April 23, 2019

Tonix Pharmaceuticals Announces Update on the Collaborative Research and Development Agreement (CRADA) with the U.S. Army Medical Materiel Development Activity (USAMMDA)

The Termination Does Not Affect Tonix's Finances or the Ongoing RECOVERY Trial of Tonmya® for the Treatment of PTSD

NEW YORK, April 23, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), announced on April 18, 2019 that the Company received a notice of termination, effective April 29, 2019, whereby USAMMDA is exercising its contractual right to terminate without cause the CRADA entered into on December 4, 2015 between the Company and USAMMDA relating to the development of Tonmya* or TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of Posttraumatic Stress Disorder (PTSD). The termination does not affect Tonix's finances or the conduct of the ongoing RECOVERY trial in PTSD.

Due to the statutory limitations on all CRADAs, Tonix's agreement with USAMMDA never contemplated nor contained any provision for funding Tonix or any PTSD study. There is, therefore, no financial impact to Tonix as a result of this action.

A key objective of the CRADA was for USAMMDA to assist Tonix in recruiting active duty personnel from military treatment facilities (MTFs) into the Phase 2 AtEase and Phase 3 HONOR studies of military-related PTSD. However, no patients were recruited by USAMMDA from MTFs into either study. The ongoing RECOVERY trial is recruiting only patients whose PTSD results from trauma that occurred less than nine years before screening. Since the large U.S. troop deployments into the war zones in Iraq and Afghanistan were more than nine years ago, the number of relevant potential trial participants in MTFs would be lower than during our previous clinical trials. Therefore, we believe there is no patient recruitment impact to Tonix as a result of this action.

Although a potential benefit of the CRADA was cooperation in planning PTSD studies, USAMMDA was not involved in the planning or execution of any Tonix PTSD study. Therefore, we believe there is no research or development impact to Tonix as a result of this action.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, "We are grateful for the CRADA over the period it has been in effect. During this time, we invited

USAMMDA to participate in FDA meetings and review our FDA correspondence and regulatory strategy. However, USAMMDA did not provide any financial resources or recruiting assistance to Tonix and thus this termination has no financial impact on the Company, and we believe no effect on recruiting trial participants or change in research or strategy. Tonix remains in active dialogue with other components of the Department of Defense and with the Department of Veterans Affairs about our PTSD program."

The ongoing Phase 3 RECOVERY study includes civilian traumas, in addition to military-related traumas. The U.S. adult PTSD population consists of approximately 12 million people, the majority of whom are civilians. Therefore, if the study is reflective of the population of U.S. adults, the majority of participants in RECOVERY are expected to be civilians.

Dr. Lederman continued, "The larger number of people affected with civilian PTSD is expected to make recruitment for the RECOVERY study easier and faster, relative to our two prior studies in which only military-related PTSD patients were recruited. We are pleased with the enrollment in the RECOVERY study thus far and we look forward to data 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 psychiatric and pain conditions, and biological products to improve biodefense through potential medical counter-measures. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate INDs to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development and the agitation in Alzheimer's program is Phase 2 ready. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but using a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Phase 1 clinical study selected oral formulation of TNX-601 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, 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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