September 16, 2019

Tonix Pharmaceuticals Announces Publication of Paper on Triple Reuptake Inhibitor TNX-1600 (formerly D-578) in the European Journal of Pharmacology

NEW YORK, Sept. 16, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the publication of a paper entitled “D-578, an orally active triple monoamine reuptake inhibitor, displays antidepressant and anti-PTSD effects in rats” in the *European Journal of Pharmacology*. The paper summarizes the behavioral pharmacological characterization of a novel triple reuptake inhibitor (TRI), TNX-1600, formerly known as D-578, which exhibits nanomolar potency at all three monoamine transporters (NET > SERT ≈ DAT) and exhibited little to no affinity for other off-target central nervous system (CNS) receptors. TNX-1600 was found to have greater efficacy in normalizing traumatic stress-induced extinction-retention learning in an animal model for posttraumatic stress disorder (PTSD) compared to paroxetine, a selective serotonin reuptake inhibitor (SSRI), which is approved by the U.S. Food and Drug Administration (FDA) to treat PTSD and other psychiatric conditions. These findings suggest TNX-1600 may reduce maladaptive retention of fearful memories via attenuation of the extinction learning and extinction retention deficits induced by traumatic stress, supporting further testing of this agent for the pharmacotherapy of PTSD. Additionally, TNX-1600 showed a robust effect in an animal model associated with antidepressant activity without affecting locomotor activity.

In August 2019, Tonix announced an exclusive license agreement with Wayne State University and an asset acquisition with TRImaran Pharma, Inc. (TRImaran) to in-license TNX-1600 to treat PTSD and potentially other CNS disorders. Under the terms of the agreement, Tonix was granted an exclusive license from Wayne State University for technology and patents related to TNX-1600 and other pyran-based compounds.

Tonix’s President and Chief Executive Officer, Seth Lederman, M.D. said, “We are pleased to see the paper on TNX-1600 published in this peer-reviewed journal, and we believe that the findings support the development of this novel TRI as a potential treatment for PTSD.”

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 and to prevent and treat organ transplant rejection. 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, is being developed 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 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 is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted outside of the U.S. 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. Finally, 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.

**Tonmya has been conditionally accepted by the 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* ((2*S*,4*R*,5*R*)-5-(((2-aminobenzo[*d*]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2*H*-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

on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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