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Tonix Pharmaceuticals Completes Pre-IND Meeting With FDA on TNX-201 for Episodic Tension-Type Headache: Clinical Development to Begin in 4Q 2014

TNX-201 Has the Potential to Become the First New Prescription Drug for Tension Headache in More Than Two Decades

NEW YORK, March 3, 2014 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP), a development stage specialty pharmaceutical company, today announced that it recently held a pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) to discuss the regulatory pathway for the development of TNX-201 (single isomer isometheptene, or IMH) for the relief of episodic tension-type headache (ETTH). ETTH is the medically-recognized term for tension headache, a common problem affecting approximately 20% of the global adult population.

"Following this informative meeting with the FDA, we can confirm the initial IND for TNX-201 will not require any additional nonclinical data to support a first-in-man study. This enables us to enter the clinic promptly with minimum risk, which is consistent with our platform of repurposing, reformulating, or rediscovering high impact prescription medications for unmet or under-served needs and particularly for pain syndromes. We are on track to evaluate TNX-201 in a clinical pharmacology study in the fourth quarter of 2014," said Seth Lederman, M.D., president and CEO of Tonix.

"Selecting a single isomer of IMH for development can potentially reduce the toxicity associated with the racemic mixture based on our pharmacology data, which is consistent with the FDA Stereoisomeric Drugs Development Policy. Although the development of TNX-201 will be based on the available information on racemic IMH, the New Drug Application (NDA) approval will conform with the current 505(b)(1) NDA requirement." noted Dr. Lederman.

TNX-201 has the potential to become the first new prescription drug for tension headache in more than 20 years. Currently, the only FDA-approved prescription medications for tension headache contain butalbital. Prescription products containing barbiturates can be habit forming and are associated with the development of Medication Overuse Headache, a chronic syndrome that is difficult to treat. "TNX-201, if approved, will provide people who suffer from tension headaches a treatment alternative to barbiturate drugs, as well as to over-the-counter medicines containing acetaminophen and caffeine," said Dr. Lederman.

About TNX-201

TNX-201 is a pure isomer of IMH, which has an extensive history of use as a prescription pharmaceutical in the U.S. as a mixture of two mirror-image isomers, also known as a racemic mixture. Racemic IMH has been marketed in combination products for the relief of tension and vascular headaches. Because racemic IMH is not FDA-approved, most patients and physicians are forced to obtain IMH-containing drugs from compounding pharmacies, raising concerns on efficacy, safety and uniformity of quality. Tonix is developing TNX-201 for the treatment of ETTH, an indication believed to affect approximately 20% of the global adult population, yet currently served in the United States by only a single class of prescription products, of which all contain the barbiturate butalbital and some contain the opiate codeine.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative prescription medications to treat fibromyalgia (FM), post-traumatic stress disorder (PTSD), and ETTH, all characterized by inadequate treatment options, dissatisfaction expressed among patients and physicians, and significant expense burden. Tonix leverages the established human safety and pharmacokinetics of known drugs and, through a directed innovation process of repurposing, reformulation, isomer purification and rediscovery, creates novel products to address important problems that often lack validated animal models or defined molecular targets. Tonix is currently enrolling patients into the first anticipated pivotal trial of TNX-102 SL in fibromyalgia, the BESTFIT trial (BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy). Tonix expects to begin clinical development of TNX-102 SL in PTSD in the third quarter of 2014. With TNX-102 SL, Tonix approaches the treatment of people suffering from fibromyalgia and PTSD by targeting their inability to obtain restorative sleep. TNX-201 is in development for ETTH, and Tonix expects to begin clinical studies of TNX-201 in the fourth quarter of 2014. 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 amended Annual Report on Form 10-K/A filed with the SEC on November 22, 2013 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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