March 1, 2019

Tonix Pharmaceuticals Provides Update on Tonmya® for the Treatment of Posttraumatic Stress Disorder

NEW YORK, March 01, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense, today announced program updates related to the development of Tonmya* (cyclobenzaprine HCl sublingual tablets) which is in Phase 3 development for the treatment of posttraumatic stress disorder (PTSD).

The U.S. Food and Drug Administration (FDA) notified the Company that the Breakthrough Therapy designation (BTD) granted for Tonmya for PTSD in December 2016 has been rescinded because interim analysis data on Tonmya from the HONOR study do not support the continuation of the BTD. The BTD granted to Tonmya was based on retrospective analysis of the effect of Tonmya 5.6 mg in the Phase 2 AtEase study in military-related PTSD, that shows a substantial improvement over existing therapies in military-related PTSD.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, “The rescission of Breakthrough Therapy designation of Tonmya for PTSD does not alter our NDA plan and will have minimum impact on our future interactions with the FDA. We are on track to start imminently the Phase 3 RECOVERY trial in civilian and military-related PTSD. We are grateful for the guidance and continued support received from the FDA. We remain committed to expedite the development of Tonmya for PTSD, especially military-related PTSD.”

Dr. Lederman continued, “Tonmya has shown potential treatment activity in large, registration-quality, double-blind placebo-controlled studies on two large cohorts of military-related PTSD in the Phase 2 and Phase 3 studies. Retrospective analysis of the Phase 3 HONOR study showed treatment activity in the subgroup with PTSD from trauma within 9 years of the study. This is a large and relevant proportion of the PTSD cases we studied, representing approximately three quarters of the Phase 2 study and half of the Phase 3 study. The results are highly comparable and consistent with the results of the Phase 2 study which formed the basis of the December 2016 BTD granted by the FDA. Tonmya was well tolerated and the most frequent side effect was an episodic and transient administration site reaction in approximately 40% of participants, described as tongue numbness. Weight gain was not observed. Systemic side effects reported in the HONOR study are consistent with those in the approved cyclobenzaprine orally ingested products.”

Dr. Lederman emphasized, “PTSD should be diagnosed and treated early. Targeting

treatment early in a condition is fundamentally different from identifying a treatment responsive subgroup, since patients with PTSD for more than 9 years have potentially missed the opportunity for treatment benefit. PTSD sufferers may converting from treatment-responsive to less-responsive or non-responsive states. Efficacy evidence from the retrospective analysis of the Phase 3 HONOR study in the subgroup with PTSD from trauma within 9 years of the study further confirms this importance."

Dr. Gregory Sullivan, Chief Medical Officer of Tonix added, "Military-related PTSD remains an unmet need. Studies have shown that currently available therapies for PTSD fail to provide a consistent therapeutic effect and long-term tolerance in the population of military-related PTSD. This indicates the urgent need for new medicines to treat PTSD, especially military-related PTSD, and we are committed to serving this important population to address the national mental health concerns in veterans, reservists and active duty personnel."

As previously communicated, Tonix received confirmation of the FDA's acceptance of the new Phase 3 RECOVERY trial in November of last year. The Company plans to start the RECOVERY trial for the treatment of PTSD in the first quarter of 2019. The new trial will incorporate several new design features, including adding participants who have experienced civilian traumas, in addition to those with military-related traumas. The trial will also restrict enrollment to individuals with PTSD whose index trauma was experienced within nine years of screening. The primary endpoint will be improvement in CAPS-5 from baseline as assessed at Week 4 with the key secondary endpoint at week 12. Topline data from this trial is expected in the first half of next year.

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 is developing Tonmya®*, which 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 under a separate IND to support a Phase 2, potential pivotal, efficacy study and has been designated a Fast Track development program by the FDA for this indication. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a unique mechanism and designed for daytime dosing. Phase 1 clinical study of TNX-601 in healthy volunteers will be conducted outside of the U.S. in 2019. 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.

**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 the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

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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