April 24, 2020

Tonix Pharmaceuticals Achieves 50 Percent Enrollment in Phase 3 RELIEF Study of TNX-102 SL (Cyclobenzaprine HCl Sublingual Tablets) for Management of Fibromyalgia

Enrollment Continues in Phase 3 RELIEF Study, with Interim Results of the First 50 Percent of Participants Expected in September 2020

Topline Results of Approximately 470 Participants with Fibromyalgia Expected in the First Quarter of 2021

NEW YORK, April 24, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that 50 percent of the planned total number of participants have been randomized in the Phase 3 RELIEF trial, a potential pivotal study of TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) 5.6 mg, a non-opioid, centrally acting analgesic, taken daily at bedtime for the management of fibromyalgia.

An interim analysis of the first 50 percent of randomized participants will be conducted shortly after the 12-week treatment period has been completed by these participants. Pending approval of the interim statistical analysis plan by the U.S. Food and Drug Administration (FDA), results from the interim analysis are expected in September 2020. The interim analysis will be conducted by an Independent Data Monitoring Committee (IDMC) which will review the unblinded data and make one of four recommendations: (1) stop the study for success; (2) continue to enroll the full study as planned; (3) continue to enroll with a specified increase in the total number of participants in the full study; or (4) stop the study for futility. The COVID-19 pandemic may lead to a delay in data monitoring activities or reduced ability of participants or sites to complete study visits which could delay the interim analysis. The COVID-19 pandemic may also lead to a delay in recruitment of the second 50% of participants and topline results, but to date trial enrollment remains on schedule.

“TNX-102 SL is a potential new, non-opioid, non-addictive analgesic that has been shown to have activity at a syndromal level, improving a broad array of fibromyalgia symptoms in prior Phase 2 and Phase 3 studies at the 2.8 mg dose,” said Seth Lederman, M.D., President and Chief Executive Officer. “If the final results from this study are positive, we believe that TNX-102 SL could provide a distinct mechanism from available pharmacotherapies that makes a significant difference in the lives of patients with fibromyalgia.”

Supported by the previous safety and efficacy findings of TNX-102 SL in fibromyalgia at 2.8

mg and posttraumatic stress disorder (PTSD) at 5.6 mg, Tonix believes that using the 5.6 mg dose of TNX-102 SL in the Phase 3 RELIEF fibromyalgia study has the potential to provide clinical evidence to support the efficacy and safety of TNX-102 SL for the management of fibromyalgia. The registration of TNX-102 SL 5.6 mg for the fibromyalgia indication is expected to be supported by the long-term safety exposure data on TNX-102 SL 5.6 mg from the PTSD program.

About the Phase 3 RELIEF Study

The RELIEF study is a double-blind, randomized, placebo-controlled adaptive design trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg in fibromyalgia. The trial is expected to enroll approximately 470 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there is a run-in period in which patients start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients have the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint is daily diary pain severity score change from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

Additional details about the RELIEF study are available atwww.theRELIEFstudy.com or clinicaltrials.gov (NCT04172831).

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. In 2020, Tonix announced a program to develop a potential vaccine, TNX-1800* (live modified horsepox virus vaccine for percutaneous administration) to protect against the novel coronavirus disease emerging in 2019, or COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform and is molecularly designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. TNX-801* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL**, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in September of 2020 and topline data in the first quarter of 2021. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya***) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second quarter of 2020. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine

esterase 200 mg, *i.v.* solution), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. 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. TNX-1200* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-1800, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

***Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

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; delays and uncertainties caused by the global COVID-19 pandemic; 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. 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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

Bradley Saenger (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9155

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

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

Source: Tonix Pharmaceuticals Holding Corp.