February 1, 2023

Tonix Pharmaceuticals Announces Research Agreement with University of Maryland, Baltimore, to Study TNX-1500 (Fc-modified anti-CD40L mAb) for the Prevention of Rejection in Heart Xenograft Transplantation in Animals

Research Study to Assess the Role of TNX-1500 in the Prevention of Heart Xenograft Rejection

Preclinical Xenotransplantation Studies are Expected to Support Regulatory Filings for TNX-1500

CHATHAM, N.J., Feb. 01, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has entered into a sponsored research agreement with the University of Maryland, Baltimore (UMB), for the prevention of rejection in heart xenograft transplantation in animals utilizing TNX-1500[1], an Fc-modified humanized monoclonal antibody directed against CD40-ligand. UMB's preclinical studies will utilize genetically-modified porcine hearts supplied by Revivicor, Inc., a subsidiary of United Therapeutics Corporation. The principal investigator is Muhammad M. Mohiuddin, M.D., MBBS, Professor of Surgery, and Director, Cardiac Xenotransplantation Program, University of Maryland School of Medicine.

"We are excited to collaborate with the University of Maryland and Dr. Mohiuddin on the development of TNX-1500 for the prevention of rejection in xenograft transplantation," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-1500 is a third generation anti-CD40L monoclonal antibody that has been designed by protein engineering to decrease FcγRII binding and to reduce the potential for thrombosis. Previous preclinical studies in non-human primates demonstrated that TNX-1500 showed activity in preventing allograft and xenograft organ rejection and was well tolerated. A positive result from this study would potentially help support an Investigational New Drug (IND) application and human clinical studies."

"Despite exciting advancements in the field of xenotransplantation, better therapeutics are needed to prevent xenograft organ rejection," said Dr. Mohiuddin. "Several lines of research indicate that anti-CD40L is required for long term xenograft acceptance. We are excited to collaborate in support of developing an effective immunosuppression regimen for patients

requiring xenograft transplantation."

The primary objective of the preclinical research study is to study the activity of TNX-1500 in preventing cardiac xenograft rejection in animals to support an IND application for human studies.

About TNX-1500

TNX-1500 (Fc-modified anti-CD40L mAb) is a humanized monoclonal antibody that interacts with the CD40-ligand (CD40L), which is also known as CD154. TNX-1500 is being developed for the prevention of allograft and xenograft rejection, for the treatment of autoimmune diseases and for the prevention of graft-versus-host disease (GvHD) after hematopoietic stem cell transplantation (HCT). A Phase 1 study of TNX-1500 is expected to be initiated in the second quarter of 2023. 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. In June 2022, Tonix announced data from three oral presentations at the 2022 American Transplant Congress of animal studies found that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. In those studies, blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate models of cardiac and kidney allograft transplantation without clinical thrombosis. Copies of the presentations are available under Scientific Presentations on the Tonix Pharmaceuticals corporate website at www.tonixpharma.com.

[1]TNX-1500 is a biologic at the pre-IND stage of development and has not been approved for any indication

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 a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022. 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 second quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the first quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first 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 and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second quarter of 2023. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801, a next-generation vaccine to prevent COVID-19, TNX-1850, a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600, and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800, recently licensed from Curia. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the second half of 2023.

[*]*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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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.