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Tonix Pharmaceuticals Provides Clinical and Regulatory Update on its Continued Development of TNX-102 SL in Fibromyalgia

Phase 3 Program to Begin in the Second Quarter of 2015

NEW YORK, Jan. 6, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) has received written guidance from the U.S. Food and Drug Administration (FDA) on its Phase 3 clinical study design for TNX-102 SL in fibromyalgia.

"Getting this confirmation from the FDA – particularly its acceptance of the 30 percent responder analysis as the primary outcome measure – represents a clear step forward in our ongoing development of TNX-102 SL in fibromyalgia," said Seth Lederman, M.D., president and chief executive officer of Tonix.

The 30 percent responder analysis is defined as an improvement in pain, as measured by the number of subjects who achieve at least a 30 percent improvement in their pain scores. In the Phase 2b BESTFIT study, TNX-102 SL demonstrated a statistically significant improvement in the 30 percent responder analysis, which was a pre-specified secondary outcome measure.

Dr. Lederman added, "Our proposed Phase 3 study design is based on our analysis and learnings from the BESTFIT trial results. We are on track to begin the Phase 3 clinical study in this debilitating condition in the second quarter of this year."

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 is preparing to initiate a Phase 3 program to support registration. A Phase 2 trial of TNX-102 SL in PTSD (AtEase) is recruiting. TNX-201 is in clinical development for episodic tension-type headache and recently completed a Phase 1 comparative pharmacokinetic and safety study. 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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