April 5, 2022

Tonix Pharmaceuticals Announces Extension of Sponsored Research Agreement with Kansas State University to Develop Live-Virus Vaccine Against COVID-19

TNX-2300, a Live Virus Vaccine Based on a Bovine Parainfluenza Virus Vector, in Development to Protect Against COVID-19

Co-Expression of the CD40-Ligand Will be Tested to Direct Immune Response

CHATHAM, N.J., April 05, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced a new preclinical research agreement with Kansas State University (K-State) to extend the research being performed under its original agreement. Tonix and K-State are working together to develop a vaccine candidate for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform, bovine parainfluenza virus, and also to test the effect of co-expression of the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity.

“Vaccines based on live replicating viruses trigger the immune system by direct stimulation of T cells, with the potential to elicit strong, long-lasting and durable immunity,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “There are currently well over 300 potential COVID-19 vaccines in various stages of development[1], but relatively very few utilize live replicating viral platforms. TNX-2300* is a live replicating virus vaccine designed to elicit T cell immunity.”

Dr. Lederman continued, “Modern live virus vaccines in development for COVID-19 use a vector system to present SARS-CoV-2 protein antigens. K-State is studying bovine parainfluenza virus as the vector. A traditional live virus vaccine approach would use a weakened version of SARS-CoV-2, but SARS-CoV-2 contains genes that weaken the immune response by thwarting innate immunity. In the first completed phase of the research project, K-State showed that vaccinating hamsters with bovine parainfluenza virus expressing SARS-CoV-2 spike protein elicited antibody responses to the SARS-CoV-2 spike protein. Our goal in utilizing bovine parainfluenza virus as a live virus vaccine vector is to develop a COVID-19 vaccine that is well tolerated, produces durable immunity, prevents forward transmission and can be rapidly and broadly deployed.”

Under the extended research agreement, K-State will continue to advance preclinical development of a live replicating virus vaccine to protect against COVID-19 based on bovine

parainfluenza virus and also to test the effect of co-expression of the CD40-ligand.

Attenuated bovine parainfluenza virus has previously been shown to be an effective antigen delivery vector in humans[2-7]. Notably and most importantly, following extensive testing in non-human primates, the attenuated BPI3V was shown to be well tolerated, infectious, immunogenic, and stable in infants and children[3,6]. The vector is well suited for mucosal immunization using a nasal atomizer, but it can also be delivered parenterally. The technology also includes a molecular stimulant called CD40-ligand, which triggers strong immunity, including T cell responses. TNX-2300 is designed to potentially stimulate immunity against the SARS-CoV-2 spike protein. The research is being directed by Dr. Waithaka Mwangi, Kansas State University, Department of Diagnostic Medicine/Pathobiology, who is the inventor of the new technology. In addition, K-State has granted Tonix an option for an exclusive license for the clinical and commercial use of K-State's intellectual property associated with coronavirus vaccines under this relationship.

**TNX-2300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[1]World Health Organization, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines, COVID-19 - Landscape of novel coronavirus candidate vaccine development worldwide, March 2022.
[2]Liang, B., et al., J. Virol. 2016. 90:10022.
[3]Karron, R. A., et al., Vaccine. 2012. 30:3975.
[4]Haller, A. A., et al., J. Gen Virol. 2003. 84:2153.
[5]Schmidt, A. C., et al., J. Virol. 2001. 75:4594.
[6]Karron, R. A., et al., J. Infec.Diseases. 1995. 171:1107.
[7]Haller, A. A., et al., J. Virol.2000. 74:11626.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of immunology, rare disease, infectious disease, and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500[1] 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 rare disease portfolio includes TNX-2900[2] for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan-Drug Designation by the FDA. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox called TNX-801[3], next-generation vaccines to prevent COVID-19, an antiviral to treat COVID-19, and a potential treatment for Long COVID. Tonix's lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850[4], which are live virus vaccines based on Tonix's recombinant pox vaccine (RPV) platform. TNX-3500[5] (sangivamycin, *i.v.* solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. TNX-102 SL[6], (cyclobenzaprine HCl sublingual tablets), is a small

molecule drug being developed to treat Long COVID, a chronic post-COVID condition. Tonix expects to initiate a Phase 2 study in Long COVID in the first half of 2022. The Company'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, is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study expected to start in the first half of 2022. Finally, TNX-1300[7] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the first half of 2022.

[1]TNX-1500 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.
[2]TNX-2900 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.
[3]TNX-801 is a live horsepox virus vaccine for percutaneous administration in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.
[4]TNX-1840 and TNX-1850 are live horsepox virus vaccines for percutaneous administration, in development to protect against COVID-19. TNX-1840 and TNX-1850 are designed to express the SARS-CoV-2 spike protein from the omicron and BA.2 variants, respectively. TNX-1840 and TNX-1850 are investigational new biologics at the pre-IND stage of development and have not been approved for any indication.
[5]TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.
[6]TNX-102 SL is an investigational new drug and has not been approved for any indication.
[7]TNX-1300 is an investigational new biologic and has 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 development of TNX-2300; 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.