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Tonix Pharmaceuticals Announces Publication in Microorganisms of Technology that Expands Company's Capabilities in Generating Potential Therapeutic Fully Human Antibodies Against SARS-CoV-2 and Other Pathogens

High-throughput, high-content imaging-based assay developed to screen convalescent sera for neutralizing antibodies to SARS-CoV-2 variants

Study highlights Tonix's internal R&D capabilities in infectious disease that include a COVID-19 vaccine selected by NIH for Project NextGen and a host-directed anti-viral program awarded a DoD/DTRA contract for up to $34 million

CHATHAM, N.J., Aug. 06, 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 the publication of a research paper in *Microorganisms*, a scientific, peer-reviewed, open access journal of microbiology. The article titled, "High-Throughput Screening Assay for Convalescent Sera in COVID-19: Efficacy, Donor Selection, and Variant Neutralization," by Kota, et al.[1], highlights proprietary high-throughput, high-content imaging technology to screen convalescent sera for generating neutralizing, fully-human monoclonal antibodies (mAbs) against SARS-CoV-2 variants and potentially other pathogens.

"This article highlights Tonix's capabilities in developing fully human mAbs against SARS-CoV-2 and other pathogens," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Our phenotypic imaging system can be used to identify antibodies to counter SARS-CoV-2 and its variants and potentially other infectious agents."

"COVID-19 rates are on the rise again, and there is growing concern that the short-term protection provided by mRNA vaccines may not be sufficient to control COVID-19 as a public health threat," continued Dr. Lederman. "Our new publication highlights the capabilities of Tonix's screening and therapeutic discovery and development technologies."

In addition to this technology, Tonix has several other research and development programs to prevent and treat viral illnesses. Tonix is developing TNX-801, a live-virus vaccine based on horsepox to protect against mpox and smallpox. TNX-801 is also the vector underlying our Recombinant Pox Virus (RPV) platform technology and to engineer vaccines to protect against other viruses. TNX-1800, which uses the RPV technology, is a potential vaccine

against COVID-19 that was selected by National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH), for inclusion in clinical trials as part of its Project NextGen for prevention of COVID-19. Tonix also is developing TNX-4200, an orally available CD45 antagonist with broad-spectrum efficacy against a range of viral families. Tonix recently was awarded a $34 million contract from the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA), to establish physicochemical properties, pharmacokinetics, and safety attributes to support an Investigational New Drug submission and to fund a first-in-human Phase 1 clinical study using TNX-4200.

In support of our infectious disease programs, Tonix's experienced team utilizes 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 our research and development center (RDC) located in Frederick, Md. The RDC is located in Maryland's "I-270 biotech corridor" and is close to the center of the U.S. biodefense research community.

About TNX-4200*
The TNX-4200 program aims to develop an orally available CD45 antagonist, with broad-spectrum efficacy against a range of viral families through preclinical evaluation. The program is expected to establish physicochemical properties, pharmacokinetics, and safety attributes to support an Investigational New Drug (IND) submission and to fund a first-in-human Phase 1 clinical study. Through our agreement with DTRA, our broad-spectrum antiviral research program will address the DoD's goal of protecting U.S. Joint Forces in the event biological weapons are introduced onto the battlefield. The $34 million five-year contract will help fund and accelerate the development of the Company's broad-spectrum antiviral program, which has the potential to reduce viral load and allow the adaptive immune system to alert the other arms of the immune system to mount a protective response. Tonix plans to leverage previous research on phosphatase inhibitors, specifically compounds that target CD45, to optimize lead compounds for therapeutic intervention of biothreat agents and provide the government with a complete and cost-effective solution for a broad-spectrum medical countermeasure. Tonix's premise is that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations, a lower dose, and a better safety profile.

About Project NextGen
Project NextGen is a $5 billion initiative to develop the next generation of vaccines and therapeutics to combat COVID-19. Based at the HHS and led by the Administration for Strategic Preparedness and Response's Biomedical Advanced Research and Development Authority and the NIH's NIAID, Project NextGen was stood up to coordinate across the federal government and the private sector to advance the pipeline of new, innovative vaccines and therapeutics into clinical trials and potential review by the U.S. Food and Drug Administration (FDA) for authorization or approval, and commercial availability for the American people. The program will focus on several areas, including mucosal vaccines, vaccines that provide broader protection against variants of concern and a longer duration of protection, pan-coronavirus vaccines, and new and more durable monoclonal antibodies.

About TNX-801* and Tonix's RPV Platform
TNX-801 (recombinant horsepox virus) is a live virus vaccine for percutaneous administration that is being developed to target smallpox, and mpox (monkeypox). TNX-801 is also the basis of the RPV platform based on a horsepox vector, which is being adapted as

a COVID-19 vaccine, term TNX-1800*. Horsepox is a live replicating, attenuated virus that has been shown to be >1,000-fold more attenuated than modern vaccinia (VACV) strains in immunocompromised mice.[2] Horsepox and the vaccinia vaccine viruses are closely related orthopoxviruses that are believed to share a common ancestor. Molecular analysis shows that horsepox is closer than modern vaccinia vaccines in DNA sequence to the vaccine discovered and disseminated by Dr. Edward Jenner. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been explored as platforms for vaccine development because they possess; (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) readily manufacturable at scale, and (7) ability to provide direct antigen presentation. Relative to vaccinia, horsepox has substantially decreased virulence in mice. The current formulation is a frozen liquid, but we believe that future lyophilized versions can be stored and shipped at standard refrigeration. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines that can be administered without sterile injection, manufactured using conventional cell culture systems with the potential for mass scale production, and packaged in multi-dose vials.

About TNX-1800*

TNX-1800 (recombinant horsepox virus) is a live virus vaccine for percutaneous administration that is designed to express the spike protein of the SARS-CoV-2 virus and to elicit a predominant T cell response. Moreover, we believe the low dose of TNX-1800 makes this technology amenable for future implementation in microneedle delivery systems. NIAID will cover the full cost of Phase 1 clinical trials, while Tonix will supply the vaccine candidate. The intent is to provide durable protection against severe disease and prevent forward transmission, primarily by eliciting a T-cell immune response. TNX-1800 expresses the spike protein of SARS-CoV-2, was immunogenic, well tolerated[3] and showed promise in protecting animals from challenge with SARS-CoV-2 delivered directly into the lungs.[4]

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 development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half 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. TNX-102 SL was awarded Fast Track designation from the FDA. Tonix expects a decision on marketing approval from the FDA in 2025. TNX-102 SL is also being developed to treat acute stress reaction. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic 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 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 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.

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. Kota, K.P. et al. (2024) Microorganisms July 23, 2024.https://doi.org/10.3390/microorganisms1208150
2. Trefry, SV et al., BioRxiv 2023.10.25.564033; doi: https://doi.org/10.1101/2023.10.25.564033
3. Awasthi M, et al. *Viruses*. 2023. 15(10):2131. doi: 10.3390/v15102131.
4. Awasthi M et al *Vaccines* (Basel). 2023. 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 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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