November 29, 2018

Tonix Pharmaceuticals Announces Additional Details of the New Phase 3 Study of Tonmya® for PTSD, Following Receipt of FDA Minutes

New Phase 3 RECOVERY Trial to Include Approximately 250 Participants

Trial to Commence First Quarter 2019 With Topline Data Expected First Half 2020

NEW YORK, Nov. 29, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), today announced that it has received the official minutes from the October 29th Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA). The minutes are consistent with the preliminary guidance the Company received at the meeting and confirm FDA's acceptance of the new Phase 3 "RECOVERY" study design.

As previously communicated, the Company plans to start the RECOVERY trial for the treatment of posttraumatic stress disorder (PTSD) in the first quarter of 2019. The new trial will incorporate several new design features including restricting enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening, instead of 2001 or later as in the Phase 3 HONOR study. The RECOVERY study will also include participants who have experienced civilian traumas in addition to those with military-related traumas. The primary endpoint, mean change from baseline in the severity of PTSD symptoms as measured by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5), is the same as that used in the Phase 3 HONOR study and the Phase 2 AtEase study, but the CAPS-5 primary endpoint will be assessed at Week 4 instead of at Week 12. In the Phase 3 HONOR study, the Week 4 assessment of CAPS-5 showed clinically meaningful improvement at this timepoint in the entire modified Intent-to-Treat sample ($p = 0.019$). Based on the Week 4 primary endpoint, approximately 250 patients will be enrolled in the RECOVERY trial, compared to approximately 550 patients targeted for the previous Phase 3 HONOR study, which utilized a primary endpoint assessed at week 12.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, "The minutes from our Breakthrough Therapy Clinical Guidance meeting with the FDA are consistent with our previous assessment. We are moving forward expeditiously to initiate the RECOVERY study in the first quarter of 2019 and expect to have topline data in the first half of 2020."

**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.

About the Phase 3 RECOVERY Study

The RECOVERY study will be a double-blind, randomized, placebo-controlled study of Tonmya 5.6 mg over 12 weeks of treatment for civilian and military-related PTSD in approximately 250 participants across approximately 25 clinical sites. The primary efficacy endpoint will be the Week 4 mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with Tonmya and those receiving placebo. A key secondary endpoint will be the Week 12 mean change from baseline in CAPS-5. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. Earlier versions of the CAPS were used to support the approval of the two currently marketed PTSD treatments.

About the Phase 3 HONOR Study

The HONOR study was a double-blind, randomized, placebo-controlled study of up to 550 participants with PTSD at 40 U.S. clinical sites. A formal unblinded interim analysis was completed when approximately 50 percent (n=274) of participants were randomized and completed the 12-week course of treatment with bedtime sublingual Tonmya 5.6 mg (2 x 2.8 mg tablets) or placebo sublingual tablets. The primary efficacy endpoint was the Week 12 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 HONOR study was stopped at the interim analysis when the primary endpoint did not cross a predefined study continuation threshold; however, a clinically meaningful improvement in CAPS-5 was observed at Week 4 ($p = 0.019$). There were no serious and/or unexpected adverse events revealed and the most frequent adverse events related to Tonmya were transient local administration site reactions.

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 is in Phase 3 development and 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 designated a Fast Track development program 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

Source: Tonix Pharmaceuticals Holding Corp.