November 26, 2019

Tonix Pharmaceuticals Announces Receipt of FDA Official Minutes from Breakthrough Therapy Type B Clinical Guidance Meeting for Tonmya® as a Potential New Treatment for PTSD

Minutes are Consistent with Guidance Received at FDA Meeting

More Than 50 Percent of Enrollment Completed for Phase 3 RECOVERY Trial of Tonmya for PTSD

Results from RECOVERY Interim Analysis Expected First Quarter 2020

Topline Data from RECOVERY Expected Second Quarter 2020, Based on Currently-Planned Sample Size

NEW YORK, Nov. 26, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it received the official minutes from the Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA) for Tonmya®* (or TNX-102 SL, cyclobenzaprine sublingual tablets) for the treatment of posttraumatic stress disorder (PTSD). The minutes are consistent with the the guidance received at the meeting. As previously announced, the primary endpoint of the RECOVERY Phase 3 trial will be at Week 12, and the Company plans to add an unblinded interim analysis that allows for a potential sample size adjustment. The ongoing RECOVERY trial is enrolling patients with PTSD from civilian or military traumas that occurred within nine years of screening.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, “The minutes from our Breakthrough Therapy Clinical Guidance meeting are consistent with the agreement that we previously announced. With more than 50 percent of the current target number of participants enrolled, we look forward to reporting the results of the interim analysis in the first quarter of 2020, followed by topline data in the second quarter of 2020.”

As previously communicated, the Phase 3 study design changes are being implemented after the FDA indicated the importance of showing persistence of treatment effect at Week 12 in a pivotal study. The primary endpoint will be mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) assessed at Week 12. Week 12 was the same timepoint analyzed for the CAPS-5 primary endpoint in the previous Phase 3 HONOR (P301) and Phase 2 AtEase (P201) studies of Tonmya for PTSD.

The unblinded interim analysis allows for a potential sample size re-estimation, to be conducted once about 50 percent (n=125) of the current target number of participants (n=250) are randomized and have either completed or discontinued the 12-week course of treatment with daily bedtime Tonmya or placebo sublingual tablets. The introduction of the potential sample size re-estimation was added to address the potential impact of more drop-outs between Week 4 and Week 12, since the study was originally powered for a Week 4 endpoint. The unblinded interim analysis data will be reviewed by an Independent Data Monitoring Committee (IDMC) which will make a non-binding recommendation to the Company.

Pending final approval by FDA, the planned interim analysis will have three possible recommendations: 1) keep the current sample size and continue as planned; 2) provide the opportunity to increase the sample size to include up to a maximum of 120 additional participants, based on certain criteria; and 3) stop the study early for futility. The proposed design will not include an option to stop for positive efficacy at the interim analysis. The proposed sample size re-estimation methodology maintains the statistical hurdle of $p < 0.05$. If the current sample size is kept at 250 participants at the interim analysis, there will be no statistical penalty on average compared to the current design. With an increase in sample size, the results from the cohorts before and after the interim analysis will be averaged with equal weight and $p < 0.05$ will still be required for success. This methodology has been successfully utilized in other pivotal studies and was a component of the Phase 3 HONOR study's interim analysis that was agreed to by the FDA.

**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.*

About the Phase 3 RECOVERY Study

The RECOVERY Phase 3 study is a double-blind, randomized, placebo-controlled study of Tonmya 5.6 mg (2 x 2.8 mg sublingual tablets) over 12 weeks of treatment for civilian and military-related PTSD. The RECOVERY Phase 3 study restricts enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening. Two previous PTSD studies of Tonmya by the Company (P201 and P301) restricted enrollment to participants who experienced traumas during military service since 2001. The primary efficacy endpoint is 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 CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. A formal unblinded interim analysis will be completed when about 50 percent (n=125) of participants have been randomized and have completed or discontinued the 12-week course of treatment with daily bedtime Tonmya 5.6 mg or placebo sublingual tablets. The Company expects to report the results of the interim analysis and the recommendation of the IDMC in the first quarter of 2020. If the current projected population of 250 study participants remains unchanged, the Company expects to report topline data in the second quarter of 2020.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing

small molecules and biologics to treat psychiatric, pain and addiction conditions. Tonix's lead product candidate, TNX-102 SL, is in development for posttraumatic stress disorder (PTSD), fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder (AUD). TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD (trade name Tonmya) and fibromyalgia. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling and results from an interim analysis are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. The Company has initiated the Phase 3 RELIEF trial in fibromyalgia and expects to enroll the first patient by year-end 2019. The agitation in Alzheimer's disease program is Phase 2 ready and the development for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix is advancing two other PTSD therapeutic programs in the pre-IND stage, with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 CR (tianeptine oxalate controlled-release tablets) and TNX-1600 (a triple reuptake inhibitor). TNX-601 CR is in clinical formulation testing outside of the U.S and is expected to be IND-ready in 2020. Tonix's programs for treating addiction conditions also include TNX-1300** (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. Finally, TNX-801 (live virus vaccine for percutaneous [scarification] administration) to potentially prevent smallpox and TNX-701 (undisclosed small molecule) to prevent radiation effects are being advanced as medical countermeasures to improve biodefense. TNX-102 SL for PTSD and TNX-1300 for cocaine intoxication have been granted FDA Breakthrough Therapy designation. TNX-102 SL for agitation in Alzheimer's disease has been granted FDA Fast-Track designation.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

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; risks related to the timing and progress of clinical development of our product candidates; 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. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the

Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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