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Tonix Pharmaceuticals Expands Intellectual Property Portfolio for TNX-102 SL

U.S. Patent Issued Covering the Use of Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) for treating Posttraumatic Stress Disorder (PTSD)

Patent Will Provide Intellectual Property Protection until at least 2030 for Use of Cyclobenzaprine in the Treatment of PTSD

NEW YORK, March 21, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense, announced today that U.S. Patent No. 9,918,948 was issued on March 20, 2018 by the U.S. Patent and Trademark Office. The U.S. patent, “Methods and Compositions for Treating Symptoms Associated with Posttraumatic Stress Disorder using Cyclobenzaprine,” covers the use of Tonmya®*, or TNX-102 SL, for the treatment of PTSD. Upon FDA approval, the patent will provide Tonix with U.S. market exclusivity until at least 2030 for the allowed claims. The term of this patent is eligible for extension depending on the regulatory review period and the approval date.

“This U.S. method of use patent for TNX-102 SL strengthens and expands our intellectual property portfolio, which already includes patents protecting novel compositions of TNX-102 SL in the U.S., the novel pharmacokinetic profile of TNX-102 SL in Japan and the use of TNX-102 SL in treating PTSD in Europe” commented Seth Lederman, M.D., President and Chief Executive Officer of Tonix. “Tonix has conducted or sponsored the development of the technology for all of its programs, including the TNX-102 SL program, and therefore does not expect to owe development-based royalties or license fees upon commercialization.”

The Tonmya eutectic formulation of cyclobenzaprine, or TNX-102 SL, is designed for under-the-tongue administration, facilitating transmucosal absorption of cyclobenzaprine, which bypasses first pass liver metabolism that is necessary for orally ingested cyclobenzaprine drug products. Marketed cyclobenzaprine drug products are limited for oral ingestion and short-term use (two-three weeks) for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Tonmya has a different pharmacokinetic profile than marketed oral cyclobenzaprine drug products and is intended as a long-term bedtime treatment for PTSD.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

About Tonmya and the Phase 3 HONOR Study

Tonmya is a sublingual transmucosal formulation of cyclobenzaprine that is in Phase 3 development. 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. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets), was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the U.S., the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants in approximately 40 U.S. sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that (i) a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive, and (ii) an additional abuse assessment study is not required for the NDA filing. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540.

The newly issued U.S. method of use patent for Tonmya extends upon the portfolio of previously granted patent claims, including those related to the composition of matter of TNX-102 SL in the U.S. (U.S. Patent No. 9,636,408), the pharmacokinetic profile of TNX-102 SL in Japan (Japanese Patent No. 6,259,452), and the method of use for the treatment of PTSD in Europe (European Patent No. 2,501,234). In addition, the Japanese Patent Office issued a Notice of Allowance for Patent Application 2016-503239 related to the composition of matter of TNX-102 SL in March 2018.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease. A Phase 2 IND (Investigational New Drug) application is planned for March 2018 after completion of a successful pre-IND meeting with the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, and periodic reports filed with the SEC on or after the date thereof. 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 thereof.

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