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Tonix Pharmaceuticals' PTSD Phase 3-Ready Drug Candidate, TNX-102 SL, Granted Breakthrough Therapy Designation by the FDA

Responding to AtEase study results in military-related PTSD population, FDA agrees to work closely with Tonix to develop and review TNX-102 SL for PTSD as efficiently as possible

NEW YORK, Dec. 19, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for PTSD, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to TNX-102 SL* for the treatment of posttraumatic stress disorder (PTSD).

The benefits of Breakthrough Therapy designation include the eligibility for priority review of the New Drug Application (NDA) within 6 months instead of 10 months and rolling submission of portions of the NDA, in addition to an organizational commitment involving FDA's senior managers contributing significant guidance. The FDA is committing to provide Tonix timely advice and interactive communications related to the design and efficient execution of a drug development program.

"We are very pleased that the FDA has granted Breakthrough Therapy designation to TNX-102 SL for PTSD," stated Seth Lederman, M.D., president & chief executive officer of Tonix. "This decision reflects the FDA's recognition that PTSD is a serious disease, and that preliminary clinical evidence from our Phase 2 AtEase study in military-related PTSD supports TNX-102 SL's potential advantage over currently-available PTSD therapies. In addition to being Phase 3-ready, the timeline for the manufacturing of commercial product to support a Breakthrough Therapy application aligns with our TNX-102 SL registration plan. As we prepare to initiate our Phase 3 HONOR study in the first quarter of 2017, we look forward to benefiting from the FDA's commitment to expedite the development and review of TNX-102 SL for PTSD by intensively involving senior staff in a proactive and collaborative effort. We believe our joint commitment to accelerate the development and registration of TNX-102 SL can potentially provide patients with PTSD, including those with military-related PTSD, an improved treatment option in the most expeditious manner possible."

Tonix held a successful End-of-Phase 2/Pre-Phase 3 meeting with the FDA in the third quarter of this year, based on positive data from its 12-week randomized, double-blind, placebo-controlled Phase 2 AtEase study. Tonix plans to begin enrolling patients into its first Phase 3 study, the HONOR study, in the first quarter of 2017 after receiving FDA agreement on the study design and interim analysis plan.

“Since TNX-102 SL is designated as a Breakthrough Therapy, we anticipate receiving FDA comments on the HONOR study protocol and proposed interim analysis plan imminently. We proposed two interim analyses for the HONOR study as part of an adaptive design, an approach recommended by the FDA to accelerate the establishment of clinical evidence of efficacy to support a Breakthrough Therapy approval,” stated Gregory Sullivan, M.D., chief medical officer of Tonix.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an Investigational New Drug and has not been approved for any indication.

About FDA Breakthrough Therapy Designation

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a drug candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include priority review of the NDA in 6 months instead of 10 months under standard review, rolling submission of portions of the application ahead of completion of the full NDA dossier, and an organizational commitment involving FDA's senior managers with more intensive guidance from the FDA. In some cases, the development program for the Breakthrough Therapy could be shorter than for other drugs intended to treat the disease being studied. However, FDA notes that a compressed drug development program still must generate adequate data to demonstrate that the drug is safe, effective and meets the statutory standard for approval. Breakthrough Therapy designation does not change the standards for approval. If a clinical development program granted Breakthrough Therapy designation does not continue to meet the criteria, FDA may rescind the designation.

According to an FDA presentation on December 14, 2016, there have been a total of 404 Breakthrough Therapy designation requests since inception in July 9, 2012 through November 30, 2016. Of those, psychiatry projects constitute approximately 5% of the requests. Out of all 404 Breakthrough Therapy designation requests, 141 (35%) have been granted so far. Of those granted, nine (6%) were for psychiatric products.

The commitment of the FDA Psychiatry Division to expediting approval of medicines with Breakthrough Therapy designation for serious psychiatric condition is exemplified in the first approval of a Breakthrough Therapy psychiatry product, NUPLAZID® (pimavanserin) for hallucinations associated with Parkinson's disease. NUPLAZID was designated as a Breakthrough Therapy in September 2014, the NDA was submitted in September 2015 and NDA approval was received in April 2016.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, with its lead program focusing on posttraumatic stress disorder. This disorder is a serious condition characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. 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, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, 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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