September 16, 2024

Tonix Pharmaceuticals Announces That its Single Dose Mpox Vaccine Candidate TNX-801 Aligns with WHO's Newly Issued Preferred Target Product Profile for Mpox Vaccines in Global Health Emergency

The World Health Organization (WHO) released its preferred target product profile (TPP) criteria for mpox vaccines at its Mpox Research and Innovation Scientific Conference held August 29-30

TNX-801, Tonix's attenuated live-virus vaccine candidate, has characteristics that align closely with WHO's TPP

On August 14, 2024, the WHO determined that the upsurge of mpox in a growing number of countries in Africa constitutes a public health emergency of international concern[1-4]: cases of the potentially lethal new Clade I mpox also detected in Sweden, Thailand and Singapore

CHATHAM, N.J., Sept. 16, 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, announced today that the World Health Organization's (WHO's) preferred target product profile (TPP), released at the WHO sponsored Mpox Research and Innovation Scientific Conference held August 29-30, 2024, aligns with the characteristics of TNX-801 (horsepox, live virus) vaccine, which is being developed for preventing mpox (formerly known as monkeypox). 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.

"The characteristics of TNX-801 align with the draft TPP released at the WHO sponsored Mpox Research and Innovation Scientific Conference," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "In animal studies TNX-801 has shown single dose protection against a lethal challenge of Clade I monkeypox virus administered by intratracheal route.[5] In addition, protected animals did not produce any infectious virus suggesting TNX-801 has the potential to block forward transmission as expected with live-virus vaccines. TNX-801 is designed for percutaneous administration using a bifurcated needle, like the products and delivery used in WHO's accelerated smallpox eradication project. Since TNX-801 is a live-virus vaccine, we expect the stability of lyophilized TNX-801 at ambient temperature to be similar to live vaccinia virus vaccines including ACAM2000. We believe TNX-801 can be

shipped and stored without the need for a costly and cumbersome ultra-cold supply chain, a particular advantage in lesser developed parts of the world. The stability of live virus vaccines eliminates the need for ultra-cold storage which complicates the widespread use of mRNA vaccines in Africa, where they are needed most right now. Finally, studies on immunocompromised animals[6] suggest that TNX-801 may be given to persons with immunocompromising conditions such as HIV, which is another property that will be essential for public health."

Dr. Lederman continued, "The recent WHO declaration of a Public Health Emergency of International Concern (PHEIC) underscores the urgent need for new vaccines to control this outbreak and save lives. We have been motivated to develop TNX-801 because single-dose vaccines simplify logistics of administration, achieve higher coverage by reducing vaccinee dropout between doses and allow for case-contact or "ring" strategies to vaccinate the contacts of confirmed mpox patients.[7,8] Ring vaccination is deemed essential for controlling mpox but requires single-dose vaccines that interrupt forward transmission."[7,8]

On August 26, 2024, Tonix announced a collaboration with Bilthoven Biologics (Bbio) to develop GMP manufacturing processes for its mpox vaccine. Bbio is part of the world's largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

The U.S. Food and Drug Administration (FDA) approved vaccines for mpox are a two-dose non-replicating vaccine called Jynneos® from Bavarian Nordic[9] and a one-dose live-virus vaccine from Emergent for people at high risk for mpox infection.[10] WHO recently authorized Jynneos for use in adults.[11] Recently data in animals have been reported for a two-dose mRNA vaccine from Moderna.[12]

About TNX-801*

TNX-801 is a live replicating attenuated vaccine based on horsepox that is believed to provide immune protection with better tolerability than 20th Century vaccinia viruses. As previously disclosed, TNX-801 protected animals against lethal challenge with intratracheal Clade I monkeypox virus.[5] After a single dose vaccination, TNX-801 prevented clinical disease and lesions and also decreased shedding in the mouth and lungs of non-human primates.[6] The Findings are consistent with mucosal immunity and suggest the ability to block forward transmission, similar to Dr. Edward Jenner's vaccinia vaccine, which eradicated smallpox and kept mpox out of the human population. TNX-801 combines immune protection with improved tolerability compared to other vaccines based on orthopoxviruses and 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] The U.S. National Institutes of Health (NIH) selected Tonix's COVID-19 vaccine, TNX-1800 for Project NextGen. TNX-1800 is an engineered version of horsepox that expresses the spike protein of SARS-CoV-2. [13,14]

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 I monkeypox virus, while the 2022 outbreak was Clade 2 monkeypox virus. The global mpox outbreak, which commenced in 2022 has affected over 90,000 persons in countries where mpox had previously not been endemic, including Europe and the US. The spread of Clade IIb strain mpox in 2022 underscores the pandemic potential of mpox. Unlike Clade IIb mpox, the Clade I strain of mpox appears to be spreading to countries neighboring the Democratic Republic of the Congo, including Burundi, Rwanda, Uganda and Kenya. Clade I mpox is typically associated with approximately twenty times the case fatality rates than Clade IIb mpox in Africa. According to the U.S. Centers for Disease Control and Prevention (CDC), and other experts, there is a significant risk that the deadlier Clade I strain may appear in the U.S.[2,3]

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in October of 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed 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. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years in an Other Transaction Agreement (OTA) 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. The company's Good Manufacturing Practice (GMP)-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801 and the GMP suites are ready to be reactivated in case of a national or international emergency. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a 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 and infectious disease. 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 and have not been approved for any indication.

This press release and further information about Tonix can be found at

www.tonixpharma.com.

[1]WHO Press Release August 14, 2024. “WHO Director-General declares mpox outbrfeak 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)

[2]McQuiston JH, et al. *U.S. Preparedness and Response to Increasing Clade I Mpox Cases in the Democratic Republic of the Congo*. 2024, MMWR Morbi Mortal Wkly Rep: United States. p. 435-440

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

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

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

[6]Trefry, SV et al. bioRxiv 2023.10.25.564033; doi: https://doi.org/10.1101/2023.10.25.564033

[7]Bipartisan Commission on Biodefense. Box the Pox: Reducing the risk of Smallpox and Other Ortho poxviruses, Washington:2024

[8]U.S. National Academies of Science. Future State of Smallpox Medical Countermeasures. Washington:2024

[9]Zaeck LM, et al. Low levels of monkeypox virus-neutralizing antibodies after MVA-BN vaccination in healthy individuals. Nat Med. 2023 Jan;29(1):270-278. doi: 10.1038/s41591-022-02090-w. Epub 2022 Oct 18. PMID: 36257333; PMCID: PMC9873555.

[10]August 30, 2024. Reuters. “US FDA approves Emergent's smallpox vaccine for people at high risk of mpox”. https://www.msn.com/en-us/health/other/us-fda-approves-emergent-s-smallpox-vaccine-for-people-at-high-risk-of-mpox/

[11]Keaton, J. Sept. 13, 2024. *Associated Press.* “WHO grants first mpox vaccine approval to ramp up response to disease in Africa.” URL: https://bit.ly/4e4yyeb

[12]Mucker et al., (in press) Comparison of protection against mpox following mRNA or modified vaccinia Ankara vaccination in nonhuman primates, Cell (2024), https://doi.org/10.1016/j.cell.2024.08.043

[13]Awasthi M, et al. *Viruses*. 2023 Oct 21;15(10):2131. Doi: 10.3390/v15102131. PMID: 37896908; PMCID: PMC10612059.

[14]Awasthi 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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