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Tonix Pharmaceuticals Announces Publication in the Peer-Reviewed Journal of Virology Assessing Virulence of the 2022 Outbreak Strain of Mpox in New Animal Models

Data show clade IIb from 2022 outbreak is 100 to 100,000-fold less virulent thanclade IIa from 2003 outbreak

Three new models for investigating mpox infection and pathogenesis identified

Tonix is advancing TNX-801, a live, attenuated, minimally replicative investigational vaccine candidate based on horsepox virus to protect against mpox disease

BERKELEY HEIGHTS, N.J., July 15, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (“Tonix” or the “Company”), a fully integrated, commercial-stage biotechnology company, today announced the publication of a paper, "Monkeypox virus clade IIb isolate exhibits reduced virulence relative to clade IIa isolates in multiple murine models," in the *Journal of Virology*, the peer-reviewed publication of the American Society for Microbiology (ASM). The research, conducted at Tonix, found new animal models for investigating mpox pathogenesis and demonstrated significant differences in virulence between the clade IIb circulating in the U.S. and the historic 2003 clade IIa. The manuscript can be accessed at: https://doi.org/10.1128/jvi.00247-26.

“Global mpox outbreaks that have caused severe human disease continue to occur due to previously unrecognized subclades,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “New approaches to understand and mitigate the spread of emerging mpox subclades are urgently needed. To examine the pathogenesis of emerging mpox clades, we identified three new murine models susceptible to mpox clade II infection, which revealed significant differences in virulence between clades. As Tonix investigates TNX-801 (live attenuated horsepox vaccine) for the prevention of mpox and smallpox, establishing additional foundational models are important to categorize and ultimately protect against the disease."

“The decreased virulence of clade IIb may have contributed to its ability to spread worldwide,” said Sina Bavari, Ph.D., Executive Vice President of Tonix and site head of Tonix’s Research and Development Center (RDC) in Frederick, Maryland. “Indolent subclinical infection is a risk factor for unintentional spread. Importantly, a deeper understanding of mpox virus (MPXV) pathogenesis will help guide the continued

development and positioning of the TNX-801 vaccine platform, a vaccine candidate against mpox. Tonix is committed to advancing the understanding of emerging mpox disease and to developing TNX-801 platform as a potential vaccine candidate to address the continuing global threat posed by mpox."

Led by Farooq Nasar, Ph.D., Director, Virology, Tonix utilized its state-of-the-art research laboratory capabilities, including a Biosafety Level 3 (BSL-3) lab and an Animal Biosafety Level 3 (ABSL-3) facility, at RDC which is close to the center of the U.S. biodefense research community.

Mpox is an emerging human disease caused by four distinct MPXV subclades (Ia, Ib, IIa, and IIb). Despite their genetic similarities, the case fatality rates differ considerably among the subclades: Ia (~11%), Ib and IIa (~4%), and IIb (~0.2%). Since 2022, multiple mpox outbreaks caused by the previously unrecognized Ib and IIb subclades have led the World Health Organization to declare two Public Health Emergencies of International Concern. Cases are currently increasing in multiple regions of the Americas. This unprecedented global spread and the marked differences in disease severity among MPXV subclades underscore the importance of investigating the pathogenesis of emerging MPXV variants. However, a critical limitation has been the lack of suitable small animal models.

This publication expands on the previously established CAST/EiJ mouse model by evaluating susceptibility to MPXV subclade IIa and IIb infection in both 7- to 8-week-old and 4- to 5-month-old mice. The demonstrated susceptibility of older CAST/EiJ mice to clade IIa infection highlights the utility of this model for evaluating long-term vaccine durability and protective efficacy. In addition, the study describes three novel C57BL/6 mouse models deficient in the interferon-α receptor, interferon-γ receptor, or both receptors for the study of MPXV infection. The study demonstrates that the emerging clade IIb isolate is up to 100,000-fold less virulent than clade IIa isolates. Collectively, these models provide valuable new tools for rapidly investigating the pathogenesis of emerging MPXV subclades and evaluating medical countermeasures, including vaccines.

About Mpox

Mpox is an acute contagious disease caused by the monkeypox virus or MPXV, which is also a member of the orthopoxvirus family. Mpox is emerging as an important zoonotic infection in humans in Central and West Africa. Until 2022, only a few cases of mpox were reported outside of Africa in patients who had been infected while in Africa. Starting in May of 2022, mpox clade II cases spread rapidly in the U.S. and other countries. The World Health Organization (WHO) declared mpox clade IIb to be a public health emergency of international concern (PHEIC). The clade II mpox affects mostly men who have sex with men in the U.S., where it has become endemic. The WHO lifted PHEIC designation for clade Ib. In August 2024, the WHO declared mpox clade Ib to be a PHEIC due to an outbreak in the Democratic Republic of the Congo that spread globally, including to the U.S. clade Ib affects children and adults. Although the WHO has lifted PHEIC designation for clade Ib, mpox continues to spread in Africa, and mutations of the virus are considered by public health experts to be an ongoing threat to be monitored for new epidemic spread.

About TNX-801

TNX-801 (recombinant horsepox virus) is an attenuated, minimally replicative, live virus

vaccine based on horsepox in pre-clinical development to prevent mpox and smallpox. TNX-801 is expected to enter a Phase 1 study in 2027 pending FDA clearance of an Investigational New Drug Application (IND). TNX-801 is in the pre-IND stages of development.

Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully integrated, commercial-stage biotechnology company focused on central nervous system (CNS) disorders, infectious diseases, immunology conditions, and rare diseases where there exists high unmet medical need. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8mg), the Company's flagship internally conceived and developed medicine, is the first new treatment for fibromyalgia in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® SymTouch® (sumatriptan injection 3 mg) and Tosymra® (sumatriptan nasal spray 10 mg). Tonix is extending the science behind TONMYA in Phase 2 clinical studies to evaluate the potential of TNX-102 SL in major depressive disorder and acute stress disorder/acute stress reaction. Tonix is also advancing a pipeline of infectious disease programs, including monoclonal antibody TNX-4800 (anti-OspA mAb) for Lyme disease prevention in the U.S. and TNX-801 (horsepox, live virus vaccine), a vaccine in development for the prevention of mpox and smallpox. Tonix has been awarded 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, Maryland. Within immunology, Tonix is developing TNX-1500 (anti-CD40L mAb), a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. Finally, the Company's rare disease portfolio includes TNX-2900, which is Phase 2 ready for the treatment of Prader-Willi syndrome. To learn more, visit www.tonixpharma.com.

*Tonix's product development candidates, including TNX-102 SL for new, unapproved indications, are investigational new drugs or biologics. Their efficacy and safety have not been established and have not been approved for any indication.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statements that are predictive in nature. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. 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 successfully launch and commercialize TONMYA® and any of our approved products; risks

related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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 in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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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