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Tonix Pharmaceuticals Achieves 50 Percent Enrollment in Phase 3 Trial of FDA-Designated Breakthrough Therapy Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) for the Treatment of PTSD

Phase 3 HONOR Study Enrollment Continues and Interim Results of the First 50 Percent of Participants Expected in Third Quarter 2018

Topline Results of Approximately 550 Participants with Military-Related PTSD Expected in Fourth Quarter 2018

NEW YORK, April 03, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense, announced that 50 percent of the planned total number of participants have been randomized in the Phase 3 HONOR study evaluating Tonmya®*, or TNX-102 SL 5.6 mg, for the bedtime treatment of military-related posttraumatic stress disorder (PTSD). Tonmya for the treatment of PTSD has been designated a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA). Clinical evidence from the Phase 2 study of Tonmya showed a potential improvement over existing therapies used to treat military-related PTSD. The FDA is committed to expediting the development and review of Tonmya for PTSD.

An interim analysis of the first 50 percent of randomized participants will be conducted shortly after the 12-week treatment period has been completed by these participants. Topline efficacy results from the interim analysis are expected in the third quarter of this year.

"Reaching randomization of 50 percent for the HONOR study is an important milestone for Tonix," said Seth Lederman, M.D., President and Chief Executive Officer. "Based on the current enrollment rate, topline data from the full study is expected in the fourth quarter of 2018, if 550 participants are needed to complete the study."

The interim analysis will be reviewed by an Independent Data Monitoring Committee, or IDMC, which will review unblinded data from this first 50 percent of participants and make one of three recommendations: (1) stop the trial for success; (2) continue to enroll the full study as planned; or (3) continue to enroll with a specified increase in the total number of

participants in the full study.

At the Cross-disciplinary Breakthrough Therapy meeting, the FDA indicated that a single-study New Drug Application (NDA) approval is possible, based on the interim or end-of-study analysis of the HONOR study, if the results are statistically persuasive. The company is ready to file an NDA for Tonmya for the treatment of PTSD in 2019 in the event of a persuasive outcome of the HONOR study.

**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 sublingual transmucosal tablet 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 U.S., 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 40 U.S. sites. An unblinded interim analysis will be conducted now that the study has accumulated efficacy results from approximately 275 randomized participants. In a Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that (i) a single-study 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.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease. A Phase 2 IND (Investigational New Drug) application was submitted in March 2018 after completion of a successful pre-IND meeting with the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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, risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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 substantial competition. 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, and periodic reports filed with the SEC on or after the date thereof. 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 thereof.

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