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Tonix Pharmaceuticals Receives Notice of Allowance for New U.S. Patent Covering Composition and Manufacture of TNX-102 SL

Patent Will Provide Intellectual Property Protection until 2034 to TNX-102 SL, an FDA-Designated Breakthrough Therapy in Phase 3 Development for Posttraumatic Stress Disorder (PTSD)

NEW YORK, March 14, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced today that the U.S. Patent and Trademark Office has issued a Notice of Allowance for U.S. Patent Application 14/214,433, “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride,” covering the proprietary sublingual formulation of TNX-102 SL*. A Notice of Allowance signifies that Tonix will be entitled to receive patent protection until 2034 in the U.S. for the allowed claims when the patent is issued. Tonix expects the patent to be issued within two months.

The allowed claims protect the pharmaceutical composition and the method of manufacturing of TNX-102 SL. The TNX-102 SL sublingual formulation is based on a eutectic between cyclobenzaprine HCl and mannitol, which protects the acidic hydrochloride salt of cyclobenzaprine from molecular interactions with the basic excipient, potassium phosphate dibasic, which is added to enhance transmucosal absorption. Transmucosal absorption of cyclobenzaprine increases the rate of absorption into the blood stream and bypasses first pass liver metabolism. TNX-102 SL is distinct from orally ingested forms of cyclobenzaprine, which are available as generic immediate-release tablets and branded extended-release capsules (AMRIX®), and are approved for short-term use (2-3 weeks) for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Since TNX-102 SL has a different route of administration and different pharmacokinetic profile from orally ingested cyclobenzaprine and is intended for a new indication (PTSD), pharmacists will not be able to substitute orally ingested forms of cyclobenzaprine for TNX-102 SL.

Tonix has filed trademarks to describe the protective eutectic, Protectic™, and the formulation that utilizes interactions at the angstrom scale, Angstro-Technology™. The Protectic™ protective eutectic and Angstro-Technology™ formulation enable TNX-102 SL to be a sublingual tablet of cyclobenzaprine HCl, while ensuring that the tablets have robust manufacturability and pharmaceutical stability.

Seth Lederman, M.D., president and chief executive officer of Tonix, stated, “This notice of allowance strengthens the value of our pipeline with near-term intellectual property

protection and highlights Tonix's innovation in proprietary pharmaceutical development. Most importantly, the Protectic™ protective eutectic and Angstro-Technology™ formulation are essential elements of the proprietary TNX-102 SL composition."

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address public health challenges. TNX-102 SL is in Phase 3 development and has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of PTSD. PTSD is a serious condition characterized by chronic disability, inadequate treatment options especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. Other development efforts include TNX-601 (tianeptine oxalate), a clinical candidate at Pre-IND (Investigational New Drug) application stage, designed for daytime use for the treatment of PTSD, and TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus (HPXV). HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection. Vaccine manufacturing activities have been initiated to support further nonclinical testing of TNX-801.

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, substantial competition; 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

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