February 26, 2020

Tonix Pharmaceuticals Announces Research Collaboration with Southern Research to Develop a Potential Vaccine to Protect Against New Coronavirus Disease 2019 (COVID-19) Based on Horsepox Virus (TNX-1800)

NEW YORK, Feb. 26, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today a strategic collaboration with Southern Research to support the development of a vaccine, TNX-1800* (live modified horsepox virus vaccine for percutaneous administration) to protect against the new coronavirus disease, COVID-19, based on Tonix's proprietary horsepox vaccine platform. Tonix is developing TNX-801 (live horsepox virus vaccine for percutaneous administration) as a potential smallpox preventing vaccine for the U.S. strategic national stockpile and as a monkeypox preventing vaccine. The Company believes that its proprietary horsepox virus has the potential to serve as a vector for vaccines to protect against other infectious agents. The new research collaboration will develop and test a potential horsepox vaccine that expresses protein from the virus that causes COVID to protect against the disease.

There are currently no vaccines to protect against COVID-19. The virus that causes COVID-19 is called SARS-CoV-2 and is reportedly highly contagious. COVID-19 is associated with a significant rate of mortality.

Under the terms of the research collaboration, Southern Research will test one or more vaccine constructs in the Tonix horsepox vector that express one or more proteins or protein fragments from the virus that causes COVID-19. The first such potential vaccine is TNX-1800. The collaboration seeks to leverage Tonix's horsepox vaccine technology that was originally developed to protect against smallpox but has capabilities as a vector for other infectious diseases. Tonix has previously reported that horsepox has efficacy as a vaccine and good tolerability in mice[1] and cynomolgus macaques[2]. Horsepox is closely related to vaccinia vaccines, which are a group of orthopoxviruses that have been used as smallpox vaccines.

Dr. Seth Lederman, CEO of Tonix Pharmaceuticals said, "Although vaccinia vectors are available, different orthopoxvirus strains may behave differently as vectors in part because of their different repertoire of genes that modulate immune responses and host range. Potential advantages of horsepox are the strong immunogenicity we observed in macaques

and mice with good tolerability. The protein synthesis connected with a replicating live virus vaccine provides direct antigen presentation, which can stimulate cellular immunity in addition to humoral immunity." Dr. Lederman was formerly an associate professor at Columbia University and made significant original contributions to immunology.

Scott Goebel, a senior scientist at Southern Research and principal investigator of the project said, "We look forward to this collaboration to advance a potential COVID-19 vaccine." Mr. Goebel has previously worked on vaccinia and orthopoxvirus vaccines for other conditions and has studied coronaviruses.

About Orthopoxvirus Vectors

Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. The name "horsepox" was derived from the animal from which the virus was isolated. The natural host is presumed to be wild rodents. The name "vaccinia" is a term that is applied to a group of related vaccine viruses that were industrially produced by infecting cows. The terms "vaccinia" and "vaccine" were originally coined by Dr. Edward Jenner (derived from the Latin "*vacca*" for "a cow") in his description of an illness in cows (cowpox) that was transferred inadvertently by human hands from horses to cows and from cows to human hands. Jenner was the first to use infectious matter (vaccinia or vaccine) from cowpox to elicit protective immunity to smallpox by intentional "vaccination". Although horsepox is not considered to be a vaccinia, modern DNA analysis reveals more variation between different vaccinia strains than between horsepox and certain vaccinia strains. 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.

About TNX-801* and TNX-1800*

TNX-801 is a live virus vaccine based on synthesized horsepox[1,2]. TNX-1800 is a modified horsepox virus that is designed to express a protein from the virus that causes COVID-19, which is known as SARS-CoV-2. Molecular analysis suggests that TNX-801 has relatively "complete" left and right inverted terminal repeats (ITRs) while different vaccinia isolates have a variety of deletions in the left and right ITRs. Therefore, TNX-801 has additional genes, relative to vaccinia vaccines, that may play roles in host immune interactions and one or more of such proteins may serve as antigens for protective immunity. Molecular analysis also shows that horsepox is closer than modern vaccines in DNA sequence to the vaccine discovered and disseminated by Dr. Edward Jenner[2,3,4]. No new gene elements were added to the natural isolate and the small plaque size in culture appears identical to the U.S. Centers for Disease Control publication of the natural isolate[5]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[1]. TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge[6].

[1]Noyce RS, et al. (2018) PLoS One. 13(1):e0188453
[2]Tulman ER, et al. (2006) J Virol. 80(18):9244-58.PMID:16940536

[3]*Schrick L et al. N Engl J Med. (2017) 377:1491.*
[4]*Qin et al. J. Virol. 89:1809 (2015).*
[5]*Trindale GS et al. Viruses (2016) (12). pii: E328. PMID:27973399*
[6]*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)*

*TNX-801 and TNX-1800 are in the pre-IND stage and have not been approved for any indication.

About Southern Research

Founded in 1941, Southern Research (SR) is an independent, 501(c)(3) nonprofit, scientific research organization with more than 400 scientists and engineers working across four divisions: Drug Discovery, Drug Development, Engineering, and Energy & Environment. SR supports the pharmaceutical, biotechnology, defense, aerospace, environmental, and energy industries. SR works on behalf of the National Cancer Institute, National Institutes of Health, the U.S. Department of Defense, the U.S. Department of Energy, NASA, major aerospace firms, utility companies, and other private and government organizations. SR pursues entrepreneurial and collaborative initiatives to develop and maintain a pipeline of intellectual property and innovative technologies that positively impact real-world problems. SR is developing 18 drugs to combat various forms of cancer, ALS, Alzheimer's, diabetes, kidney disease, Parkinson's and tuberculosis, among others. SR has developed 20 other drugs, including seven FDA-approved cancer drugs—a number rivaling any other U.S. research institute. SR is headquartered in Birmingham, Alabama with additional laboratories and offices in Wilsonville, Alabama; Frederick, Maryland; Cartersville, Georgia; and Houston, Texas.

Further information about SR can be found at https://southernresearch.org.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat pain, addiction and psychiatric conditions. Tonix's lead product candidate, TNX-102 SL*, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in the third quarter of 2020 and topline data in the first half of 2020. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya**) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second quarter of 2020. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation and the development for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating addiction conditions also include TNX-1300*** (double-mutant cocaine esterase), which is in Phase 2 development for the

treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression as well as PTSD and steroid-induced cognitive changes. The first efficacy study will be performed outside the U.S. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity being developed as a daytime treatment for PTSD. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. TNX-801 (live horsepox virus vaccine for percutaneous administration) and TNX-1200 (live vaccinia virus vaccine for percutaneous administration) are vaccines to protect against smallpox and monkeypox. TNX-1800 is in development as a potential vaccine to protect against the new coronavirus, COVID-19. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

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

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic 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, risks related to 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 forth in the Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contacts

Bradley Saenger (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.