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Tonix Pharmaceuticals Announces Issuance of U.S. Patent for the Composition and Formulation of TNX-102 SL

NEW YORK, July 25, 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. 10,357,465 to the Company on July 23, 2019. This patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride," includes 14 claims directed to eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics. This patent is expected to provide Tonix with U.S. market exclusivity until 2035.

Tonix's proprietary eutectic formulation of cyclobenzaprine, or TNX-102 SL, is designed for chronic sublingual (under-the-tongue) administration daily at bedtime, which 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 three indications: posttraumatic stress disorder (PTSD), fibromyalgia and agitation in Alzheimer's disease. Marketed oral cyclobenzaprine products are indicated for the relief of muscle spasm.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, "We are committed to building our intellectual property covering the unique properties of TNX-102 SL in multiple markets around the world. These newly issued claims strengthen and expand TNX-102 SL's overall patent portfolio and provide Tonix with significant intellectual property protection for TNX-102 SL in the U.S."

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, and biological products to improve biodefense through potential medical counter-measures. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate Investigational New Drug applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development and the agitation in Alzheimer's program is Phase 2 ready. TNX-1300** (double-mutant cocaine esterase) is being

developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted outside of the U.S. TNX-801 (live virus vaccine for percutaneous (scarification) administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biological product 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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