August 20, 2019

Tonix Pharmaceuticals Expands Preclinical Pipeline with Triple Reuptake Inhibitor, TNX-1600, for the Treatment of PTSD

NEW YORK, Aug. 20, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today an exclusive agreement to in-license a triple reuptake inhibitor (TRI), TNX-1600 (formerly D-578), to treat posttraumatic stress disorder (PTSD) and potentially other central nervous system (CNS) disorders. The compound was developed and pharmacologically characterized by Aloke Dutta, Ph.D., professor of Pharmaceutical Sciences at Wayne State University, with funding from a National Institutes of Health grant (grant number MH084888), and the patents covering the compounds were licensed to TRImaran Pharma, Inc. (TRImaran). The transaction announced today is a license agreement with Wayne State and an asset acquisition with TRImaran.

“We are excited to expand our pipeline and are looking forward to developing TNX-1600 as a potential treatment for PTSD,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “We plan to utilize our clinical experience in PTSD to evaluate the therapeutic benefit of TNX-1600. PTSD is a heterogeneous condition, so we believe different PTSD patients may respond to different medicines. In some cases, more than one drug will be required for effective treatment. TNX-1600 is our third drug candidate in development for PTSD. Our most advanced candidate is TNX-102 SL, which is in Phase 3 development. We are also developing TNX-601 which is entering a Phase 1 trial imminently. TNX-1600 is in the pre-IND phase of development with encouraging data from animal models of PTSD.”

Frank Bymaster, Chief Scientific Officer and co-founder of TRImaran Pharma Inc. said, “TNX-1600 is a novel TRI that inhibits simultaneously the reuptake of three key neurotransmitters: serotonin, norepinephrine and dopamine. Each of these three neurotransmitters plays a key modulatory role in many CNS processes. Inhibiting reuptake of all three may provide an effective treatment for PTSD.”

According to Dr. Aloke Dutta, “We have developed an innovative triple reuptake inhibitor, D-578, based on a unique pyran molecular scaffold to address the current therapeutic needs for PTSD and other neurological disorders. Based on our preliminary data, we expect a pharmacological synergy from their potent modulatory effect on the level of monoamine neurotransmitters in the brain which should facilitate effective treatment of these disorders.”

Under the terms of the agreement, Tonix has been granted an exclusive license from Wayne State University for technology and patents related to TNX-1600 and other pyran-based

compounds. Another member of the class, D-473, has also shown effects in a rodent model of depression[2,3].

[1]Bymaster, FP, Lisieski M, Harutyunyan, A, Das, D, Liberzon, I, Hsu,T, Reith, MEA, Perrine, SA, Dutta, AK, A Novel Orally Active Triple Reuptake Inhibitor for the Treatment of Post-traumatic Stress Disorder (PTSD): D-578 Attenuates Abnormal Fear Behavior in a Rodent Model of Traumatic Stress.

[2]Soumava Santra, S, Gogoi, S, Gopishetty, B, Antonio, T, Zhen, J, Reith, MEA and Dutta, AK. Structural Exploration of (3S,6S)-6-Benzhydryl-N- benzyltetrahydro-2H-pyran-3-amine Analogues: Identification of Potent Triple Monoamine Reuptake Inhibitors as Potential Antidepressants. ChemMedChem, 2012

[3]Dutta, AK, Santra, S, Sharma, H, Voshavar, C Xu,L, Mabrouk, O, Antonio, T and Reith, MEA. Pharmacological and behavioral characterization of an orally active triple reuptake inhibitor D-473: Effects of drug on extracellular levels of dopamine, serotonin and norepinephrine. Plos One, 2014, 9, e11342 0.

About TRImaran

TRImaran Pharma, Inc. was co-founded by Frank Bymaster (CSO), Dr. Timothy Hsu (CMO) and Walter Piskorski (CEO), along with Aloke Dutta, Ph.D. (inventor/scientific advisor), to apply their psychiatric drug development expertise, particularly for TRIs. TRImaran originally in-licensed the exclusive rights to these compounds from Wayne State University and, as part of this transaction, transferred those rights to Tonix.

About Wayne State University

Wayne State University is one of the nation's pre-eminent public research universities in an urban setting. Through its multidisciplinary approach to research and education, and its ongoing collaboration with government, industry and other institutions, the university seeks to enhance economic growth and improve the quality of life in the city of Detroit, state of Michigan and throughout the world. For more information about research at Wayne State University, visit http://www.research.wayne.edu.

About Triple Reuptake Inhibitors (TRIs)

TRIs inhibit simultaneously the reuptake of three key neurotransmitters: serotonin, norepinephrine and dopamine. Single selective serotonin reuptake inhibitors are known as SSRIs and have been successful in a number of psychiatric conditions and include the drugs Prozac® (fluoxetine), Paxil® (paroxetine), Zoloft® (sertraline), and Celexa® (escitalopram). Double serotonin and norepinephrine inhibitors are known as SNRIs and include successful drugs like Effexor® (venlafaxine) and Cymbalta® (duloxetine). A number of TRIs are in development, but none have been approved by the FDA for marketing.

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 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, to be 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. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by 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. 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 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.*

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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals

investor.relations@tonixpharma.com
(212) 980-9159

Scott Stachowiak (media)
Russo Partners
scott.stachowiak@russopartnersllc.com
(646) 942-5630

Peter Vozzo (investors)
Westwicke Partners
peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.