March 2, 2017

Tonix Pharmaceuticals Announces Demonstrated Vaccine Activity in First-Ever Synthesized Chimeric Horsepox Virus

Pre-Clinical Smallpox-Preventing Vaccine Candidate TNX-801 May Qualify for Priority Review Voucher if FDA-Approved Under Provisions in the 21st Century Cures Act

NEW YORK, March 02, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, working with researchers from the University of Alberta, a leading Canadian research university, today announced the successful synthesis of a potential smallpox-preventing vaccine. This vaccine candidate, TNX-801, is a live form of horsepox virus (HPXV) that has been demonstrated to have protective vaccine activity in mice.

“Presently, the safety concern of existing smallpox-preventing vaccines outweigh the potential benefit to provide immunization of first responders or the general public. By developing TNX-801 as a horsepox vaccine to prevent smallpox infection, we hope to have a safer vaccine to protect against smallpox than is currently available,” stated Seth Lederman, M.D., president and chief executive officer of Tonix. “Vaccines are a critical component of the infrastructure of global public health. Vaccination protects those who are vaccinated and also those who are not vaccinated, by decreasing the risk of contagion.”

“Our goal is to improve on current methods that protect the public from possible viral outbreaks,” 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.

HPXV 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 the TNX-801 patent. Under their research and development agreement, Tonix wholly owns the synthesized HPXV virus stock and related sequences. Professor Evans and Dr. Noyce also demonstrated that HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection. Vaccine manufacturing activities have been initiated by Tonix to support further nonclinical testing of TNX-801.

Dr. Lederman stated, “Our research collaboration is dedicated to creating tools and innovative products that better protect public health.”

About Horsepox (HPXV) and Smallpox

Horsepox, an equine disease caused by a virus and characterized by eruptions in the mouth and on the skin, is believed to be eradicated. No true HPXV outbreaks have been reported since 1976, at which time the United States Department of Agriculture obtained the viral sample used for the sequence published in 2006 that allowed the synthesis of TNX-801. In 1798, Dr. Edward Jenner, English physician and scientist, speculated that smallpox is a human version of pox diseases in animals. Jenner had a strong suspicion that his vaccine began as a pox disease in horses and went on to show that it could be used to vaccinate against smallpox. Smallpox was eradicated as a result, and no cases of naturally occurring smallpox have been reported since 1977. Jenner's vaccine appears to have evolved considerably in the vaccinia stocks maintained in different countries around the world, since vaccinia was mostly selected for growth and production. Being able to provide safe and effective smallpox-preventing vaccines remains important and necessary for addressing and protecting public health.

About the Material Threat Medical Countermeasures Provisions in the 21st Century Cures Act

In 2016, the 21st Century Cures Act (Act) was signed into law to support ongoing biomedical innovation. One part of the Act, Section 3086, is aimed at "Encouraging Treatments for Agents that Present a National Security Threat." This section of the Act created a new priority review voucher program for "material threat medical countermeasures." The Act defines such countermeasures as drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat, or to treat harm from a condition that may be caused by administering a drug or biological product against such an agent. The priority review vouchers are awarded at the time of FDA approval and are fully transferrable and may be sold to other companies to be used for priority review of any New Drug Application (NDA) or Biologic Licensing Application (BLA).

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address public health challenges, with TNX-102 SL in Phase 3 development for posttraumatic stress disorder (PTSD). TNX-102 SL is designed for bedtime use and is believed to improve overall PTSD symptoms by improving sleep quality in PTSD patients. PTSD is a serious condition characterized by chronic disability, inadequate treatment options especially for military-related PTSD and overall high utilization of healthcare services creating significant economic burden. TNX-102 SL was recently granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. Other development efforts include TNX-601, a clinical candidate at Pre-IND (Investigational New Drug) application stage, designed for daytime use for the treatment of PTSD, and TNX-801, a potential smallpox-preventing vaccine.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

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, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. 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 hereof.

Contacts
Jessica Smiley
Investor Relations
investor.relations@tonixpharma.com
(212) 980-9155 x185

Edison Advisors (investors)
Tirth Patel
tpatel@edisongroup.com
(646) 653-7035

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

Source: Tonix Pharmaceuticals Holding Corp.