

May 31, 2023



Tonix Pharmaceuticals Announces Presentations Involving TNX-1500 (anti-CD40L mAb) at the 2023 American Transplant Congress

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

CHATHAM, N.J., May 31, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an upcoming oral presentation by Ryo Otsuka, Ph.D., and poster presentation by Kohei Kinoshita, M.D at the 2023 American Transplant Congress (ATC). Both presenters are faculty members at the Center for Transplantation Sciences, Massachusetts General Hospital, and collaborators of Tonix. The Congress is being held June 3-7, 2023, in San Diego, Calif. The research involves studies of Tonix's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) for the prevention of renal and cardiac allograft rejection. A copy of the presentation and poster will be made available on the [Scientific Presentations](#) page of the Tonix website at www.tonixpharma.com following the congress.

Oral Presentation Details

Title: Fc-Modified Anti-Cd154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications
Authors: R. Otsuka, G. Lassiter, T. Hirose, A. Karadagi, T. Tomosugi, I. Rosales, T. Kawai
Date: Tuesday, June 6, 2023
Time: 6:00 p.m. PT
Location: Ballroom 6E Upper Level, San Diego Convention Center, San Diego, Calif.
Number: Presentation 544

Poster Presentation Details

Title: aCD154mAb (TNX-1500) Alone, or in Combination with Rapamycin, MMF, or aCD28mAb (VEL-101) Prolongs Cynomolgus Cardiac Allograft Survival
Authors: K. Kinoshita, A. Maenaka, Z. Habibabady, G. McGrath, R. Chaban, I. Ilek, M. Ma, V. Diaz, I. Rosales, S. Fogarty, P. Maguire, B. Daugherty, S. Lederman, R. Pierson III
Date: Saturday, June 3, 2023
Time: 5:30 – 7:30 p.m. PT
Location: Exhibit Halls A & B1, San Diego Convention Center, San Diego, Calif.
Number: Poster Board A030

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 second half of 2023. 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Maddie Stabinski (media)
Russo Partners
madeline.stabinski@russopartnersllc.com
(212) 845-4273

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



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