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Tonix Pharmaceuticals Receives IND Clearance From U.S. Food and Drug Administration for TNX-102 SL in Post-Traumatic Stress Disorder

Phase 2 Clinical Trial Expected to Begin in the Third Quarter of 2014

NEW YORK, June 10, 2014 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP), a clinical-stage pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to develop TNX-102 SL, a proprietary sublingual formulation of cyclobenzaprine HCl, for the treatment of post-traumatic stress disorder (PTSD). PTSD is a serious mental illness triggered by a traumatic event and is believed to affect more than eight million U.S. adults. Under this IND, Tonix will be able to move forward in the third quarter of this year with its planned U.S.-based Phase 2 clinical trial designed to evaluate the safety and efficacy of TNX-102 SL in patients with PTSD.

"The clearance of this IND represents an important milestone for Tonix and for the estimated eight million U.S. adults with PTSD, a serious illness with unmet needs and limited treatment options," stated Seth Lederman, M.D., Chairman and Chief Executive Officer of Tonix. "As with our IND of TNX-102 SL for fibromyalgia, our goal is to develop a new approach to a common central nervous system disorder with the potential to alter treatment paradigms. We are very excited about investigating the safety and efficacy of TNX-102 SL in PTSD while our potential pivotal study in fibromyalgia, the BESTFIT trial, has completed enrollment with top-line results available later this year."

The planned randomized, double-blind, placebo-controlled Phase 2 clinical trial (TNX-CY-P201) will investigate the safety and efficacy of two doses of TNX-102 SL and placebo administered once daily at bedtime. This 12-week study is expected to enroll approximately 220 patients with military-related PTSD at about 30 sites in the U.S. The primary efficacy analysis will compare differences in mean scores on the Clinician-Administered PTSD Scale (CAPS).

About Post-Traumatic Stress Disorder

PTSD is a type of anxiety disorder believed to affect approximately eight million people in the U.S., and is a common problem among veterans, first-responders and other military-related personnel. PTSD can develop from witnessing or experiencing traumatic events, and is linked to suicide and to impulsive violent behavior.

About Tonix Pharmaceuticals Holding Corp.

Tonix develops first-in-class medicines for common disorders of the central nervous system. Fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache are characterized by inadequate treatment options, dissatisfaction among patients and physicians, and significant economic impact. Tonix is currently conducting 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 a Phase 2 trial of TNX-102 SL in PTSD in the third quarter of 2014. Tonix designed TNX-102 SL to decrease pain in fibromyalgia and in PTSD by improving sleep quality. Tonix's second clinical stage investigational new drug, TNX-201, is in development for episodic tension-type headache, 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 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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