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Tonix Pharmaceuticals Receives Notice of Allowance for New U.S. Patent for the Active Ingredient in Tonmya® (Cyclobenzaprine HCl Sublingual Tablets)

Patent Will Provide Intellectual Property Protection until 2030 for Use of Cyclobenzaprine in the Treatment of Posttraumatic Stress Disorder (PTSD)

NEW YORK, Jan. 23, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix) announced today that the U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application 12/948,828, "Methods and compositions for treating symptoms associated with posttraumatic stress disorder using cyclobenzaprine," covering the use of Tonmya*, or TNX-102 SL, for the treatment of posttraumatic stress disorder (PTSD). A Notice of Allowance signifies that Tonix will be entitled to receive patent protection until 2030 in the U.S. for the allowed claims when the patent is issued. Tonix expects the patent to be issued within two months. Tonix is in Phase 3 development of Tonmya, a U.S. Food and Drug Administration (FDA)-designated Breakthrough Therapy for the treatment of PTSD.

This patent protects the method of using Tonmya's active ingredient cyclobenzaprine to treat PTSD. The Tonmya eutectic formulation of cyclobenzaprine was designed for sublingual (under-the-tongue) administration to enable transmucosal absorption of cyclobenzaprine, which bypasses first pass liver metabolism. Other oral formulations of cyclobenzaprine are approved for short-term use (two-three weeks) for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Sublingual administration of Tonmya provides a different pharmacokinetic profile than the oral marketed formulations of cyclobenzaprine and is suitable as a bedtime treatment for two new indications, PTSD and agitation in Alzheimer's disease, which are under development by Tonix.

This method of use patent for Tonmya extends upon previously granted patents related to the composition of matter (U.S. Patent No. 9,636,408) and the active ingredient in Tonmya (European Patent No. 2,501,234).

*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 patented 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 United States, 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 45 U.S. sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent 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 <http://www.thehonorstudy.com> or <https://clinicaltrials.gov/ct2/show/NCT03062540>.

The U.S. Patent and Trademark Office issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034. Tonix was also awarded European patent (Patent No. 2,501,234, "Methods and Compositions for Treating Symptoms Associated with Posttraumatic Stress Disorders Using Cyclobenzaprine"). This patent is expected to provide Tonmya, upon European marketing authorization, with European market exclusivity until November 2030 and the exclusivity may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges and diseases with significant unmet needs. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Due to the unique mechanism of action of the active ingredient (TNX-102 or cyclobenzaprine hydrochloride) in Tonmya to improve sleep quality, TNX-102 SL is being developed as a bedtime treatment for agitation in Alzheimer's disease. Tonix is planning to submit an IND for this additional indication in 1Q2018 after completing a successful pre-IND meeting with the FDA in 4Q2017. TNX-601 (tianeptine oxalate) is in the pre-IND (Investigational New Drug) 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, 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, 2016, as filed with the Securities and Exchange Commission (the “SEC”) on April 13, 2017, 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.

Contacts

Jessica Morris (investors)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Rich Allan (media)
Russo Partners
rich.allan@russopartnersllc.com
(646) 942-5588



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