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Tonix Pharmaceuticals Receives Fast Track Designation from the U.S. FDA for TNX-102 SL for Treatment of Agitation in Alzheimer's Disease

NEW YORK, July 16, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its investigational new drug, TNX-102 SL, for the treatment of agitation in Alzheimer's disease. The same drug, TNX-102 SL, or Tonmya[®]*, for the treatment of posttraumatic stress disorder (PTSD), has previously been designated as a Breakthrough Therapy by the FDA. It is currently in a Phase 3 study for military-related PTSD, with an interim analysis expected in the third quarter of 2018.

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The benefits of a Fast Track designation include rolling submission of portions of the New Drug Application (NDA) for the drug candidate and eligibility for priority review of the NDA. Additionally, more frequent meetings and written communication with the FDA regarding the development plan and trial design for the drug candidate are encouraged throughout the entire drug development and review process, with the goal of having earlier drug approval and access for patients.

"Fast Track designation reflects the recognition by the FDA that TNX-102 SL has the potential to address a large unmet medical need for a serious condition," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "Currently, there are no FDA-approved treatments for agitation in Alzheimer's disease, despite a high disease burden and a need for an effective therapy. We are eager to work closely with the FDA to advance the development TNX-102 SL for the treatment of agitation in Alzheimer's disease."

Tonix received clearance of the Investigational New Drug Application, or IND, from the FDA for TNX-102 SL 5.6 mg in April of this year which supports the initiation of a Phase 2, potential pivotal efficacy study of TNX-102 SL in patients with agitation in Alzheimer's disease. In addition to evaluating the safety and efficacy of TNX-102 SL after 8 weeks of bedtime treatment, the Phase 2 study will analyze genomic DNA to identify biomarkers that may be associated with treatment response.

** Tonmya has been conditionally accepted by the 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 Agitation in Alzheimer's Disease

Agitation in Alzheimer's disease, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of the behavioral complications of Alzheimer's disease. Agitation in Alzheimer's disease has significant negative consequences for patients as well as their caregivers and is one of the most common reasons for patients having to transition to nursing homes and other long-term care settings. Agitation is likely to affect more than half of the 5.3 million Americans who currently suffer from Alzheimer's disease, and this number is expected to nearly triple by 2050. The presence of agitation nearly doubles the cost of caring for patients with Alzheimer's disease, and agitation is estimated to account for more than 12 percent of the \$256 billion in healthcare and societal costs associated with Alzheimer's disease for the year 2017 in the United States. Currently, there is no FDA approved treatment for behavioral symptoms in Alzheimer's disease such as agitation and aggression. There is widespread off-label use of atypical anti-psychotic medications for these behavioral symptoms, despite the lack of evidence for their effectiveness and significant medical risks associated with their use in this population.

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 a Breakthrough Therapy in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL, which has been granted Fast Track designation by the FDA, as a bedtime treatment for agitation in Alzheimer's disease under a separate IND to support a Phase 2, potential pivotal, efficacy study. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a unique mechanism and 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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