May 7, 2020

# Tonix Pharmaceuticals Enters into Research Collaboration and Exclusive License Agreement with University of Alberta to Develop Novel Horsepox-Based Vaccines, TNX-1810, TNX-1820 and TNX-1830, for the Prevention of COVID-19

## TNX-1810, TNX-1820 and TNX-1830 are Designed to Express Protein Antigens from SARS-CoV-2 That are Different from TNX-1800, Which is Designed to Express Spike Protein

NEW YORK, May 07, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, and the University of Alberta, a leading Canadian research university, announced today a new research collaboration and exclusive licensing agreement for three new vaccines for the prevention of COVID-19, the novel coronavirus disease identified in 2019 which is caused by SARS-CoV-2 virus. The new collaboration will develop three new potential vaccines to protect against COVID-19 based on the horsepox vector platform, but designed to express different SARS-CoV-2 antigens than TNX-1800, which is designed to express SARS-CoV-2 Spike protein.

“We are excited to expand our pipeline and look forward to developing three additional potential vaccines, TNX-1810, TNX-1820 and TNX-1830 to protect against COVID-19,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “We are delighted to extend our relationship with David Evans, Ph.D., FCAHS, Professor and former Vice-Dean (Research) Faculty of Medicine and Dentistry at the University of Alberta and principal investigator of the TNX-1810, TNX-1820 and TNX-1830 research project, and Ryan Noyce, Ph.D., Research Associate in Professor Evans’ laboratory at the University of Alberta. Drs. Evans and Noyce synthesized horsepox, which is now our TNX-801 potential vaccine for smallpox and monkeypox. Horsepox is the vector system that is the backbone of the TNX-1800 vaccine that is designed to express the SARS-CoV-2 Spike protein, which Tonix is developing for the prevention of COVID-19 in collaboration with the Southern Research Institute. Horsepox is also the vector system for the new TNX-1810, TNX-1820 and TNX-1830 vaccines. TNX-801 is designed to elicit predominantly T cell responses, while the new vaccines are designed to elicit almost purely T cell responses.”

“We are excited to extend our productive collaboration with Tonix. Tonix brings expertise in immunology, particularly with Dr. Lederman’s direct involvement in these programs, which

complements our expertise in virology. TNX-1810, TNX-1820 and TNX-1830 are designed to express different protein antigens from SARS-CoV-2," said Dr. Evans. "It is currently unknown what type of vaccine and which antigens from SARS-CoV-2 will provide effective protection from COVID-19. Orthopoxviruses like horsepox induce strong innate and adaptive immunity and long-lasting T-cell immunity. We have designed TNX-1810, TNX-1820 and TNX-1830 to express and induce immunity to SARS-CoV-2 proteins that are different from Spike. We are delighted to be extending our collaboration with Tonix to bring these candidate vaccines through further development and testing."

Under the terms of the research collaboration agreement, Tonix has been granted an exclusive license from the University of Alberta for technology and patents related to TNX-1810, TNX-1820 and TNX-1830. Tonix will conduct further studies to test the safety and efficacy of TNX-1810, TNX-1820 and TNX-1830 in preventing COVID-19. TNX-1810, TNX-1820 and TNX-1830 are in the Pre-Investigational New Drug (IND) application stage of development.

**About TNX-1800***

TNX-1800 (live modified horsepox virus vaccine for percutaneous administration) is a modified horsepox virus that is designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. TNX-801 is a live virus vaccine based on synthesized horsepox. 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. TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge.

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. Tonix is developing four potential vaccines, based on the horsepox viral vector platform to protect against the novel coronavirus disease emerging in 2019, or COVID-19: TNX-1800, TNX-1810, TNX-1820 and TNX-1830*. TNX-1800 is designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. TNX-1810, TNX-1820 and TNX-1830 are designed to express different proteins from SARS-CoV-2. TNX-801* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced 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 September of 2020 and topline data in the first quarter of 2021.

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 program for AUD is in the pre-Investigational New Drug (IND) application stage. 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 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 corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a 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-1200* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-1800, TNX-1810, TNX-1820, TNX-1830, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.

**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.

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; 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, 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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Source: Tonix Pharmaceuticals Holding Corp.