

March 23, 2020



## **Tonix Pharmaceuticals to Deliver Virtual Presentation for Spring Investor Summit**

NEW YORK, March 23, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) announced today that Seth Lederman, M.D., President and Chief Executive Officer of Tonix, will be conducting a virtual presentation in conjunction with the Spring Investor Summit on Wednesday, March 25, 2020, at 1:50 p.m. ET.

A live webcast and subsequent archived recording of the Company's virtual presentation will be available under the IR Events tab of the Investor Relations section of the Tonix website at [www.tonixpharma.com](http://www.tonixpharma.com).

### **About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases and small molecules and biologics to treat pain, psychiatric and addiction conditions. In 2020, Tonix announced a program to develop a potential vaccine, TNX-1800\* (live modified horsepox virus vaccine for percutaneous administration) to protect against the novel coronavirus disease emerging in 2019, or COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform and is molecularly designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. TNX-801\* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL\*\*, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in the third quarter of 2020 and topline data in the first half of 2021. These projections may be affected by COVID-19 related issues such as state, county or city activity and travel restrictions, such as "stay at home" and "shelter in place" orders.

The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya\*\*\*) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second quarter of 2020. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating

addiction conditions also include TNX-1300\* (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study in depression will be performed outside the U.S. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. TNX-1200\* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

\*TNX-1800, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.

\*\*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 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; risks related to the timing and progress of clinical development of our product candidates; 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.

## Contacts

Bradley Saenger (corporate)  
Tonix Pharmaceuticals  
[investor.relations@tonixpharma.com](mailto:investor.relations@tonixpharma.com)  
(212) 980-9155

Travis Kruse (media)  
Russo Partners  
[travis.kruse@russopartnersllc.com](mailto:travis.kruse@russopartnersllc.com)  
(212) 845-4272

Peter Vozzo (investors)  
Westwicke  
[peter.vozzo@westwicke.com](mailto:peter.vozzo@westwicke.com)  
(443) 213-0505



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