November 6, 2018

Tonix Pharmaceuticals Presented Results and Retrospective Analyses of Phase 3 P301 “HONOR” Study in Poster Presentation at CNS Summit 2018

Retrospective Analysis Revealed Clinically Meaningful Response to Tonmya® in Female PTSD Participants Overall and for Non-Combat-Related Traumas Experienced Within Nine Years Prior to Screening

Results from Phase 3 P301 HONOR Study Retrospective Analyses Inform Design of a New Phase 3 Trial of Tonmya, which is Expected to Commence First Quarter 2019

NEW YORK, Nov. 06, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) presented a poster at CNS Summit 2018 held November 1-4, 2018, in Boca Raton, Fla. A poster, entitled “Time Since Trauma in PTSD: Phase 3 Multi-Center, Double-Blind, Placebo-Controlled Trial of TNX-102 SL*, a Sublingual Formulation of Cyclobenzaprine, in Military-Related PTSD (Study TNX-CY-P301)” includes results and retrospective analyses from the Phase 3 P301 study (“HONOR”). TNX-102 SL, or Tonmya*, is being developed for the treatment of posttraumatic stress disorder (PTSD). The poster can be found on the Scientific Presentations page of Tonix’s website.

The poster presentation reports that a retrospective analysis revealed a treatment effect in participants who experienced trauma less than or equal to nine years prior to screening (approximately 50% of the modified intent-to-treat population). For this subgroup, the p-value of the primary endpoint at Week 12, using mixed model repeated measures with multiple imputation (MMRM with MI), was 0.039. In contrast, there was no benefit relative to placebo in the participants who experienced trauma more than nine years prior to screening.

A retrospective analysis of female participants overall, and of military participants with non-combat index traumas experienced less than or equal to nine years from screening, suggests clinically meaningful separation from placebo at Weeks 4 and 12 in these specific subgroups. The female subgroup (n = 27) experienced an 11.5 point improvement in CAPS-5 at Week 4 and 9.1 point improvement at Week 12, while the non-combat participant subgroup (n = 24) experienced a 4.8 point improvement at Week 4 and 4.4 point improvement at Week 12. In addition, the Week 4 assessment of CAPS-5 in the Phase 3 HONOR study showed clinically meaningful improvement at this time point in the entire modified intent-to-treat population (difference from placebo of -3.6 CAPS-5 points, p = 0.019).

Furthermore, for study participants who experienced trauma less than or equal to nine years prior to screening, all five secondary measures showed a p-value of <0.05 at the Week 12

endpoint, indicating possible global and functional recovery, and improved sleep quality and mood after 12 weeks of Tonmya treatment compared with placebo.

Based on these findings and following a recent Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA), the Company plans to incorporate several new design features into the new Phase 3 study, including restricting enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening; enrolling participants who have experienced civilian traumas, in addition to those with military-related traumas; and a CAPS-5 primary endpoint assessed at Week 4 instead of at Week 12.

Dr. Seth Lederman, CEO of Tonix commented, “Data analyses from our Phase 3 HONOR study, as well as recent feedback from the FDA, has informed and strengthened the next Phase 3 trial design which increases the probability of success as a potential pivotal efficacy study to support the Tonmya NDA approval for PTSD. The innovative Phase 3 study design has preliminary acceptance from the FDA and will be initiated in the first quarter of 2019.”

Dr. Gregory Sullivan, Chief Medical Officer of Tonix commented, “The findings of P301 show that in PTSD, time since trauma is important in the treatment response to Tonmya. In addition, the primary and secondary efficacy results from females and military personnel with non-combat index traumas in the Phase 3 HONOR study supports the expansion of our next Phase 3 study to include civilians with PTSD, the majority of whom are female.”

There were no serious and unexpected adverse events (AEs) in the HONOR/P301 study with TNX-102 SL 5.6 mg. The AEs observed in both PTSD studies, P301 and previously in Phase 2 P201, were comparable and also consistent with the experience in prior studies with TNX-102 SL 2.8 mg in fibromyalgia. Observed systemic AEs were consistent with those described in approved oral cyclobenzaprine product labels. Similar severity and incidence of oral hypoesthesia (tongue/mouth numbness) has been observed across studies (37% in P301; 36% in P201) for TNX-102 SL or Tonmya 5.6 mg.

**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 the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

The Phase 3 HONOR Study (P301)

The HONOR study was a randomized, placebo-controlled study that was planned to enroll 550 participants with military-related PTSD at 44 U.S. clinical sites. The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with Tonmya and those receiving placebo. The CAPS-5 is a structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. A planned, unblinded interim analysis was completed in July 2018 when approximately 50 percent (n=274) of planned participants were randomized and completed 12 weeks of treatment with either bedtime sublingual Tonmya 5.6 mg (2 x 2.8 mg tablets) or placebo sublingual tablets. Based on a pre-specified study continuation threshold at Week 12, the study was discontinued due to inadequate separation from placebo in the primary efficacy endpoint. Meaningful improvement in overall PTSD

symptoms was observed at Week 4, at which time the Tonmya treated group separated from placebo in CAPS-5 ($p = 0.019$) and in the Clinical Global Impression – Improvement (CGI-I) scale ($p = 0.015$), a key secondary endpoint. Also, at Week 4, sleep quality improved as measured by both the PROMIS Sleep Disturbance scale and the CAPS-5 sleep disturbance item, supporting the proposed mechanism of action of Tonmya. Retrospective analysis of the discontinued Phase 3 P301 Study revealed clinically meaningful response to Tonmya in PTSD participants with trauma experienced within nine years prior to screening but not in participants with trauma experienced greater than nine years prior to screening. Additional details of the HONOR study are available at https://clinicaltrials.gov/ct2/show/NCT03062540.

About Tonmya and PTSD

Tonmya or TNX-102 SL is a sublingual transmucosal tablet formulation of cyclobenzaprine. PTSD is a serious condition that affects approximately 11 million U.S. adults, and is 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.

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 is developing Tonmya, which has been granted Breakthrough Therapy designation, as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under a separate IND to support a Phase 2, potential pivotal, efficacy study and has been granted Fast Track designation by the FDA for this indication. 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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