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Tonix Pharmaceuticals Reports Outcomes from U.S. FDA Breakthrough Therapy CMC Guidance Meeting of Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) for PTSD

NEW YORK, Oct. 17, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical and biological products to address public health challenges, announced today the receipt of official minutes from a chemistry, manufacturing and controls (CMC) guidance meeting with the U.S. Food and Drug Administration (FDA) regarding the CMC data required to support the Tonmya* (cyclobenzaprine HCl sublingual tablets), or TNX-102 SL, New Drug Application (NDA) and the commercial product. Tonix is in Phase 3 development of Tonmya, an FDA-designated Breakthrough Therapy for the treatment of posttraumatic stress disorder (PTSD).

Seth Lederman, M.D., president and chief executive officer of Tonix, stated, “Tonix has been successfully implementing the commercial production strategy for TNX-102 SL in addition to manufacturing final drug product to support the required clinical studies for the Tonmya NDA. The CMC guidance meeting we had with the FDA in September is part of our effort to ensure our NDA CMC plan is supportive of the Tonmya’s registration plan, which is usually a big challenge for an accelerated Breakthrough Therapy development program. In general, our proposed CMC data package to support the Tonmya’s NDA and commercial manufacturing plans was accepted by the FDA. The FDA official minutes reflect our readiness to manufacture Tonmya commercial product at production scale, which is critical to the successful launch of a potentially improved treatment option for PTSD patients, especially those patients with military-related PTSD.”

*Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.

About Tonmya and the Phase 3 HONOR Study

Tonmya is a patented sublingual transmucosal formulation of cyclobenzaprine that is in Phase 3 development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets), was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by

the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the United States, the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants in approximately 45 U.S. sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that (i) a single-study new drug application (NDA) approval could be possible if the topline data from the HONOR study are statistically very persuasive, and (ii) an additional abuse assessment study is not required for the NDA filing. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540. The U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034.

Tonix was awarded European patent (Patent No. 2501234, "Methods and Compositions for Treating Symptoms Associated with Posttraumatic Stress Disorders Using Cyclobenzaprine"). This patent is expected to provide Tonmya, upon European marketing authorization, with European market exclusivity until November 2030 and the exclusivity may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges. In addition to Tonmya for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage, designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, to be developed as a potential smallpox-preventing vaccine.

This press release and further information about Tonix can be found at 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," "expect," 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 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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, 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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