July 28, 2022

Tonix Pharmaceuticals Announces Collaboration with Kenya Medical Research Institute to Develop TNX-801 in Kenya as a Vaccine for the Prevention of Monkeypox and Smallpox Infection

Phase 1 Clinical Study Expected to be Initiated in Kenya in the First Half of 2023

World Health Organization Has Declared Monkeypox a Global Health Emergency

CHATHAM, N.J., July 28, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced a collaboration with the Kenya Medical Research Institute (KEMRI) to plan, seek regulatory approval for and conduct a Phase 1 clinical study in Kenya to develop TNX-801[1] as a vaccine to protect against monkeypox and smallpox. The study is expected to start in the first half of 2023.

“We are excited to collaborate with KEMRI on the clinical development of TNX-801 as a vaccine to protect against monkeypox and smallpox in Kenya,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Since ending routine vaccination for smallpox in the 1960’s, monkeypox has emerged as a growing problem among people in West and Central Africa. People who received the live virus vaccine for smallpox prior to eradication appear to maintain durable protective immunity against monkeypox. TNX-801 is a live virus vaccine that we believe is closer to the smallpox vaccines used in the U.S. and Europe before 1900 than the modern vaccinia smallpox vaccines. TNX-801 has reduced virulence in animals, and we believe it has the potential for widespread use to protect against monkeypox.”

“KEMRI is excited to plan this clinical trial with Tonix, and ultimately to lead the trial,” said Professor Samuel Kariuki, Director General and CEO of KEMRI. “Monkeypox has spread in Central and West Africa, and there’s a concern that we could begin seeing cases in the Eastern and Central Africa or from foreign travelers. Recently, monkeypox has been reported in over 30 countries outside of Africa that were not endemic for monkeypox virus. We are grateful that Tonix is committed to sponsoring clinical studies and making TNX-801 available for this important problem.”

Professor Matilu Mwau, PhD, of KEMRI said, “The recent global outbreak of monkeypox has exemplified the need to be prepared with a vaccine that is efficacious, that provides for durable immunity and that blocks forward transmission. Tonix’s live virus vaccine technology is designed to achieve these outcomes. The West African strain which has recently spread

outside of Africa has a low fatality rate, but the Central African strain is reportedly fatal in approximately 10% of infected individuals. We want Kenya to be prepared with a vaccine that provides protection and can be widely deployed without the need for sterile injections or ultra-cold shipping and storage."

About TNX-801

TNX-801 is a live virus vaccine based on synthesized horsepox[2,3]. Tonix is developing TNX-801 for percutaneous administration as a vaccine to protect against monkeypox and smallpox. TNX-801 was developed as part of research collaboration between Tonix and Professor David Evans, Ph.D. and Ryan Noyce, Ph.D., the Department of Cell Biology, University of Alberta. Tonix has previously reported positive data from a monkeypox challenge study in non-human primates[4]. Tonix's TNX-801 was synthesized[2] based on the sequence of the 1976 natural isolate Mongolian horsepox clone MNR-763. Molecular analysis of DNA sequences suggests that TNX-801 is closer than modern smallpox vaccines to the vaccine discovered and disseminated by Dr. Edward Jenner in 1798[6-8]. For example, recent studies[9,10] have shown approximately 99.7% colinear identity between TNX-801 and the circa 1860 U.S. smallpox vaccine VK05[11]. The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[12]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Dr. Edward Jenner invented vaccination in 1798 and the procedure was called "vaccination" because 'cow' is 'vacca' in Latin and the inoculum material was initially obtained from lesions on the udders of cows affected by a mild disease known as cowpox. However, Dr. Jenner suspected that cowpox originated from horses[8]. Subsequently, Dr. Jenner and others immunized against smallpox using material directly obtained from horses. The use of vaccines from horses was sometimes called 'equination' from the Latin 'equus' which means 'horse'[13]. Equination and vaccination were practiced side-by-side in Europe[13,14].

About Monkeypox

Monkeypox[15] is a contagious disease caused by infection with monkeypox virus, a virus closely related to variola virus, which causes smallpox. Monkeypox virus belongs to the Orthopoxvirus genus in the family Poxviridae. The Orthopoxvirus genus also includes variola virus (which causes smallpox), vaccinia virus (used in the smallpox vaccine), and cowpox virus. After routine smallpox vaccination was stopped in about 1970, monkeypox has become a growing problem in Africa. Recently more than 16,000 cases have been identified outside of Africa[17].

About the Kenya Medical Research Institute (KEMRI)

The Kenya Medical Research Institute is a State Corporation established in 1979 as a Research Institute under the Science and Technology (Repealed) Act, Cap 250 Laws of Kenya and operates as such under Legal Notice No. 35 of March 2021. KEMRI's vision is to be the leading centre of excellence in research for human health. The mission is to improve human health and quality of life through research, capacity building, innovation and service delivery. KEMRI has grown from its humble beginning over 40 years ago to become a regional leader in human health research. KEMRI is the Medical Research arm of the

Government of Kenya. It provides advice to the Ministry on various aspects of healthcare and delivery. National diseases surveillance and rapid response capacity for major disease outbreaks (including, Cholera, Chikungunya Virus, H1N1 Flu, Yellow Fever, Rift Valley Fever, Ebola, and Aflatoxicosis. In line with constitutional requirements, KEMRI has developed a comprehensive framework under which the Institute has devolved its research activities and services, through seven regional clusters that serves the forty seven counties under the strategic pillar of health research in the context of devolution.

About Tonix Pharmaceuticals Holding Corp.[1]

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 quarter of 2022 and interim data expected in the first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the third quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is mid-Phase 2 and has been granted Breakthrough Therapy Designation by the FDA. 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 second half 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. TNX-601 ER (tianeptine hemioxalate extended-release tablet) is being developed as an antidepressant in the U.S., with a Phase 2 study expected to be initiated in first quarter of 2023 pending IND clearance. 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 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 called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. 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.

[1]*All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

[2]*Noyce RS, et al. (2018) PLoS One. 13(1):e0188453.*

[3]*Tulman ER, et al. (2006) J Virol. 80(18):9244-58.PMID:16940536.*

[4]*Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference – January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)*

[5]*Tonix Press Release March 16, 202a https://ir.tonixpharma.com/news-events/press-*

releases/detail/1255/tonix-pharmaceuticals-reports-positive-covid-19-vaccine.
[6]Schrick L et al. N Engl J Med. (2017) 377:1491.
[7]Qin et al. J. Virol. 89:1809 (2015).
[8]Jenner E. "An Inquiry Into the Causes and Effects of the Variolae Vaccinae: A Disease Discovered in Some of the Western Counties of England, Particularly Gloucestershire, and Known by the Name of the Cow Pox." London: Sampson Low, 1798.
[9]Brinkmann A et al, Genome Biology (2020) 21:286https://doi.org/10.1186/s13059-020-02202-0
[10]Duggan A et al. Genome Biology (2020) 21:175https://doi.org/10.1186/s13059-020-02079-z.
[11]Tonix press release. Dec 4, 2020https://ir.tonixpharma.com/news-events/press-releases/detail/1236/vaccine-genome-researchers-report-99-7-colinear-identity.
[12]Trindale GS et al. Viruses (2016) (12). Pii: E328. PMID:27973399.
[13]Esparza E, et al Vaccine. (2017) 35(52):7222-7230.
[14]Esparza J et al. Vaccine. (2020); 38(30):4773-4779.
[15]www.cdc.gov/poxvirus/monkeypox/about.html
[16]Mandavilli, A. The New York Times. May 26, 2020. "Who is protected against monkeypox".

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, 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.