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Tonix Pharmaceuticals Receives IND Clearance by U.S. FDA for TNX-102 SL in Agitation in Alzheimer's Disease

Agitation in Alzheimer's Disease, a Potential New Indication for TNX-102 SL, currently in Phase 3 Development as a Treatment for Posttraumatic Stress Disorder (PTSD)

NEW YORK, May 01, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), announced today that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to support the initiation of a Phase 2, potential pivotal efficacy study of TNX-102 SL* 5.6 mg in patients with agitation in Alzheimer's disease. TNX-102 SL, or Tonmya®# is a FDA-designated Breakthrough Therapy in Phase 3 development for the treatment of posttraumatic stress disorder (PTSD).

"This potential new indication for TNX-102 SL expands our clinical development pipeline, leveraging our understanding of the TNX-102 SL mechanism of action on sleep quality and our understanding of its potential clinical benefit in patients with agitation in Alzheimer's disease," commented Seth Lederman, M.D., President and Chief Executive Officer. "The investigation of TNX-102 SL for agitation in Alzheimer's disease may bring a new treatment targeting sleep disturbances in patients experiencing this condition. 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. A Fast Track designation request will be filed next month to potentially accelerate the development and review of this unmet medical need."

** TNX-102 SL is an investigational new drug and has not been approved for any indication.*
 # Tonmya is the FDA conditionally accepted proprietary name for TNX-102 SL for the treatment of PTSD

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 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. 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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