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Tonix Pharmaceuticals Announces Presentation on TNX-801 Vaccine Protection Against Monkeypox at the 4th Symposium of the Canadian Society for Virology

Poster Presentation Includes Preclinical Data from Tonix's Program to Develop a Vaccine for Monkeypox and Smallpox

CHATHAM, N.J., June 08, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that Ryan Noyce, Ph.D., and David Evans, Professor, Department of Cell Biology, University of Alberta, together with scientists from Tonix presented data from a research collaboration between Tonix Pharmaceuticals and The University of Alberta in a poster presentation at the 4th Symposium of the Canadian Society for Virology held in Edmonton, Alberta, Canada on June 5, 2022. Copies of the poster are available on the Tonix Pharmaceuticals corporate website at www.tonixpharma.com.

The poster titled, "*Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox,*" describes data from animals vaccinated with TNX-801[1] to protect against monkeypox. The poster presentation reports that all animals (eight of eight) vaccinated with TNX-801 were fully protected with sterilizing immunity from a challenge with intra-tracheal monkeypox. The vaccinations with TNX-801 were well tolerated. Synthetic horsepox virus is the basis for the Company's TNX-801 vaccine in development to protect against monkeypox and smallpox and for the Company's Recombinant Pox Virus (RPV) platform to protect against other pathogens, including SARS-CoV-2.

"Our research work, in collaboration with Dr. Noyce and Professor Evans at The University of Alberta, shows that vaccination with TNX-801 has the ability to protect against monkeypox infection," said Seth Lederman, M.D., President and Chief Executive Officer. "Monkeypox infection of humans was rare during the time people were vaccinated to protect against smallpox. After the eradication of smallpox, vaccination with live-virus vaccinia was stopped in most of the world. Monkeypox cases have been rising in Africa for several years. Very recently a strain of monkeypox from West Africa has caused clusters of monkeypox cases in many countries outside of Africa. We believe that vaccination with live-virus vaccines like TNX-801 has the potential to control monkeypox again."

About TNX-801, TNX-1840 and TNX-1850

TNX-801 is a live virus vaccine based on synthesized horsepox[2,3]. Tonix is developing TNX-801 for percutaneous administration as a vaccine to protect against monkeypox and smallpox. Tonix has previously reported positive data from a monkeypox challenge study in non-human primates[4]. Tonix is also developing TNX-1840 and TNX-1850 (horsepox-based live virus vaccines) for the prevention of COVID-19. TNX-1840 and TNX-1850 are designed to express the spike protein from the omicron and BA.2 variants of SARS-CoV-2, respectively. Tonix has previously reported positive data from a SARS-CoV-2 challenge study in non-human primates in which animals were vaccinated with TNX-1800, a horsepox-based vaccine expressing spike protein from the Wuhan strain[5]. Tonix's TNX-801 was synthesized[2] based on the sequence of the 1976 natural isolate Mongolian horsepox clone MNR-763. Molecular analysis of DNA sequences suggests that TNX-801 is closer than modern smallpox vaccines to the vaccine discovered and disseminated by Dr. Edward Jenner in 1798[6-8]. For example, recent studies[9,10] have shown approximately 99.7% colinear identity between TNX-801 and the circa 1860 U.S. smallpox vaccine VK05.[11] The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[12]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Dr. Edward Jenner invented vaccination in 1798 and the procedure was called "vaccination" because 'cow' is 'vacca' in Latin and the inoculum material was initially obtained from lesions on the udders of cows affected by a mild disease known as cowpox. However, Dr. Jenner suspected that cowpox originated from horses[8]. Subsequently, Dr. Jenner and others immunized against smallpox using material directly obtained from horses. The use of vaccines from horses was sometimes called 'equination' from the Latin 'equus' which means 'horse'[13]. Equination and vaccination were practiced side-by-side in Europe[13,14].

About the Recombinant Pox Virus (RPV) Platform

Horsepox virus and vaccines based on its use as a vector are live replicating viruses that elicit strong immune responses. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been exploited 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) manufacturable at scale, and (7) ability to provide direct antigen presentation. Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, that can be manufactured using conventional cell culture systems, with the potential for mass scale production and packaging in multi-dose vials. Tonix's TNX-801 and RPV vaccine candidates are administered percutaneously using a two-pronged, or "bifurcated" needle. The major cutaneous reaction or "take" to vaccinia vaccine was described by Dr. Edward Jenner in 1796 and has been used since then as a biomarker for protective immunity to smallpox, including in the World Health Organization's (WHO) accelerated smallpox eradication program that successfully eradicated smallpox in the 1960's. The "take" is a measure of functional T cell immunity validated by the eradication of smallpox, a respiratory-transmitted disease caused by variola.

About Monkeypox and Smallpox

Monkeypox[15] and smallpox[16] are diseases in humans called by the monkeypox and smallpox (or variola) viruses, respectively. Monkeypox and variola are closely related orthopox viruses. Vaccination against smallpox with live virus vaccines based on horsepox or vaccinia protects against monkeypox. After routine smallpox vaccination was stopped in about 1970, monkeypox has become a growing problem in Africa. Recently approximately 300 cases have been identified outside of Africa.[17] Smallpox is considered eradicated, but there are concerns about malicious reintroduction.

About Tonix Pharmaceuticals Holding Corp.[1]

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the second quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the second quarter of 2022. TNX-1300 has been granted Breakthrough Therapy Designation by the FDA. Finally, TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the second half of 2022. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan-Drug Designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500 which is a humanized monoclonal antibody targeting CD40-ligand being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second half of 2022. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. Tonix's lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850, which are live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform.

[1]*All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

[2]*Noyce RS, et al. (2018) PLoS One. 13(1):e0188453*

[3]*Tulman ER, et al. (2006) J Virol. 80(18):9244-58.PMID:16940536*

[4]*Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference – January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)*

[5]*Tonix Press Release March 16, 202a https://ir.tonixpharma.com/news-events/press-releases/detail/1255/tonix-pharmaceuticals-reports-positive-covid-19-vaccine*

[6]*Schrick L et al. N Engl J Med. (2017) 377:1491.*

[7]*Qin et al. J. Virol. 89:1809 (2015).*

[8]*Jenner E. "An Inquiry Into the Causes and Effects of the Variolae Vaccinae: A Disease Discovered in Some of the Western Counties of England, Particularly Gloucestershire, and Known by the Name of the Cow Pox." London: Sampson Low, 1798.*

[9]*Brinkmann A et al, Genome Biology (2020) 21:286 https://doi.org/10.1186/s13059-020-02202-0*

[10]*Duggan A et al. Genome Biology (2020) 21:175 https://doi.org/10.1186/s13059-020-02079-z*

[11]*Tonix press release. Dec 4, 2020 https://ir.tonixpharma.com/news-events/press-releases/detail/1236/vaccine-genome-researchers-report-99-7-colinear-identity*

[12]*Trindale GS et al. Viruses (2016) (12). Pii: E328. PMID:27973399*

[13]*Esparza E, et al Vaccine. (2017) 35(52):7222-7230.*

[14]*Esparza J et al. Vaccine. (2020); 38(30):4773-4779.*

[15]*www.cdc.gov/poxvirus/monkeypox/about.html*

[16]*www.cdc.gov/smallpox/research/*

[17]*Mandavilli, A. The New York Times. May 26, 2020. "Who is protected against monkeypox"*

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

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; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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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