November 1, 2024

Tonix Pharmaceuticals Presented Data on Potential Mpox Vaccine TNX-801 at World Vaccine Congress-Europe 2024

New data show tolerability and no evidence of spreading to blood or tissues even at high doses of Tonix's attenuated live-virus, minimally replicating vaccine candidate TNX-801 in immunocompromised animals

TNX-801, has characteristics that align closely with the World Health Organization's (WHO) preferred target product profile (TPP) criteria for mpox vaccines

WHO-declared public health emergency of international concern (PHEIC)[1-4]: Mpox cases of the new clade Ib mpox detected in Sweden, Thailand, Singapore, India, Germany and England

TNX-801 vaccination demonstrated efficacy in protecting animals from lethal challenge with clade I monkeypox and is in development as an mpox vaccine

CHATHAM, N.J., Nov. 01, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company with marketed products and a pipeline of development candidates, presented data in an oral presentation at the World Vaccine Congress-Europe 2024, held October 28-31, 2024 in Barcelona, Spain. A copy of the Company's presentation is available under the Scientific Presentations tab of the Tonix website atwww.tonixpharma.com following the conference.

The presentation titled, "*A Novel, Single-dose, Live, Attenuated, Minimally Replicating Mpox Vaccine*", highlighted positive preclinical efficacy data, demonstrating tolerability in immunocompromised animals and showed that TNX-801 is unable to spread in blood or tissues in these animals, even at an approximately 100-fold higher dose than 20th century vaccinia vaccines.

TNX-801 is an attenuated live-virus vaccine based on synthesized horsepox that has been shown to provide single-dose immune protection against a monkeypox challenge with better tolerability than 20th century vaccinia live-virus vaccines in animals. TNX-801 has previously been shown to protect animals against lethal challenge with intratracheal clade I monkeypox virus.[1] After a single dose vaccination, TNX-801 prevented clinical disease and lesions and also decreased shedding in the mouth and lungs of animals challenged with clade I monkeypox.[1] These findings are consistent with TNX-801 inducing mucosal immunity and suggest TNX-801 has the ability to block forward transmission. An outbreak of clade I mpox has recently been declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO).[2,3] Starting from an outbreak in the Democratic

Republic of the Congo, clade I mpox has spread to sixteen Central African Countries and cases have been reported in Sweden, Thailand, Singapore, India, Germany and England. According to the U.S. Centers for Disease Control and Prevention (CDC), and other experts, there is a significant risk that clade I strain may appear in the U.S.[4]

“Data continue to support TNX-801’s strong tolerability and efficacy profiles by continually displaying protective immunity to animals with single-dose administration,” said Seth Lederman, M.D., Chief Executive Officer of Tonix. “Synthetic biology is an important technology for vaccine development as viral diseases continue to rapidly evolve. The new data demonstrate that TNX-801 is highly attenuated relative to 20th century vaccinia vaccines in immunocompromised animals.[5] With TNX-801’s target profile, favorable shipping and storing requirements and our manufacturing collaboration agreements, we believe TNX-801 is in a strong position to make an impact towards preventing mpox and control mpox epidemics.”

In September 2024, Tonix announced that the World Health Organization’s (WHO’s) preferred target product profile (TPP), released at the WHO sponsored Mpox Research and Innovation Scientific Conference, aligns with the 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 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.

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.[1] 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.[1] 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. On August 26, 2024, Tonix announced a collaboration to develop GMP manufacturing processes for its mpox vaccine with Bilthoven Biologics (Bbio), part of the world’s largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

On the horsepox platform, Tonix is developing TNX-1800 (horsepox expressing SARS-CoV-2 spike protein) for protecting against COVID-19. TNX-1800 is an engineered version of horsepox that expresses the spike protein of SARS-CoV-2. In preclinical studies of TNX-1800 highlighted in the presentation, TNX-1800 was tested for immunogenicity and efficacy of TNX-1800 in nonhuman primates following a SARS CoV-2 challenge. [6,7] TNX-1800 vaccination results in a neutralizing antibody response that was associated with significant reduction in virus replication/shedding in the respiratory tract and tolerability. [2,3] TNX-1800

was selected by the NIH's, Project NextGen for inclusion in clinical trials as part of a select group of next generation COVID-19 vaccine candidates with the intent to identify promising vaccine platforms. NIH plans to conduct a Phase 1 trial of TNX-1800 and cover the full cost of the study, while Tonix provides the vaccine candidate.

About Mpox*

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, the second such declaration in the past two years called in response to an mpox outbreak. The current outbreak was caused by clade I monkeypox virus, while the 2022 outbreak was clade II 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. 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.[4]

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 Institude 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 recently announced 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 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.

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

[2]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)

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

[4]CDC. 2022-2023 Mpox: US Map and Case Count.

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

[6]Awasthi M et al *Vaccines* (Basel). 2023 11(11):1682. doi: 10.3390/vaccines11111682.PMID: 38006014

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

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; 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 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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