

May 21, 2019



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

NEW YORK, May 21, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) today announced that it will be presenting pharmacokinetic analyses of TNX-102 SL\* in a poster at the American Society of Clinical Psychopharmacology (ASCP) 2019 Annual Meeting. The meeting is being held May 28-31, 2019 in Scottsdale, Ariz.

## **Details of poster presentation at ASCP 2019**

**Title:** Steady-State Pharmacokinetic Properties of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL): Comparison to Simulations of Oral Immediate Release CBP

**Date and Time:** Poster Session 1 on Wednesday, May 29, 2019, 11:15 a.m. - 1:00 p.m. ET

**Location:** Palomino Room 4-10, Hotel Fairmont Scottsdale Princess

**Poster Number:** W30

**Presenter:** Gregory M. Sullivan, M.D., Chief Medical Officer, Tonix Pharmaceuticals Holdings Corp.

## **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 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. 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.

*\* 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.*

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://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



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