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Tonix Pharmaceuticals Announces Issuance of Patent in China for the Composition and Formulation of TNX-102 SL

Patent Expected to Provide Intellectual Property Protection until 2034 in China

NEW YORK, June 13, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company focused on developing small molecules and biologics to treat psychiatric, pain and addiction conditions as well as to improve biodefense, today announced that the China National Intellectual Property Administration issued Chinese Patent No. ZL 201480024011.1 to the Company on April 16, 2019. This patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride," is directed to a unique eutectic that characterizes TNX-102 SL*, and claims pharmaceutical compositions containing that eutectic and methods of making those compositions.

Tonix's proprietary eutectic formulation of cyclobenzaprine, or TNX-102 SL, is designed for long-term daily use at bedtime and sublingual (under-the-tongue) administration, 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 indicated 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.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products 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. TNX-102 SL for the treatment of PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation. 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. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. 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-1300 is a recombinant protein enzyme produced through rDNA technology in E. coli bacteria. TNX-1300 for cocaine intoxication has FDA Breakthrough Therapy designation. 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.

**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 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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