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Tonix Pharmaceuticals Announces Outcome of Interim Analysis of Phase 3 RALLY Study of TNX-102 SL for the Management of Fibromyalgia

RALLY Study Will Stop Enrolling New Participants Following Recommendation from an Interim Analysis Indicating Inadequate Separation from Placebo at Week-14 in the First 50% of Participants, Based on the Original Targeted Study Size

Company Plans to Unblind and Report Topline Results in the Fourth Quarter of 2021 Following Completion of Study for Currently Enrolled Participants

RALLY Study Follows Announcement in December 2020 of Positive Results from First Phase 3 Study, RELIEF, of TNX-102 SL 5.6 mg for the Management of Fibromyalgia

CHATHAM, N.J., July 23, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today that the Company has decided to stop enrollment in the Phase 3 RALLY study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the management of fibromyalgia following an unblinded, pre-planned interim analysis by the Independent Data Monitoring Committee (IDMC) of the RALLY study. Based on interim analysis results of the first 50% (n=337) enrolled participants, the IDMC recommended stopping the trial for futility as TNX-102 SL is unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in daily diary pain severity scores between those treated with TNX-102 SL 5.6 mg (2x 2.8 mg tablets) and those receiving placebo. Tonix remains blinded to the detailed interim analysis results and only received the recommendation made by the IDMC. Preliminary blinded safety data from these participants did not reveal any new safety signals, and the decision to discontinue enrolling new participants is not related to safety. The Company intends to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data, with the topline results expected to be reported in the fourth quarter of 2021, to determine the next steps in this program.

“We are surprised and disappointed that the interim analysis did not support continued enrollment in this Phase 3 RALLY study, especially considering the previous Phase 3 RELIEF study, which had a similar design and achieved statistical significance on the primary endpoint. After the currently enrolled participants complete the study, we will proceed with a full analysis of the unblinded data from the study to determine the next steps in this program,” commented Seth Lederman, M.D., President and Chief Executive Officer. “These results underscore the difficulty in managing and treating fibromyalgia. We thank the

patients, caregivers and investigators who participated in the RALLY study."

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 has enrolled 514 participants 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.

Additional details about the RALLY study are available at clinicaltrials.gov (NCT04508621).

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 6-12 million adults in the U.S., approximately 90% of whom are women. 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. Physicians and patients report common dissatisfaction with currently marketed products.

About TNX-102 SL

TNX-102 SL is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride which provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. As a multifunctional agent with potent binding and antagonist activities at the serotonin-2A, alpha-1 adrenergic, histamine-H1, and muscarinic-M1 receptors, TNX-102 SL is in clinical development as a daily bedtime treatment for fibromyalgia, PTSD, alcohol use disorder and agitation in Alzheimer's disease. The U.S. Patent and Trademark Office (USPTO) has issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in these patents are important elements of Tonix's proprietary TNX-102 SL composition. These patents are expected to provide TNX-102 SL, upon NDA approval, with U.S. market exclusivity until 2034/2035.

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 Company's 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. Tonix's immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800[2], 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 reported positive efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801[2], 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]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 clinical trials, 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, 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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