September 3, 2020

Tonix Pharmaceuticals Initiates Enrollment in Second Potentially Pivotal Phase 3 Study, the RALLY Study, of TNX-102 SL for the Management of Fibromyalgia

Interim Analysis Results from Ongoing Phase 3 RELIEF Study Expected in September; Topline Results Expected in Fourth Quarter 2020

Positive Outcomes in Both Trials Would Support Submission of NDA in Second Half 2022

NEW YORK, Sept. 03, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the first participant was enrolled in the Phase 3 RALLY study (TNX-CY-F306) of TNX-102 SL 5.6 mg for the management of fibromyalgia.

RALLY is the Company's second of two potentially pivotal Phase 3 studies of TNX-102 SL, a proprietary sublingual tablet formulation of cyclobenzaprine HCl taken daily at bedtime for the management of fibromyalgia.

"This is an important milestone for Tonix and potentially for the nation's roughly 8 million adult fibromyalgia sufferers," said Seth Lederman, M.D., President and Chief Executive Officer. "Our team is dedicated to advancing TNX-102 SL, which is being developed as a novel, non-opioid, non-addictive, centrally-acting analgesic."

"Not only has the number of fibromyalgia sufferers remained high, the stigma associated with a fibromyalgia diagnosis has decreased due to greater knowledge of the neurobiological underpinnings," Dr. Lederman continued. "And many people with fibromyalgia are still dissatisfied with available treatments. Tolerability can be a problem for some with the approved medications. Addiction can be a problem with off-label use of opiates. TNX-102 SL has the potential to provide relief from the pain, fatigue, sleep disturbance and dysfunction from fibromyalgia with good tolerability and without addictive potential."

Both of the current Phase 3 trials are studying TNX-102 SL at a dose of 5.6 mg which is twice the 2.8 mg dose used in the Company's prior Phase 2 and 3 studies in fibromyalgia. Tolerability of the higher dose was documented in an earlier Phase 3 trial of TNX-102 SL in posttraumatic stress disorder (PTSD). Both of the current Phase 3 fibromyalgia studies are being conducted using essentially the same protocol.

An interim analysis of the first of the current fibromyalgia trials, RELIEF, is expected by the end of September, with topline results expected by year end. If the RALLY study maintains current enrollment timelines and objectives, it is expected to report topline data in the

second half of next year. Positive outcomes in both studies may potentially put Tonix in a position to file a New Drug Application (NDA) with the FDA for marketing approval in the second half of 2022.

About the Phase 3 RALLY Study

The RALLY study is a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets). The two-arm trial is expected to enroll approximately 470 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there will be a run-in period in which patients will start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients will 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 (TNX-102 SL 5.6 mg vs. placebo) from baseline (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts an estimated 6-12 million adults in the U.S, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell immune response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix is also developing TNX-2300*, a second live replicating vaccine candidate for the prevention of COVID-19 which employs bovine parainfluenza virus as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an interim analysis in September 2020 and topline data in the fourth quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). Both the agitation in Alzheimer's disease and AUD programs are Phase 2 ready, and the agitation in Alzheimer's disease program has FDA Fast Track designation. 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 life-threatening cocaine

intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a once-daily treatment for depression, while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD; 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-1800, TNX-801, TNX-2300, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have 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; 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.

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Source: Tonix Pharmaceuticals Holding Corp.