October 3, 2019

Tonix Pharmaceuticals Announces Completion of Long-Term Exposure Studies in Participants with PTSD to Evaluate the Tolerability of TNX-102 SL 5.6 mg

Company Expects this Long-Term Safety Exposure Data to Satisfy Long-Term Exposure Requirements for Potential New Drug Applications for TNX-102 SL for PTSD and Fibromyalgia

NEW YORK, Oct. 03, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced Tonix has completed collecting the required long-term safety exposure data of TNX-102 SL 5.6 mg in participants with posttraumatic stress disorder (PTSD) to support the TNX-102 SL New Drug Application (NDA) for the treatment of PTSD. The data provide Tonix with exposure data of daily dosing of TNX-102 SL 5.6 mg for at least 12 months in more than 50 individuals, and daily dosing of TNX-102 SL 5.6 mg for at least 6 months in more than 100 individuals. The data was collected in open label extension (OLE) studies of the PTSD program.

“We are pleased to have reached this important milestone,” said Seth Lederman, M.D., President and Chief Executive Officer. “PTSD is a serious chronic psychiatric condition, and, based on our agreement with the FDA regarding the requirements for the long-term safety exposure data needed to support an NDA submission, we believe that Tonix now has sufficient long-term exposure data to meet the requirement and support the NDA. Importantly, TNX-102 SL 5.6 mg is the same drug candidate in Phase 3 development for the treatment of fibromyalgia and we believe the long- term exposure data from the PTSD program may also support the fibromyalgia NDA.”

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions, to improve biodefense through potential medical counter-measures, to treat transplant rejection and to treat gastric and pancreatic cancers. 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, agitation in Alzheimer’s disease and alcohol use disorder, under separate Investigational New Drug applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is

in Phase 3 development, the agitation in Alzheimer's program is Phase 2 ready and the alcohol use disorder program is in the pre-IND application stage. TNX-1300** (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of life-threatening cocaine intoxication. Tonix has two other programs in the pre-IND application stage of development for PTSD, but with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate) and TNX-1600***, a triple reuptake inhibitor. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data on TNX-601 from a Phase 1 clinical formulation selection pharmacokinetic study that is being conducted outside of the U.S. is expected in the second half of 2019. TNX-801 (live virus vaccine for percutaneous [scarification] administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. TNX-1500 is being developed to prevent and treat organ transplant rejection, as well as to treat autoimmune conditions, and is in the pre-IND application stage. Finally, TNX-1700 is being developed to treat gastric and pancreatic cancers and is 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 for the treatment of PTSD. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

**TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.

***TNX-1600 ((2S,4R,5R)-5-(((2-aminobenzo[d]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2H-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine), or a "triple reuptake" inhibitor.

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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