

December 11, 2019



Tonix Pharmaceuticals Announces New European Patent for the Composition and Formulation of TNX-102 SL

NEW YORK, Dec. 11, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the European Patent Office ("EPO") issued European Patent No. 2968992 to the Company on December 11, 2019. This patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Mannitol," includes 14 claims directed to compositions comprising eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions. This patent is expected to provide Tonix with market exclusivity until 2034.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, "The issuance of this European patent is an important step forward in our efforts to broaden our intellectual property estate on a global basis for TNX-102 SL*."

Tonix's proprietary eutectic formulation of cyclobenzaprine, or TNX-102 SL, is designed for chronic sublingual (under-the-tongue) administration daily at bedtime, which the Company believes facilitates transmucosal absorption of cyclobenzaprine and bypasses first pass liver metabolism. Marketed cyclobenzaprine drug products are limited to short-term use (two to three weeks) and formulated for oral ingestion, which results in significant liver metabolism. Sublingual TNX-102 SL has a different pharmacokinetic profile than marketed oral cyclobenzaprine drug products. TNX-102 SL is being developed as a treatment for four indications: posttraumatic stress disorder (PTSD), fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder. Marketed oral cyclobenzaprine products are indicated for the relief of muscle spasm.

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 has started enrollment in the Phase 3 RELIEF trial 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 controlled-release tablets) and TNX-1600 (a triple reuptake inhibitor). TNX-601 CR 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.

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 quarterly and periodic reports 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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