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# **Tonix Pharmaceuticals Reports Preliminary Results from a Phase 1 Pivotal Multiple-Dose Bridging Pharmacokinetic (PK) Study of Tonmya® or TNX-102 SL**

## **Results from Preliminary PK Analyses Confirm the Applicability of the 505(b)(2) Regulatory Pathway for TNX-102 SL (Cyclobenzaprine HCl Sublingual Tablets) New Drug Application Approval**

NEW YORK, May 24, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), announced preliminary results from a Phase 1 pivotal multiple-dose bridging pharmacokinetic study of Tonmya®\*, or TNX-102 SL, which is required to support the 505(b)(2) NDA submission for TNX-102 SL, using AMRIX®# (cyclobenzaprine HCl extended-release [ER]) capsules) as the reference listed drug (RLD). The design of this study had been previously accepted by the FDA.

Specifically, the study compared the plasma levels and the safety profile of TNX-102 SL 5.6 mg (administered as 2 x 2.8 mg tablets) taken sublingually versus the recommended dose of the RLD, AMRIX 30 mg ER capsule, over 20 consecutive days of daily dosing under fasting conditions in healthy subjects aged 18-65 years old. Tonmya is in Phase 3 development for the bedtime treatment of military-related posttraumatic stress disorder (PTSD) and TNX-102 SL has an effective IND for a Phase 2 efficacy study for the treatment of agitation in Alzheimer's disease. TNX-102 SL 5.6 mg is the proposed therapeutic dose for PTSD and agitation in Alzheimer's disease.

Results from preliminary PK analyses showed the plasma levels and exposure of sublingual TNX-102 SL 5.6 mg are less than AMRIX 30 mg after 20 days of dosing. In addition, the systemic exposure of cyclobenzaprine and the major active metabolite norcyclobenzaprine from TNX-102 SL is less than the RLD AMRIX at the steady-state. Preliminary and unaudited adverse event (AEs) data were generally as expected, considering dosing in this PK study was daily in the early morning, in contrast to the intended use at bedtime. The majority of AEs were mild and transient, and none led to study discontinuation."

Dr. Seth Lederman, M.D., President and Chief Executive Officer of Tonix stated, "We are pleased the preliminary PK analyses results support and confirm our regulatory strategy to register Tonmya, or TNX-102 SL, for PTSD under Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act using AMRIX® ER capsules 30 mg as our RLD. As agreed upon by the FDA and consistent with the 505(b)(2) regulatory pathway, we believe the approval of our FDA designated Breakthrough Therapy, Tonmya for the treatment of PTSD,

can rely on the safety information of the currently marketed orally ingested cyclobenzaprine drug products' labeling."

*\*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 which has been designated as a Breakthrough Therapy in December 2016. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

*# AMRIX (cyclobenzaprine HCl extended-release capsules) is indicated for 2-3 weeks use as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. The recommended adult dose for most patients is one AMRIX 15 mg capsule taken once daily. Some patients may require up to 30 mg/day, given as one AMRIX 30 mg capsule taken once daily or as two (2) AMRIX 15 mg capsules taken once daily.*

### **About Tonmya and the Phase 3 HONOR Study**

Tonmya is a sublingual transmucosal tablet 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 U.S., 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 40 U.S. sites. An interim analysis will be conducted based on approximately the first 50% of randomized participants. In a 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 [www.thehonorstudy.com](http://www.thehonorstudy.com) or <https://clinicaltrials.gov/ct2/show/NCT03062540>.

### **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 under an effective IND. TNX-102 SL is cleared to enter a Phase 2, potential pivotal efficacy study in 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](http://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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