June 7, 2023

Tonix Pharmaceuticals Announces Data Presentations Involving TNX-1500 (anti-CD40L mAb) for the Prevention of Rejection in Kidney and Heart Allograft Transplantation in Animal Models at the 2023 American Transplant Congress

Research Directed by Faculty of the Center for Transplantation Sciences, Massachusetts General Hospital

TNX-1500 is Expected to Enter Phase 1 Clinical Development in Third Quarter 2023

CHATHAM, N.J, June 07, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced data from two oral presentations and one poster presentation at the 2023 American Transplant Congress (ATC) by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital. The data involve studies of Tonix's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) in development for the prevention of organ transplant rejection. The molecular target of TNX-1500 is CD40-ligand (CD40L), which is also known as CD154. Copies of the presentations are available on the Tonix Pharmaceuticals website at www.tonixpharma.com.

The oral presentations titled, "*Fc-Modified anti-CD154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications*" by Dr. Ryo Otsuka *et al.* and "*Efficacy of CD154 Blockade with TNX-1500 to prevent heart allograft immune injury*" by Dr. Ikechukwu Ileka *et al.*, and the poster presentation titled "*anti-CD154 mAb (TNX-1500) Alone, or in Combination with Rapamycin, MMF, or anti-CD28 mAb (VEL-101) Prolongs Cynomolgus Cardiac Allograft Survival*" by Dr. Kohei Kinoshita *et al.* include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently prevented pathologic alloimmunity in non-human primate kidney and cardiac allograft models without clinical thrombosis. Dr. Kinoshita was recognized with "Poster of Distinction" for his poster presentation.

"The animal studies found that TNX-1500 retains activity to prevent rejection and preserve graft function, which we believe provides strong rationale for us to pursue development of TNX-1500 to prevent rejection in human transplant," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We expect to begin a Phase 1 trial with TNX-1500 in the third quarter of 2023. There remains a significant need for new treatments with

improved activity and tolerability to prevent organ transplant rejection. TNX-1500 is a third generation anti-CD40L mAb that has been designed by protein engineering to decrease FcγRII binding and to reduce the potential for thrombosis. We believe TNX-1500 has the potential for treating and preventing organ transplant rejection. Beyond transplantation, we believe TNX-1500 has potential for treating autoimmune conditions including systemic lupus erythematosus, Sjögren's syndrome and multiple sclerosis."

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix'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 (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth quarter of 2023. TNX-4300 (estianeptine) is a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer's disease and Parkinson's disease. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the third quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the first quarter of 2024. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

**All of Tonix's product candidates are investigational new drugs or 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 the 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, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2023, 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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