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Tonix Pharmaceuticals Enrolls First Patient in COV-LOGIC, an Observational Study to Assess Antibody and T Cell Responses to SARS-CoV-2, the Virus that Causes COVID-19

Results from COV-LOGIC Study Expected in First Half of 2021

NEW YORK, Sept. 15, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the first patient was enrolled in the observational COV-LOGIC study (TNX-C001), a study of humoral (antibody) and cellular (T cell) immune responses to SARS-CoV-2 in volunteers who have recovered or remain asymptomatic after exposure to COVID-19. The research is part of an ongoing and broader collaboration between Tonix and Southern Research to develop and conduct animal testing of Tonix's TNX-1800, which is a live replicating, attenuated virus vaccine designed to protect against COVID-19.

"This represents a significant milestone for the Company as the data we plan to collect from recovered and asymptomatic COVID-19 volunteers in this study will help inform vaccine development on how to safely provide the same immune responses that others got from recovering from actual SARS-CoV-2 infection," said Seth Lederman, M.D., President and CEO of Tonix. "Our goal with TNX-1800 is to develop a vaccine that is well tolerated, produces strong, long-lasting immunity, and can be rapidly and broadly deployed. The features of a protective immune response to SARS-CoV-2 remain unknown. But since SARS-CoV-2 is a virus, we believe that T cell responses, in particular T Helper Type 1, or TH1 responses, will play an important, if not dominant, role in protecting against serious illness from COVID-19."

About the COV-LOGIC Study (TNX-C001)

The COV-LOGIC study is an observational multi-cohort sample collection study designed to collect the blood and nasopharyngeal (NP) swabs from individuals who have, and have not, been previously infected with SARS-CoV-2, or who have been intimately exposed to persons confirmed to have been infected with SARS-CoV-2, in order to analyze their antibody titers and T-cell responses to specific proteins of SARS-CoV-2 and to detect SARS-CoV-2 RNA which may be persistent in the nasopharynx at the time of sampling. For those individuals in whom viral RNA is detected during initial sampling, repeat blood and NP swab samples may be collected to examine temporal virus/immune response dynamics. In addition, blood will be collected for DNA extraction and exome sequencing in order to assess whether host

genetic factors might influence these humoral or cellular responses or viral persistence (if identified).

About TNX-1800

TNX-1800 is a live modified horsepox virus vaccine for percutaneous administration that is designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19 and to elicit a predominant T cell response. Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. 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[1]. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, which can be manufactured on conventional cell culturing systems, with the potential for mass scale production.

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

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 three divisions: Drug Discovery, Drug Development, and Engineering. SR has supported the pharmaceutical, biotechnology, defense, aerospace, environmental, and energy industries. SR works on behalf of the National Institutes of Health, the U.S. Department of Defense, the U.S. Department of Energy, NASA and other major aerospace firms, utility companies, and other external academic, industry and government agencies. 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 has numerous ongoing drug discovery programs, which encompass 18 drug candidates to combat various forms of cancer, amyotrophic lateral sclerosis (ALS), Alzheimer's, schizophrenia, opioid use disorder, human immunodeficiency virus, diabetes, kidney disease, Parkinson's, tuberculosis, influenza, and others. SR's strong history, which includes over 75 years of successful collaborations to solve complex problems, has led to the discovery of seven FDA-approved cancer drugs—a number rivaling any other U.S. research institute. Furthermore, experts at SR are well-equipped to assist with the challenging landscapes of drug design and development technologies and market viability. SR is headquartered in Birmingham, Alabama with additional laboratories and offices in Frederick, Maryland.

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, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to

prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix is also developing TNX-2300* and TNX-2600*, live replicating vaccine candidates for the prevention of COVID-19, but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth quarter of 2020. Tonix is also currently enrolling patients in a second Phase 3 study for the management of fibromyalgia using TNX-102 SL, the results for which are expected in the second half of 2021. 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 AUD program is also Phase 2 ready. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD; 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-1800, TNX-801, TNX-2300, TNX-2600, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have 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; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; 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, 2019, as filed with the Securities and Exchange Commission (the “SEC”) on March 24, 2020, 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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