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# Tonix Pharmaceuticals Announces Exclusive Option and Research Collaboration with Kansas State University to Develop LNP-Free mRNA Vaccines

*New Zinc Nanoparticle (ZNP) Technology Replaces the Lipid Nanoparticle (LNP) Technology Employed in Current mRNA COVID-19 Vaccines*

*ZNP Technology Expected to Improve mRNA Vaccine Temperature Stability for Storage and Transport*

*TNX-3700 is a ZNP mRNA COVID-19 Vaccine in Development in Collaboration with Kansas State*

CHATHAM, N.J., Jan. 04, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an exclusive option agreement and research collaboration with Kansas State University (K-State) to develop zinc nanoparticle (ZNP) mRNA vaccines that replace the lipid-nanoparticle (LNP) technology in current COVID-19 vaccines. The new ZNP technology has the potential to confer increased stability to mRNA vaccines over a wide range of temperature. The temperature-sensitive nature of LNP mRNA formulations restricts vaccine shipping and storage to ultralow temperatures which limits rapid global deployment. Under the research agreement, K-State will advance preclinical development of a new ZNP mRNA vaccine to protect against COVID-19 based on the spike protein from SARS-CoV-2.

“The Pfizer-BioNTech and Moderna vaccines against COVID-19 have shown that mRNA technology is rapidly deployable and is likely to be one of the first lines of defense for future pandemics,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “The ZNP technology invented and developed by scientists at K-State has the potential to make mRNA vaccines that are free from LNPs, which we believe has the potential to improve the stability of mRNA vaccines at room temperature and facilitate their deployment in places without ultra-cold chain supply systems. We have now learned that pandemics need to be controlled globally.”

Robert K. DeLong, Ph.D., associate professor in the Nanotechnology Innovation Center of Kansas State within the Department of Anatomy and Physiology and inventor of the core technology said, “The LNP technology of current mRNA COVID-19 vaccines limits our ability to deploy these vaccines in many parts of the world. The technology we have developed uses zinc to replace LNPs and has the potential to result in more temperature stable mRNA vaccines. Unlike LNPs, the ZNPs are believed to be stable over a range of temperatures including room temperature. Eliminating the need for LNPs in mRNA vaccines could speed

deployment of new vaccines and make them more available globally."

The COVID-19 vaccine research under the research agreement will be directed by Dr. DeLong together with his colleagues, Dr. Waithaka Mwangi, Kansas State University, Department of Diagnostic Medicine/Pathobiology, and Dr. Juergen Richt, Director of the Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD) and Director of the NIH COBRE Center on Emerging and Zoonotic Infectious Diseases (CEZID) at Kansas State University.

Dr. Mwangi said, "Our goal in utilizing a new mRNA formulation technology is to vaccinate people all over the world to save lives globally and reduce the emergence of variants of COVID-19 that can evade vaccine immunity."

The mRNA vaccines developed by Pfizer-BioNTech and Moderna are based on LNPs. Because of the limitations of LNP technology, these mRNA vaccines require ultra-cold storage and transport because they are unstable at room temperature or even in standard refrigerators or freezers. The new ZNP technology confers increased stability to mRNA vaccines over a wide range of temperature in model systems.

"TNX-3700 is another step in the strategic broadening of Tonix's portfolio of vaccine platforms and vaccines," added Dr. Lederman. "We expect mRNA vaccines to be one of the first line platforms to deploy against new pandemics as envisioned in the American Pandemic Preparedness Plan, or AP3[1,2]. The rapid ability to deploy mRNA vaccines will remain an advantage, even as second-generation vaccines, such as live virus vaccines, are developed with potentially longer duration of immune protection and the ability to protect against forward transmission."

*[1]Sept 3, 2021 https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf*
*[2]Sept 3, 2021 https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/*

**About Kansas State University**

Kansas State University, or K-State, is 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. Part of K-State's land-grant mission to serve, is to deploy their innovations at scale. For this reason, K-State faculty are encouraged to combine forces with collaborative corporate partners.

**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 primarily composed of immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. 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[1] (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300[2] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the first quarter of 2022. Tonix's lead vaccine candidate for COVID-19, TNX-1800[3], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study in the first quarter of 2022. 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. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to initiate a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

*[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.*

*[2]TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

*[3]TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is 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-2100 is an investigational new biologic and has 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.*

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-3700; 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, 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
(212) 688-9421

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

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