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Tonix Pharmaceuticals Announces Publication Reporting Synthesis, Construction and Characterization of a Potential Smallpox-Preventing Vaccine Candidate TNX-801 (Live Horsepox Virus from Cell Culture)

Successful Development of TNX-801 May Lead to an Improved Smallpox-Preventing Vaccine

NEW YORK, Jan. 19, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company developing innovative pharmaceutical and biological products to address major public health challenges, today announced the publication of research describing the successful synthesis and characterization of a potential smallpox-preventing vaccine based on horsepox virus. The research was conducted in conjunction with scientists from the University of Alberta, a leading Canadian research university.

The peer-reviewed article, “Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments,” published in the journal *PLOS ONE,* follows the announcement in March of 2017 of the complete synthesis of horsepox virus using synthetic biology technology. The synthetic horsepox virus demonstrated the ability to protect against lethal vaccinia infection in a mouse model which may be indicative of vaccine protection in humans. Tonix is developing the synthetic version of horsepox virus from cell culture, designated TNX-801, as a potential vaccine to prevent smallpox infection in humans. TNX-801 is at pre-Investigational New Drug (IND) application stage.

“Evolutionary evidence is building that the vaccines which largely eradicated smallpox in the U.S. and Europe in the 19th Century were closely related to horsepox,” stated Seth Lederman, M.D., President and Chief Executive Officer of Tonix. Dr. Lederman continued, “We are excited to verify the vaccine protection activity of TNX-801 in additional animal models and to develop it as a vaccine to prevent smallpox in humans. Current smallpox vaccines are used to protect first responders and military service members who face increased risks of outbreak, but due to detrimental side effects, they are typically stockpiled in the U.S. Strategic National Stockpile, but rarely used in practice. We believe that U.S. servicemembers in the Army’s Global Response Force are typically vaccinated against smallpox. Because of the toxicity of modern smallpox vaccine, the U.S. has decided to stockpile vaccine for use in case of need, rather than immunizing the whole at-risk population which was the policy prior to eradication. Our goal is to develop an improved

smallpox preventing vaccine that has a better safety profile and is more suitable for broader usage."

"Our hope is that this research will contribute to informed discussions relating to the potential applications of synthetic biology to improve public health, stimulate new evaluation of horsepox-based vaccines, and advance the manufacturing process to rapidly produce next-generation vaccines and therapeutics," said Professor David Evans, Ph.D., FCAHS, Professor and Vice-Dean (Research), Faculty of Medicine and Dentistry at the University of Alberta, in Edmonton, Alberta, Canada, and principal investigator of the TNX-801 research project.

"A new and improved smallpox vaccine would address a well-recognized risk of the intentional re-introduction of the smallpox virus - a risk for which governments should prepare," commented José Esparza, M.D., Ph.D., former President of the Global Virus Network, former Senior Advisor on Global Health (Vaccines) to the Bill and Melinda Gates Foundation and currently adjunct professor at the Institute of Human Virology at the University of Maryland School of Medicine, who was not involved in the research. "To ignore the risk of smallpox intentional re-introduction or to rely on current vaccines, which have limitations, would not be a wise choice of biodefense for public health policy makers."

Horsepox was synthesized by Professor Evans and Research Associate Ryan Noyce, Ph.D., at the University of Alberta, with Dr. Lederman as co-investigator of the research and co-inventor of TNX-801. Under their research and development agreement, Tonix wholly owns the synthesized horsepox virus stock and related sequences. Process development work to support TNX-801 pre-IND activities has begun.

About Horsepox and Smallpox

Horsepox is an equine disease caused by the horsepox virus, and is believed to have become extinct through some natural process. No known horsepox outbreaks have been reported since 1976, at which time the U.S. Department of Agriculture obtained the viral sample used for the sequence published in 2006 (Tulman, ER. Genome of Horsepox Virus. Journal of Virology, 2006, 80:9244) on which is based TNX-801. In 1798, Dr. Edward Jenner, English physician and scientist, speculated that a vaccine derived from cowpox could protect humans against smallpox. Jenner had a strong suspicion that his vaccine, which he isolated from what he called cowpox in cows, began as a pox disease in horses. As a result of Jenner's vaccine, smallpox was eradicated. No cases of naturally occurring smallpox have been reported since 1977. A recent analysis of a 1902 U.S. vaccine showed 99.7% similarity to horsepox in the core genome (Schrick, L. *et al.* (2017), An Early American Smallpox Vaccine Based on Horsepox, New England Journal of Medicine 2017; 377:1491). The modern vaccines were developed after smallpox had been largely eradicated from the U.S. and Europe and before it was known that the 19th Century vaccines were closely related to horsepox. Smallpox-preventing vaccines are maintained in the U.S. Strategic National Stockpile.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges and diseases with significant unmet needs. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for

PTSD. Due to the unique mechanism of action of the active ingredient (TNX-102 or cyclobenzaprine hydrochloride) in Tonmya to improve sleep quality, TNX-102 SL is being developed as a bedtime treatment for agitation in Alzheimer's disease. Tonix is planning to submit an IND for this additional indication in 1Q2018 after completing a successful pre-IND meeting with the FDA in 4Q2017. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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, substantial competition; 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, 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.

Contacts

Jessica Morris (investors)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Rich Allan (media)
Russo Partners
rich.allan@russopartnersllc.com
(646) 942-5588

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