

November 20, 2019



# **Tonix Pharmaceuticals Completes Pre-IND Meeting with FDA for TNX-102 SL as a Clinical Candidate for Alcohol Use Disorder**

## **FDA Official Meeting Minutes Support Tonix's Plan to file an Investigational New Drug (IND) Application in the First Quarter of 2020 for a Phase 2 Proof-of-Concept Study**

NEW YORK, Nov. 20, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has received the official meeting minutes from a recent Type B pre-IND meeting with the U.S. Food and Drug Administration (FDA). The FDA provided guidance and feedback supportive of Tonix's clinical development plans for TNX-102 SL\* as a potential treatment for alcohol use disorder (AUD). Based on this feedback, Tonix plans to submit an IND application in the first quarter of 2020 to support a Phase 2 proof-of-concept study.

"An estimated 36 million adults in the United States have AUD, a chronic relapsing brain disease characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using alcohol," said Gregory Sullivan, M.D., Chief Medical Officer of Tonix. "We believe that by improving sleep quality, the rate of successful recovery for people with AUD after detox can be improved."

Seth Lederman, M.D., President and Chief Executive Officer of Tonix, stated, "Subsequent to potentially receiving clearance for the IND application for AUD, Tonix expects to have four active IND's for its lead compound TNX-102 SL, including posttraumatic stress disorder (PTSD), fibromyalgia and agitation in Alzheimer's disease. TNX-102 SL is in Phase 3 development for PTSD, for which interim and topline results are expected next year, as well as for fibromyalgia. TNX-102 SL is Phase 2 ready as a treatment for agitation in Alzheimer's disease."

### **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. Tonix's lead product candidate, TNX-102 SL, is in development for posttraumatic stress disorder (PTSD), fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder (AUD). TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD (trade name Tonmya\*\*) and fibromyalgia. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling and results from an interim analysis are expected in the first quarter of 2020 and topline data are

expected in the second quarter of 2020 if the sample size remains the same. The Company is planning the Phase 3 RELIEF trial (F304) in fibromyalgia. The agitation in Alzheimer's disease program is Phase 2 ready and the development for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix is advancing two other PTSD therapeutic programs in the pre-IND stage, with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 CR (tianeptine oxalate) and TNX-1600 (a triple reuptake inhibitor). TNX-601 is in clinical formulation testing outside of the U.S and is expected to be IND-ready in 2020. Tonix's programs for treating addiction conditions also include TNX-1300\*\*\* (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication. 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. Finally, TNX-801 (live virus vaccine for percutaneous [scarification] administration) to potentially prevent smallpox and TNX-701 (undisclosed small molecule) to prevent radiation effects are being advanced as medical countermeasures to improve biodefense.

\*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](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. 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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