October 30, 2023

Tonix Pharmaceuticals Announces New Data Involving TNX-1500 (Fc-modified dimeric anti-CD40L mAb) in Heart Xenotransplantation in Animal Models at the ACS Clinical Congress and IPITA-IXA-CTRMS Joint Congress

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

TNX-1500 is currently in Phase 1 Clinical Development

Tonix is Developing TNX-1500 for Prevention of Kidney Allograft Rejection as the First Indication; Multiple Other Indications, including Autoimmune Disorders, are Planned

CHATHAM, N.J., Oct. 30, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced data from two oral presentations which were delivered recently at the American College of Surgeons (ACS) Clinical Congress 2023, and The International Pancreas and Islet Transplant Association (IPITA), the International Xenotransplantation Association (IXA), and the Cell Transplant and Regenerative Medicine Society (CTRMS) Joint Congress by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital (MGH) in October 2023. The data involve Tonix's TNX-1500 (Fc-modified dimeric anti-CD40L monoclonal antibody [mAb]) which is currently in Phase 1 development for the prevention of organ transplant rejection. Copies of the presentations are available under the Scientific Presentations tab of the Tonix Pharmaceuticals website atwww.tonixpharma.com.

The oral presentations titled, "*Pilot Evaluation of a Clinical Xeno Heart Transplant Regimen in a Preclinical Model*" and "*Extended Survival of 9- and 10-Gene Edited Pig Heart Xenografts with Ischemia Minimization and CD154 Costimulation Blockade-Based Immunosuppression*" by Dr. Ikechukwu Ileka *et al*. include data demonstrating the use of TNX-1500 as maintenance therapy after xeno heart transplant in non-human primates. In both studies, genetically engineered (GE) pigs in baboon transplants were treated with cold-perfused ischemia minimization and a novel costimulation-based immunosuppressive regimen including TNX-1500. The multi-GE pigs were provided by eGenesis and Revivicor.

"The results of these preclinical studies are encouraging and demonstrate the potential of genetically engineered pig hearts in the context of a clinically applicable regimen," said Seth

Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Because anti-CD40L treatment is widely recognized as critical to the success of xeno organ transplant, no animals were transplanted without anti-CD40L treatment.”

“These and other data[1,2,3] confirm the rationale for us to pursue development of TNX-1500 to prevent rejection in human transplantation,” said Dr. Lederman. “We are currently enrolling in a Phase 1 trial in healthy volunteers to support the development of TNX-1500 for the prevention of allograft rejection. However, long term we hope to develop TNX-1500 for xenotransplantation in which the donor organ comes from genetically engineered pigs.”

[1]Lassiter G., et al. Am. J. Transplant. 2023.https://doi.org/10.1016/j.ajt.2023.03.022

[2]Miura S., et al. Am. J. Transplant. 2023.https://doi.org/10.1016/j.ajt.2023.03.025

[3]Anand R.P., et al. Nature. 2023. 622, 393–401.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix’s development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’s CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, having completed enrollment of a potentially confirmatory Phase 3 study in the third quarter of 2023, with topline data expected in late December 2023. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 proof-of-concept study has been completed, and topline results were reported in the third quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily oral formulation being developed as a treatment for major depressive disorder (MDD), that completed enrollment in a Phase 2 study in the third quarter of 2023, with topline results expected in early November of 2023. TNX-4300 (estianeptine) is a single isomer version of TNX-601, a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer’s disease and Parkinson’s disease. Relative to tianeptine, estianeptine lacks activity on the mu-opioid receptor while maintaining activity and the ability to activate PPAR-β/δ and neuroplasticity in tissue culture. TNX-1900 (intranasal potentiated oxytocin), is in development as a preventive treatment in chronic migraine, and the clinical phase of a Phase 2 proof-of-concept study is now completed with topline data expected in early December 2023. TNX-1900 is also being studied in binge eating disorder, pediatric obesity and social anxiety disorder by academic collaborators under investigator-initiated INDs. 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 fourth quarter of 2023. Tonix’s rare disease development

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 development 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 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases, including TNX-1800, in development as a vaccine to protect against COVID-19. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

*Tonix's product development 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.

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