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Tonix Pharmaceuticals Presented Additional Phase 2 Clinical Results in Military-Related PTSD and Design of Ongoing Phase 3 Trial at the 2017 Military Health System Research Symposium

Phase 2 Study of U.S. FDA-Designated Breakthrough Therapy Tonmya® (Cyclobenzaprine HCI Sublingual Tablets) in PTSD Indicates Early Sleep Quality Improvements Correlate with Later Response to Treatment

Phase 3 HONOR Study Designed to Confirm Phase 2 Results and Address Needs and Culture of Population with PTSD from Trauma During Military Service

NEW YORK, Aug. 29, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company in Phase 3 development of Tonmya*, or TNX-102 SL, a U.S. Food and Drug Administration (FDA)-designated Breakthrough Therapy for the treatment of posttraumatic stress disorder (PTSD), and in various development stages for other innovative pharmaceutical and biological products to address public health challenges, today presented additional analyses of the Phase 2 AtEase study of Tonmya for PTSD as well as the design features of the ongoing Phase 3 HONOR study of Tonmya for military-related PTSD.

Retrospective analysis of the AtEase study demonstrated a link between improvements in sleep quality at Week 4 and symptom improvement at Week 12 as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), supporting the mechanistic hypothesis that sublingual cyclobenzaprine acts by improving sleep quality and improving sleep-dependent memory processing to produce the therapeutic effect observed in the Phase 2 study.

The Phase 3 HONOR study is designed to confirm the Phase 2 results. The execution of the Phase 3 HONOR study addresses the needs of study participants by appreciating the military and veteran culture and respecting the sensitivity of traumatic memories for participants suffering from PTSD. To assist in enrollment and retention, all participants who complete the 12-week double-blind phase of HONOR will be eligible to continue to a 12-week open-label extension study, in which they will all receive the study drug Tonmya.

“Leveraging our expertise in PTSD research and development, Tonix continues to lead in the development of pharmacotherapies for military-related PTSD as we explore approaches that could lead to new treatment paradigms,” commented Seth Lederman, M.D., president and chief executive officer of Tonix. “The link between improvement in sleep quality and

subsequent improvement in PTSD observed in the AtEase Phase 2 trial supports the mechanistic hypothesis that Tonmya improves sleep-dependent memory processing. In addition, the execution of the Phase 3 trial builds on our experiences from Phase 2 to obtain high quality data, and efficiently enroll and retain participants suffering from military-related PTSD."

The results were presented today in two poster presentations at the 2017 Military Health System Research Symposium in Kissimmee, Florida. The presentations can be found on the Scientific Presentations page of the Tonix website.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (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 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 new drug application (NDA) approval could be possible if the topline data from the HONOR study are statistically very persuasive and 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 claimed in the patent are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon FDA approval of the NDA, with U.S. market exclusivity until 2034.

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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