July 6, 2017

Tonix Pharmaceuticals Announces Conditional Acceptance of Tonmya® as Proposed Brand Name for TNX-102 SL (Cyclobenzaprine HCl Sublingual Tablets) for the Treatment of PTSD

NEW YORK, July 06, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix) a company that is developing innovative pharmaceutical products to address public health challenges today reported that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proposed trade name Tonmya (*ton-MY-ah*) for TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) for the management of posttraumatic stress disorder (PTSD). Tonix recently launched the Phase 3 HONOR study of Tonmya in military-related PTSD, from which topline results are expected to be reported in the second half of 2018. Tonmya was designated a Breakthrough Therapy by the FDA for the treatment of PTSD.

A request for proprietary name review for Tonmya will be submitted once the PTSD New Drug Application (NDA) is submitted. FDA's final approval of Tonmya is subject to NDA approval. A request for review of Tonmya as the proposed name for TNX-102 SL for the management of fibromyalgia has been withdrawn at the FDA. The U.S. Patent and Trademark Office has granted the federal registration of the Tonmya mark.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets)/Tonmya is an investigational new drug and has not been approved for any indication.

About Tonmya and the Phase 3 HONOR Study

Tonmya (cyclobenzaprine HCl sublingual tablets) 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 across approximately 35 clinical 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 a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive. 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 claimed in the patent 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.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical 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.

Contacts

Jessica Smiley
Investor Relations
investor.relations@tonixpharma.com
(212) 980-9155 x18

Russo Partners (media)
Rich Allan
rich.allan@russopartnersllc.com
(646) 942-5588

Source: Tonix Pharmaceuticals Holding Corp.