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Tonix Pharmaceuticals Receives European 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, Sept. 14, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company developing innovative pharmaceutical and biological products to address major public health challenges, today announced that Tonix has received a European patent (Patent No. 2501234, “Methods and Compositions for Treating Symptoms Associated with Posttraumatic Stress Disorders Using Cyclobenzaprine”). This patent protects the use of Tonmya*, or TNX-102 SL, for the treatment of PTSD. The patent expires in November 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD. Tonix is in Phase 3 development of Tonmya, a U.S. Food and Drug Administration (FDA)-designated Breakthrough Therapy for the treatment of PTSD.

“The grant of this European methods and compositions use patent is a big step forward for the global Tonmya development program,” commented Seth Lederman, M.D., president and chief executive officer of Tonix. “Adding this European use patent to the existing Tonmya U.S. composition of matter patent** can provide us broad protection of using cyclobenzaprine to treat PTSD in major pharmaceutical markets.”

This patent protects the use of Tonmya’s active ingredient cyclobenzaprine for the treatment of PTSD. The Tonmya eutectic formulation of cyclobenzaprine for under-the-tongue administration allows transmucosal absorption of cyclobenzaprine, which bypasses first pass liver metabolism. Other forms of cyclobenzaprine are approved for short-term use (two-three weeks) for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Tonmya has a different route of administration and different pharmacokinetic profile than other marketed formulations of cyclobenzaprine and is intended for a new indication (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.

** U.S. Patent 9,636,408 was issued covering the proprietary sublingual formulation of

cyclobenzaprine. This patent is expected to provide Tonix with U.S. market exclusivity until 2034.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges. In addition to Tonmya for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage, designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, to be developed as a potential smallpox-preventing vaccine.

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 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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