

June 9, 2022



Tonix Pharmaceuticals Announces Data Presentations Involving TNX-1500 (Fc-modified anti-CD40L mAb) for the Prevention of Rejection in Kidney and Heart Allograft Transplantation in Animal Models at the 2022 American Transplant Congress

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

CHATHAM, N.J., June 09, 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 at the 2022 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) 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 [Scientific Presentations](#) on the Tonix Pharmaceuticals corporate website at www.tonixpharma.com.

The presentations titled, "[Long-Term Rejection Free Renal Allograft Survival with Fc-Modified Anti-CD154 Antibody Monotherapy in Nonhuman Primates](#)," "[TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival](#)," and "[Novel Targetable Pathways in Costimulation Pathway Blockade](#)" 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 and safely prevented pathologic alloimmunity in a non-human primate cardiac allograft model 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 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.”

About Tonix Pharmaceuticals Holding Corp.¹

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 first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the second quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the second quarter of 2022. TNX-1300 has been granted Breakthrough Therapy Designation by the FDA. Finally, 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 second half 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 immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500 which is a humanized monoclonal antibody targeting CD40-ligand 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 half of 2022. Tonix’s infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. Tonix’s lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850, which are live virus vaccines based on Tonix’s recombinant pox live virus vector vaccine platform.

¹All 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.

Contacts

Jessica Morris (corporate)

Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 799-8599

Olipriya Das, Ph.D. (media)

Russo Partners
Olipriya.Das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)

ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505



Source: Tonix Pharmaceuticals Holding Corp.