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Tonix Pharmaceuticals Expands Research Collaboration to Develop Precision Medicine Techniques for COVID-19 Vaccines and Therapeutics

Collaboration Will Continue to Work Towards Identifying Biomarkers for Protective Immunity Against SARS-CoV-2

Immune Correlates of Protection May Support Development of New and Specialized Vaccines to Protect Against COVID-19

Potential for Developing Antibody-Based COVID-19 Therapeutics as a Result of the Collaboration

CHATHAM, N.J., Sept. 23, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has expanded its research collaboration with Columbia University. The research collaboration is focused on studying immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were asymptomatic, as well as studying in vitro T cell and antibody responses to SARS-CoV-2, the virus that causes COVID-19. The research is designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation for tailoring vaccines and therapeutics to appropriate individuals with precision medicine.

The two principal investigators for the collaboration are Ilya Trakht, Ph.D., Associate Research Scientist and Sergei Rudchenko, Ph.D., Assistant Professor of Medical Sciences at Columbia University Vagelos College of Physicians and Surgeons.

Dr. Trakht is studying T cell and antibody responses in a variety of ways, including at the cellular level by stimulating T cells in vitro with CoV-2 antigens and by generating fully human monoclonal antibodies against SARS-CoV-2. This research has the potential to lead to the isolation, characterization and cloning of therapeutically relevant fully human neutralizing monoclonal antibodies to SARS-CoV-2.

Dr. Rudchenko is generating DNA aptamer-based anti-idiotypes to certain monoclonal antibodies identified by Dr. Trakht. Such aptamers have the potential to identify biomarkers for protective CoV-2 immunity and accelerate the design of precision medicine-driven vaccines against COVID-19.

"Based on the progress and results of the initial phase of these projects, we are excited to expand our research collaboration with Columbia University on these precision medicine

technologies and also to potentially develop new monoclonal antibody therapeutics,” stated Seth Lederman, M.D., President and Chief Executive Officer of Tonix. “Data from this collaboration may provide a roadmap and tools to potentially guide the selection of appropriate individuals for COVID-19 vaccine trials and to help determine which vaccine is appropriate for each individual based on the condition of their immune system or other physiological features.”

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 immunology and central nervous system (CNS) product candidates. Tonix’s immunology portfolio includes a COVID-19 platform of product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to COVID-19. Tonix’s lead vaccine candidate for COVID-19, TNX-1800¹, 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 reported positive efficacy data from animal studies of TNX-1800 in the first quarter of 2021 and expects to start a Phase 1 study in humans in the first half of 2022. TNX-3500² (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-Investigational New Drug (IND) stage of development. TNX-102 SL³ (cyclobenzaprine HCl sublingual tablets) is a small molecule drug being developed to treat Long COVID, a chronic condition, and is also in the pre-IND stage. Finally, Tonix is developing TNX-2100, an *in vivo* diagnostic to measure the presence of functional T cell immunity to COVID-19. Tonix intends to initiate a first-in-human clinical study of TNX-2100⁴ in the fourth quarter of 2021, pending IND clearance. Tonix’s immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases. The Company’s CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead CNS candidate, TNX-102 SL³, is in mid-Phase 3 development for the management of fibromyalgia.

¹*TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox.*

²*TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.*

³*TNX-102 SL is an investigational new drug and has not been approved for any indication.*

⁴*TNX-2100 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 our research collaboration efforts, 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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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