontinued due to treatment-emergent adverse events. Preliminary top-line results showed that, among all treated subjects, the four adverse events that were deemed to be possibly related to treatment were mild forehead erythema and pruritis (one TNX-201 70 mg subject), mild sensation of warmth (one placebo subject), and mild temporal headache (one placebo subject). No adverse event was reported in the highest dose TNX-201 (140 mg) group.

Subjects treated with TNX-201 showed a dose-related increase in the plasma concentrations of (R)-isometheptene; mean maximum plasma concentration (Cmax) and area under the curve (AUC) were highest in the 140 mg group and lowest in the 35 mg group. Plasma concentrations of (R)-isometheptene were similar in the subjects who received 35 mg of TNX-201 or 70 mg of racemic isometheptene mucate, indicating the lack of isomer interconversion.

"The TNX-201 program exemplifies Tonix's mission of developing proprietary pharmaceutical products that are supported by a substantial history of use. We believe TNX-201 may offer differentiation from currently-approved options for episodic tension-type headache," said Seth Lederman, M.D., Tonix's president and chief executive officer. "We look forward to reporting top-line results from our upcoming Phase 2 trial in episodic tension-type headache by year-end. In addition, our non-clinical investigations have generated data

that, we believe, are the first to illustrate the mechanism by which TNX-201 may provide relief in episodic tension-type headache. More broadly, these data support the development of non-imidazoline selective I1 receptor (NISIR) ligands as a therapeutic strategy for providing central analgesia."

About TNX-201

The active ingredient in TNX-201 is (R)-isometheptene mucate, a single 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 U.S. Food and Drug Administration (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. Preclinical 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, administered as a single agent, significantly increases the pain threshold in standard animal models of acute pain response as compared to vehicle control.

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 Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals is a clinical-stage company developing first-in-class medicines for common disorders of the central nervous system, including fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. Tonix's lead candidate, TNX-102 SL, is intended to be a first-line treatment for fibromyalgia and for PTSD. A Phase 2b trial of TNX-102 SL in fibromyalgia (BESTFIT) has been completed, and Tonix will initiate a Phase 3 program in the second quarter of 2015 to support product registration in the U.S. A Phase 2 trial of TNX-102 SL in PTSD (AtEase) is recruiting. A Phase 2 trial of TNX-201 for episodic tension-type headache will begin in the second quarter of 2015. To learn more, please visit 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" 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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 March 28, 2014 and future periodic reports filed with the Securities and Exchange Commission. All of the Company'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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