September 15, 2022

Tonix Pharmaceuticals Announces Data Presentations Involving TNX-1500 (Fc-Modified Anti-CD40L mAb) for the Prevention of Rejection in Allograft and Xenograft Transplantation in Animal Models at the International Congress of The Transplantation Society (TTS 2022)

TNX-1500 Treatment Prevents Organ Rejection and Preserves Function for Both Allograft and Xenograft Transplants in Animal Studies

CHATHAM, N.J., Sept. 15, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced data from three oral presentations by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital Center at the 29th International Congress of The Transplantation Society (TTS 2022) held September 10-14, 2022 in Buenos Aires, Argentina. The data involve studies of Tonix's TNX-1500 (Fc modified anti-CD40L monoclonal antibody) product candidate 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 under the Scientific Presentations tab of the Tonix website atwww.tonixpharma.com.

The presentations titled, *"Long-term rejection-free renal allograft survival with Fc-modified anti-CD154 antibody monotherapy in nonhuman primates,"* and "*Monotherapy with TNX-1500, a Fc-modified anti-CD154mAb, prolongs cardiac allograft survival in cynomolgus monkeys*," include data demonstrating that TNX-1500 treatment showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate cardiac and kidney allograft models without clinical thrombosis.

The presentation titled, "*Long-term (>1 year) rejection-free survival of kidney xenografts with triple xenoantigen knockout and multiple human transgenes in nonhuman primates*," includes data demonstrating that TNX-1500 treatment showed activity in preventing xenograft kidney rejection and was well tolerated in non-human primates. Xenografts are transplanted organs from donors of a different species from the recipient, and in this study, the xenografts originated from genetically engineered pigs. Blockade of CD40L with TNX-

1500 monotherapy consistently and safely prevented pathologic xenoimmunity in non-human primate kidney xenograft models without clinical thrombosis.

“There remains a significant need for new treatments with improved activity and tolerability to prevent organ transplant rejection,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “To date, there has not been a humanized anti-CD40L antibody that can effectively prevent transplant rejections with an acceptable level of tolerability. 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. The animal studies found that TNX-1500 retains activity to prevent rejection and preserve graft function. We believe TNX-1500 has the potential for treating and preventing organ transplant rejection in both allograft and xenograft transplants. Tonix expects to initiate a Phase 1 trial of TNX-1500 in the first half of 2023. Preventing transplant rejection is the first indication we are pursuing, but based on results of anti-CD40L in numerous animal models, we believe that TNX-1500 has the potential for treating a number of autoimmune conditions.”

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 and expects interim data in the first half of 2023. 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 first 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 fourth quarter of 2022. 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 infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. 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 first half of 2023. Tonix’s lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix’s recombinant pox live virus vector vaccine platform. A Phase 1 study of the COVID-19 vaccine is expected to be initiated 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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