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Tonix Pharmaceuticals Presents Results and Retrospective Analyses of Two Double-Blind, Randomized Placebo-Controlled 12-Week Studies of Tonmya® in Military-Related PTSD at the 2018 Military Health System Research Symposium

Retrospective Analysis of the Discontinued Phase 3 P301 "HONOR" 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 More Than Nine Years Prior to Screening

Treatment Effect Seen in Phase 3 P301 Participants with Trauma Experienced Within Nine Years Replicated the Results of the Tonmya 5.6 mg Group in the Phase 2 P201 "AtEase" Study

NEW YORK, Aug. 21, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix) is presenting a poster today at the 2018 Military Health System Research Symposium (MHSRS) in Kissimmee, Fla. The poster, entitled "Effect of Time Since Trauma on Response to TNX-102 SL* (Cyclobenzaprine Sublingual Tablets) in Military-Related PTSD: Results of Two Double-Blind Randomized Placebo-Controlled Studies" includes results and retrospective analyses from the Phase 3 P301 study ("HONOR") and the Phase 2 P201 study ("AtEase"). 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.

Tonix recently reported that the Phase 3 P301 study was stopped at the pre-planned interim analysis because it did not achieve a study continuation threshold on the primary outcome of improvement in the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) at Week 12 in the modified intent-to-treat (mITT) population. Today's 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 mITT 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 in the participants who experienced trauma more than nine years prior to screening. The impact of time since trauma on Tonmya treatment response was not evident in the Phase 2 P201 trial, which might relate to the fact that P201 had relatively fewer participants who experienced trauma greater than nine years before screening. There

were no serious and unexpected adverse events (AEs) in P301 or P201. The AEs observed in both studies were comparable and also consistent with the experience in prior studies 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 Tonmya 5.6 mg.

Dr. Seth Lederman, CEO of Tonix commented, “The P301 and P201 studies help to advance the clinical development of TNX-102 SL for PTSD. Future studies will focus on patients with more recent trauma (less than nine years). The finding that treatment response to Tonmya in P301 decreases as the time since trauma gets longer, suggests that military service members and veterans with PTSD are transitioning from a Tonmya-treatment responsive state to a non-responsive state after approximately nine years. These results emphasize the urgency for early diagnosis and treatment for PTSD, especially for military-related PTSD.”

Dr. Gregory Sullivan, Chief Medical Officer of Tonix commented, “Trauma is the cause of PTSD, but PTSD is a complex condition with clear evidence of a dynamic pathophysiology which changes over time. Treatment responsiveness over the course of the disease may vary with different pharmacological classes, and may also differ between PTSD from combat versus other types of trauma. Yet it is unclear what specific features of PTSD change over time and make it less treatment responsive. These findings of P301 and P201 show that in PTSD, time since trauma is important in the treatment response to Tonmya. Other aspects of PTSD have been observed to depend on time since trauma, such as a decrease in the rates of remission the more years out from the trauma.[1] The subgroup with trauma less than nine years prior to screening in P301 may include more participants within the 'remitting' phase of PTSD, while the greater than nine years since trauma subgroup in P301 may include more participants in the 'persistent' phase of PTSD, which have been described in longitudinal studies of PTSD in the literature.[1-6]”

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

[1]Kessler et al. Arch Gen Psychiatry 1995;52:1048-1060.[2]Armenta et al. BMC Psychiatry 2018;18:48.[3]Galatzer-Levy et al. PLOS ONE 2013;8:e70084.[4]Perkonigg et al. Am J Psychiatry 2005;162:1320-1327.[5]Santiago et al. PLOS ONE 2013;8:e59236.[6]Davidson & Connor. Eur Neuropsychopharmacol 2001;11(Supp3):S148-S149.

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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Scott Stachowiak (media)
Russo Partners
scott.stachowiak@russopartnersllc.com
(646) 942-5630

Peter Vozzo (investors)
Westwicke Partners
peter.vozzo@westwicke.com
(443) 213-0505

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