

January 24, 2020



Tonix Pharmaceuticals Announces Successful Completion of a Fed-Fasting and Dose Proportionality Study of TNX-102 SL

Tonix Expects the Data to Satisfy Pharmacokinetic Requirements for Potential New Drug Applications for TNX-102 SL for PTSD and Fibromyalgia

Lack of a Food Effect for TNX-102 SL Supports Predictability of Therapeutic Effect

NEW YORK, Jan. 24, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix), a clinical-stage biopharmaceutical company, today announced that it has completed the required fed-fasting and dose proportionality tests of TNX-102 SL in healthy volunteers to support the New Drug Application (NDA) of TNX-102 SL for the treatment of posttraumatic stress disorder (PTSD) and fibromyalgia.

The preliminary results of the study showed no significant effect of a fatty meal on the rate or extent of absorption of TNX-102 SL 5.6 mg administered as 2 x 2.8 mg sublingual tablets. The absence of a food effect is consistent with transmucosal absorption after sublingual administration. Oral cyclobenzaprine products approved for treating muscle spasm have significant increases in absorption with food. Food effects which change plasma drug levels can add unpredictability for patients in terms of therapeutic benefits or side effects. The study also showed the rate and extent of absorption of cyclobenzaprine increase in a dose proportional manner from 2.8 mg to 5.6 mg for TNX-102 SL. The dose proportionality observed in this study confirms an earlier study using a prototype 2.4 mg formulation.

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 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 for a potential sample size adjustment 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. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. Tonix has started enrollment in the Phase 3 RELIEF trial in fibromyalgia. 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 for AUD is in the pre-Investigational New Drug (IND) application stage. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime

treatment for PTSD, as well as for depression. The first efficacy study will be performed outside the U.S. and it is expected to be IND-ready in 2020. TNX-1600 (a triple reuptake inhibitor) is a third product candidate being developed for PTSD, as a daytime treatment. 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 and has FDA Breakthrough Therapy Designation. 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 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; 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
(212) 688-9421

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

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



Source: Tonix Pharmaceuticals Holding Corp.