

Tonix Pharmaceuticals Announces Oral Presentations Involving TNX-1500 (Fc-Modified Anti-CD40L mAb) at the International Congress of The Transplantation Society (TTS 2022)

CHATHAM, N.J., Sept. 06, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced three oral presentations by academic collaborators at the 29th International Congress of The Transplantation Society (TTS 2022) being held September 10-14, 2022 in Buenos Aires, Argentina, and virtually. Copies of the presentations will be available under the <u>Scientific Presentations</u> tab of the Tonix website at <u>www.tonixpharma.com</u> following the conference.

Oral Presentation Details

Title: Long-term rejection free renal allograft survival with Fc-modified anti-CD154

antibody monotherapy in nonhuman primates

Date: Monday, September 12, 2022 Time: 4:35 p.m. EDT (17:35 ART)

Session: Campfire Session: Models, mechanisms & therapies Presenter Grace Lassiter, M.D., Research Fellow of the Kawai Lab

Monotherapy with TNX-1500, a Fc-modified anti-CD154mAb, prolongs cardiac

Title: allograft survival in cynomolgus monkeys

Date: Tuesday, September 13, 2022 Time: 3:25 p.m. EDT (16:25 ART)

Session: Mini-Oral Abstracts Session: Snap-shots of thoracic transplantation

Presenter Kohei Kinoshita, M.D., Research Fellow of the Pierson Lab

Title: Long-term (>1 year) rejection/TMA free survival of kidney xenografts with triple

xenoantigen knockout and multiple human transgenes in nonhuman primates

Date: Wednesday, September 14, 2022

Time: 10:00 a.m EDT (11:00 ART)

Session: Mini-Oral Abstracts Session: Xenotransplantation

Presenter Grace Lassiter, M.D., Research Fellow of the Kawai Lab

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 guarter of 2022 and interim data expected in the second guarter 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 guarter 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 guarter 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 (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 first half of 2023. 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.

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

^{*}All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.

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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