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Tonix Pharmaceuticals Enters into Research and Exclusive License Option Agreement with Kansas State University to Develop Vaccine Against COVID-19

Research to Develop Live Replicating Vaccine (TNX-2300) to Protect Against COVID-19 Based on Bovine Parainfluenza Virus

TNX-2300 Will Be Tonix's Second Live Replicating Virus Vaccine Platform

TNX-2300 Is Designed to Utilize the CD40-Ligand to Drive T cell Immunity

NEW YORK, July 13, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced a new preclinical research and option agreement with Kansas State University (K-State) to develop a vaccine candidate for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform and the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity.

Under the research agreement, K-State will advance preclinical development of a live replicating virus vaccine to protect against COVID-19 based on bovine parainfluenza virus. Attenuated bovine parainfluenza virus has previously been shown to be an effective antigen delivery vector in humans[1-6]. 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[2, 5]. 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. The vaccine is designed to potentially stimulate immunity against the SARS-CoV-2 spike protein. The research will be 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.

"This marks our second live viral vaccine vector platform for the prevention of COVID-19," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "Our lead vaccine in development, TNX-1800, is based on horsepox virus. The K-State program is based on bovine parainfluenza virus. Because vaccines based on live replicating viruses trigger the immune system by direct stimulation of T cells, they typically evoke strong, long-lasting and durable immunity. Live replicating virus vaccines for other infectious diseases, such as

smallpox, are known to inhibit forward transmission or contagion, which is the process that spreads infectious diseases. Inhibiting contagion is a critical need in controlling a pandemic, particularly the COVID-19 pandemic since spread of SARS CoV-2 by asymptomatic individuals is a key feature of how this diabolical virus coopts human social interactions to propagate. There are currently well over 100 potential COVID-19 vaccines in various stages of develpment[7], but relatively few utilize live replicating viral platforms, such as Merck's measles-based and VSV-based programs. Like Tonix's TNX-1800 based on horsepox, TNX-2300 is a live replicating virus vaccine designed to elicit T cell immunity. Both are currently in preclinical development."

Dr. Waithaka Mwangi said, "Our goal in utilizing a live replicating virus vaccine and CD40-ligand as a molecular adjuvant is to develop a COVID-19 vaccine that is well tolerated, produces durable immunity, prevents forward transmission and can be rapidly and broadly deployed."

"TNX-2300 is another step in the strategic broadening of Tonix's portfolio of live viral vaccines, which are designed for durable T cell immunity and prevention of forward transmission. We are excited to be exploiting bovine parainfluenza virus for this purpose. We are also excited that Dr. Mwangi is combining it with CD40-ligand to selectively stimulate immunity. CD40-ligand is a cell surface molecule that I discovered and characterized in 1991[8] when I was a tenure track assistant professor at Columbia University directing a laboratory that conducted research on viruses and immunity. It's gratifying to see that CD40-ligand may potentially play a role as we move forward in the fight against COVID-19," added Dr. Lederman.

"As the world's foremost global food and biosecurity science university, K-State is committed to understanding and combatting zoonotic diseases and the viruses that cause them like SARS-CoV-2," said Dr. Peter Dorhout, Vice President for Research at K-State. "To deploy our innovations at scale, our faculty need to combine forces with collaborative corporate partners like Tonix Pharmaceuticals as part of our land-grant mission to serve."

[1]Liang, B., et al., *J. Virol. 2016.* 90:10022.
[2]Karron, R. A., et al., *Vaccine. 2012.* 30:3975.
[3]Haller, A. A., et al., *J. Gen Virol. 2003.* 84:2153.
[4]Schmidt, A. C., et al., *J. Virol. 2001.* 75:4594.
[5]Karron, R. A., et al., *J. Infec. Diseases. 1995.* 171:1107.
[6]Haller, A. A., et al., *J. Virol. 2000.* 74:11626.
[7]World Health Organization, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines, DRAFT landscape of COVID-19 candidate vaccines –24 June 2020.
[8]Lederman S. et al., *J. Exp. Med. 1992* 175:1091. doi: 10.1084/jem.175.4.1091.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to

prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor) , a new molecular entity being developed as a treatment for PTSD, TNX-1500* (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700* (rTFF2), a biologic being developed to treat gastric and pancreatic cancers.

*TNX-1800, TNX-801, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs 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 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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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