May 30, 2019

Tonix Pharmaceuticals Presented Results from Pharmacokinetic Analyses of TNX-102 SL in a Poster Presentation at the American Society of Clinical Psychopharmacology

NEW YORK, May 30, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) a clinical-stage biopharmaceutical company focused on developing small molecules and biologics to treat psychiatric, pain and addiction conditions as well as to improve biodefense, presented a poster at the American Society of Clinical Psychopharmacology (ASCP) 2019 Annual Meeting held May 28-31, 2019, in Scottsdale, Ariz. The poster, titled “Steady-State Pharmacokinetic Properties of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL*): Comparison to Simulations of Oral Immediate Release CBP” includes pharmacokinetic, or PK, analyses of TNX-102 SL. The poster can be found on the Scientific Presentations page of Tonix’s website.

The poster presentation reports PK results of TNX-102 SL, a sublingual form of cyclobenzaprine (CBP), studied in a comparative PK, open-label, randomized, parallel, two-arm, multiple-dose bridging study, with the reference listed drug AMRIX® (cyclobenzaprine HCl extended release capsules). TNX-102 SL is being developed as a potential treatment for posttraumatic stress disorder (PTSD), fibromyalgia (FM) and agitation in Alzheimer’s disease (AAD), which are central nervous system (CNS) conditions in which sleep disturbances are believed to play essential roles in the illness expression.

Gregory M. Sullivan, M.D., Chief Medical Officer, Tonix Pharmaceuticals Holdings Corp., commented, “We believe this study serves to bridge TNX-102 SL to the safety findings and relevant labeling information of AMRIX, qualifying it for the 505(b)(2) regulatory approval pathway, which is intended to streamline the U.S. Food and Drug Administration (FDA) approval of pharmaceutical products that incorporate already-approved pharmacological agents.”

Dr. Sullivan added, “Designing a drug begins with the active ingredient, but formulation is key to improving characteristics such as how much of the administered drug gets to the target organ and how quickly it gets there. For TNX-102 SL the target organ is the brain, and CBP is known to efficiently pass from the blood stream to the brain. We believe that data from this PK study confirms that TNX-102 SL as a sublingual tablet delivers CBP dynamically into the blood stream with reduced formation of nCBP, which are properties that we consider optimized for a sleep quality drug. We believe these data support the use of TNX-102 SL as a potential chronic bedtime treatment for PTSD, FM and AAD.”

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat psychiatric, pain and addiction 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. TNX-102 SL for the treatment of PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate Investigational New Drug applications (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-1300*** (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution) is being developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. TNX-1300 (formerly known as RBP-8000) is a recombinant protein enzyme produced through rDNA technology in a non-disease-producing strain of *E. coli* bacteria. TNX-1300 for cocaine intoxication has FDA Breakthrough Therapy designation. 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. A Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 will be conducted outside of the U.S. in 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-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

***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-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.