

May 31, 2022



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

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

NEW YORK, May 31, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced two upcoming oral presentations by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital at the 2022 American Transplant Congress (ATC), being held June 4-8, 2022, in Boston, Mass. The research groups are led by Professor Tatsuo Kawai and Professor Richard Pierson. The research involves studies of Tonix's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) in development for the prevention of rejection of organ transplants. The molecular target of TNX-1500 is CD40-ligand (CD40L), which is also known as CD154. Copies of the presentations will be made available on the Tonix Pharmaceuticals corporate website following the presentations at www.tonixpharma.com.

Oral Presentation Details

Title: Long-Term Rejection Free Renal Allograft Survival with Fc-Modified Anti-CD154 Antibody Monotherapy in Nonhuman Primates

Authors: *G. Lassiter, T. Hirose, A. D'Attilio, T. Kawai*

Date: Sunday, June 5, 2022

Time: 6:20 p.m. ET

Location: Hynes Ballroom A, John B. Hynes Convention Center, Boston, Mass.

URL: [Long-Term Rejection Free Renal Allograft Survival with Fc-Modified Anti-cd154 Antibody Monotherapy in Nonhuman Primates - ATC Abstracts \(atcmeetingabstracts.com\)](http://atcmeetingabstracts.com)

Title: TNX-1500, an Fc-Modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival

Authors: S. Miura, Z. Abady, F. Pollok, M. Ma, K. Kinoshita, S. Fogarty, P. Maguire, B. Daugherty, S. Lederman, R. Pierson III

Date: Tuesday, June 7, 2022

Time: 5:50 p.m. ET

Location: Hynes Room 304 / 306, John B. Hynes Convention Center, Boston, Mass.

URL: [TNX-1500, an Fc-Modified Anti-cd154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival - ATC Abstracts \(atcmeetingabstracts.com\)](https://atcmeetingabstracts.com/abstract/TNX-1500_an_Fc-Modified_Anti-cd154_Antibody_Prolongs_Nonhuman_Primate_Cardiac_Allograft_Survival/)

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.

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