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Tonix Pharmaceuticals Announces Research Agreement with Kenya Medical Research Institute (KEMRI) to Design, Plan and Seek Regulatory Approval for a Phase I Clinical Study of TNX-801 for Mpox in Kenya

Proposed clinical study in Kenya intended to test the safety, tolerability, and immunogenicity of TNX-801, a vaccine being developed to prevent mpox (formerly called monkeypox)

The World Health Organization (WHO) declared mpox a public health emergency of international concern (PHEIC) ¹⁻⁴: cases of the new Clade Ib mpox detected in Sweden, Thailand, Singapore, India, Germany and England

In preclinical data, TNX-801, Tonix's attenuated live-virus vaccine candidate, demonstrated efficacy as a vaccination against mpox in animal models

CHATHAM, N.J., Nov. 04, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that it has entered into a sponsored research agreement with the Kenya Medical Research Institute (KEMRI) to design, plan and seek regulatory approval for a Phase I clinical study in Kenya to test the safety, tolerability, and immunogenicity of TNX-801 (horsepox, live virus) as a vaccine to prevent mpox and smallpox. Tonix will be the sponsor and KEMRI will lead the execution of the proposed clinical trial.

"We are excited to advance development of TNX-801 under this research agreement with KEMRI," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "There is an urgent need for the worldwide availability of a single dose mpox vaccine with durable protection. TNX-801 has demonstrated encouraging preclinical data and was recently shown to align with the World Health Organization's (WHO's) newly issued preferred target product profile (TPP) for mpox vaccines. Further, TNX-801 can be scaled up for manufacturing, distribution and storage without a costly supply chain. We believe TNX-801 has the potential to address and help interrupt the spread of mpox worldwide."

In September 2024, Tonix announced that the preferred target product profile (TPP), released at the WHO sponsored Mpox Research and Innovation Scientific Conference, aligns with the potential characteristics of TNX-801. Key elements of the WHO draft TPP include single-dose, durable protection, administration without special equipment, and

stability at ambient temperature. Other potential beneficial characteristics include the ability to limit forward transmission, use in case-contact vaccination strategies and suitability for use in immunocompromised individuals.

In August 2024, Tonix announced a collaboration with Bilthoven Biologics (Bbio) to develop GMP manufacturing processes for TNX-801. Bbio is part of the world's largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

About TNX-801*

TNX-801 is a live minimally-replicating attenuated horsepox vaccine that is believed to provide immune protection against mpox in animals with better tolerability than 20th century vaccinia viruses. Vaccinia vaccines from the 20th century are descendants of Edward Jenner's circa 1800 that have become more virulent in connection with losing regulatory elements in their genomes. Given the modern understanding that Jenner's circa 1800 vaccine would be called "horsepox" today, TNX-801 was designed to be similar to Jenner's vaccine. After a single dose vaccination, TNX-801 protected animals against lethal challenge with intratracheal Clade Ia monkeypox virus.⁵ In this experiment, TNX-801 vaccination prevented clinical disease and skin lesions and also decreased shedding in the mouth and lungs. The findings are consistent with mucosal immunity and suggest the ability to block forward transmission. In addition, TNX-801 has decreased virulence in immunocompromised animals relative to 20th Century vaccinia viruses.⁶ Based on animal studies, TNX-801 combines immune protection with improved tolerability compared to live-virus vaccinia vaccines. TNX-801 is administered with a single dose which has advantages over two-dose regimens. The focus on single-dose vaccines confirms early recommendations by the Bipartisan Commission on Biodefense,⁷ and the U.S. National Academies of Science.^{7,8} The National Academies of Science (NAS) report highlights the difficulty of a ring vaccination strategy with even a two-dose regimen.⁷ TNX-1800 is an engineered version of horsepox that expresses the spike protein of SARS-CoV-2.^{9,10} The U.S. National Institutes of Health (NIH) selected Tonix's COVID-19 vaccine, TNX-1800 for Project NextGen.

About Mpox*

On August 14, 2024, the WHO determined that the upsurge of mpox in a growing number of countries in Africa constitutes a PHEIC, the second such declaration in the past two years called in response to an mpox outbreak.¹ The current outbreak is caused by Clade Ib monkeypox virus while the 2022 outbreak was caused by Clade IIb monkeypox virus. The 2022 global mpox outbreak, which is ongoing, has affected over 90,000 persons in countries where mpox had previously not been endemic, including Europe and the US. The rapid spread of Clade IIb strain mpox in 2022 underscores the pandemic potential of mpox. Unlike Clade IIb mpox, the Clade Ib strain of mpox appears to be spreading in Africa, particularly those neighboring the Democratic Republic of the Congo, including Burundi, Rwanda, and Uganda, but now affecting 16 countries. According to the U.S. Centers for Disease Control and Prevention (CDC), and other experts, there is a significant risk that the Clade Ib monkeypox may appear in the U.S.^{2,3}

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix's

development portfolio is focused on central nervous system (CNS) disorders, and its priority is to progress TNX-102 SL, a product candidate for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation and its development is supported by a grant from the U.S. National Institute of Drug Abuse and Addiction. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix has a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to \$34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

* Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found at www.tonixpharma.com.

¹WHO Press Release August 14, 2024. "WHO Director-General declares mpox outbreak a public health emergency of international concern". URL: www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern (accessed 8-15-24)

²McQuiston JH, et al. *U.S. Preparedness and Response to Increasing Clade I Mpox Cases in the Democratic Republic of the Congo*. 2024, MMWR Morbidity and Mortality Weekly Report: United States. p. 435-440

³CDC. 2022-2023 Mpox: US Map and Case Count. <https://www.cdc.gov/poxvirus/mpox/response/2022/us-map.html>

⁴World Health Organization SAGE meeting highlights on updated mpox vaccine recommendations. 2024, March

⁵Noyce RS, et al. *Viruses*. 2023 Jan 26;15(2):356. Doi: 10.3390/v15020356. PMID: 36851570; PMCID: PMC9965234

- ⁶Trefry, SV et al.
bioRxiv 2023.10.25.564033; doi: <https://doi.org/10.1101/2023.10.25.564033>
- ⁷Bipartisan Commission on Biodefense. Box the Pox: Reducing the risk of Smallpox and Other Ortho poxviruses, Washington:2024
- ⁸U.S. National Academies of Science. Future State of Smallpox Medical Countermeasures. Washington:2024
- ⁹Awasthi M, et al. *Viruses*. 2023 Oct 21;15(10):2131. Doi: 10.3390/v15102131. PMID: 37896908; PMCID: PMC10612059.
- ¹⁰Awasthi M et al *Vaccines* (Basel). 2023 Nov 2;11(11):1682. Doi: 10.3390/vaccines11111682.PMID: 38006014

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 Toni’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; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the “SEC”) on April 1, 2024, and periodic reports filed with the SEC on or after the date thereof. All of Toni’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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