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Tonix Pharmaceuticals Achieves 50 Percent Enrollment in RALLY, the Second Phase 3 Study of TNX-102 SL for Management of Fibromyalgia

Enrollment Continues in Phase 3 RALLY Study, with Interim Analysis of the First 50 Percent of Participants Expected Third Quarter 2021

Topline Results of Approximately 670 Participants in RALLY Expected Fourth Quarter 2021

Positive Topline Results from RELIEF, the First Phase 3 Study of TNX-102 SL for Management of Fibromyalgia, Previously Announced December 2020

CHATHAM, N.J., March 15, 2021 (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 RALLY study (TNX-CY-F306) for the management of fibromyalgia. RALLY is the Company's second of two potential pivotal Phase 3 studies of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg, a non-opioid, centrally acting analgesic, taken daily at bedtime. The RALLY study utilizes the same protocol design as the Company's first positive Phase 3 study, RELIEF, but with an additional 200 patients.

"We believe that achieving this milestone keeps us on plan for the anticipated release of interim results from RALLY in the third quarter and topline data in the fourth quarter of this year," said Tonix's President and Chief Executive Officer, Seth Lederman, M.D. "If the topline results are positive, we expect to be in a position to submit a New Drug Application (NDA) for TNX-102 SL for fibromyalgia to the U.S. Food and Drug Administration (FDA) in 2022."

In December 2020, the Company reported positive topline results from the RELIEF study, its first Phase 3 study for TNX-102 SL 5.6 mg in fibromyalgia. In the RELIEF study, the 5.6 mg dose achieved statistically significant pain reduction over placebo at Week 14 (primary endpoint, p=0.01). In addition, TNX-102 SL was generally well tolerated with an adverse event profile comparable to prior studies, and no new safety signals observed.

An interim analysis of the first 50 percent of randomized participants in the RALLY study will be conducted shortly after the 14-week treatment period has been completed by these participants. Pending approval of the interim statistical analysis plan by the FDA, results from the interim analysis are expected in the third quarter of 2021. 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.

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 670 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there is a run-in period in which participants start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all participants 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.

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 CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL[1], is in mid-Phase 3 development for the management of fibromyalgia, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY, in the third quarter of 2021[2] and topline data in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800[3], is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801[3], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

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

[2] Pending submission and agreement from FDA on statistical analysis plan.

[3] TNX-1800 and TNX-801 are investigational new biologics 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 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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