

October 23, 2019



# **Tonix Pharmaceuticals Announces Issuance of U.S. Patent for Crystalline Tianeptine Oxalate Salt, the Active Ingredient of TNX-601**

NEW YORK, Oct. 23, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,449,203 to the Company on October 22, 2019. This patent, "Tianeptine Oxalate Salts and Polymorphs," includes claims directed to crystalline tianeptine oxalate salts, and disclosures directed to methods of using those crystalline forms and their compositions. This patent, excluding possible patent term extensions, is expected to provide Tonix with U.S. market exclusivity until December 28, 2037.

Tonix's novel oral formulation of one of the claimed tianeptine oxalate salts, or TNX-601, is being developed as a potential treatment for posttraumatic stress disorder (PTSD) and also as a potential treatment for neurocognitive dysfunction associated with corticosteroid use. Tianeptine modulates the glutamatergic system indirectly and reverses the neuroplastic changes that are observed during periods of stress and corticosteroid use. Tianeptine is a weak mu-opioid receptor agonist, but does not have significant affinity for other known neurotransmitter receptors. Currently there is no tianeptine-containing product approved in the U.S., though tianeptine sodium (amorphous) has been available in Europe, Asia, and Latin America for the treatment of depression since 1987. TNX-601 is designed for daytime dosing and may provide improved stability, consistency, and manufacturability as compared to the amorphous sodium salt. TNX-601 is being developed under Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act (FDCA).

## **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, with topline data in PTSD expected in the first half of 2020. 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 (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 has two programs for treating addiction conditions: TNX-1300\*\*\* (double-mutant cocaine esterase) is in Phase 2 development for the treatment of cocaine intoxication and TNX-102 SL is in pre-IND development for AUD. 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; 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.

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