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Tonix Pharmaceuticals Extends Research Collaboration with the University of Alberta to Develop Antiviral Drugs Against SARS-CoV-2

Tonix Exercises Option to License Antiviral Technology Platform

NEW YORK, May 18, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has entered into a license agreement and extended a research collaboration with the University of Alberta, a leading Canadian research university, focused on identifying and testing broad-spectrum antiviral drugs against future variants of SARS-CoV-2 and other emerging viruses.

"We are excited to extend our collaboration with Tom Hobman, Ph.D., Professor, Department of Cell Biology, University of Alberta, and to have exercised an option to license the technology," said Seth Lederman, M.D., President and Chief Executive Officer. "Antiviral therapeutics are needed to mitigate the effects of SARS-CoV-2 and future coronavirus outbreaks, and Professor Hobman's work is designed to facilitate the identification and testing of novel broad-spectrum antiviral drugs. SARS-CoV-2 is very sensitive to interferon (IFN) treatment and therefore, drugs that upregulate IFN production and/or signaling may reduce virus replication."

"The research collaboration is focused on the development and testing of Wnt/β-Catenin signaling pathway inhibitors as broad-spectrum antivirals against SARS-CoV-2 and other emerging viruses," said Professor Tom Hobman. "During the first phase of the sponsored research, we showed that small molecules that inhibit this pathway also decrease replication of SARS-CoV-2 genomic RNA and dramatically reduce infectious viral titers. Drugs in this class seem to work by inducing peroxisome biogenesis, which in turn enhance production of Type I and III IFNs when cells detect viral genetic material. Peroxisomes are key antiviral signaling platforms that are important for IFN induction and antiviral defense. We believe this work has the potential to lead to drugs that limit the spread and disease burden of SARS-CoV-2 and other RNA viruses, which will support the goal of pandemic preparedness."

About Tonix Pharmaceuticals Holding Corp.¹

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both

small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second guarter of 2022 and interim data expected in the first guarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the second guarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the second guarter of 2022. TNX-1300 has been granted Breakthrough Therapy Designation by the FDA. Finally, TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the second half of 2022. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan-Drug Designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500 which is a humanized monoclonal antibody targeting CD40-ligand being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second half of 2022. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, nextgeneration vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. Tonix's lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850, which are live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform.

¹All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.

This press release and further information about Tonix can be found at <u>www.tonixpharma.com</u>.

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 the 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, 2021, as filed with the Securities and Exchange

Commission (the "SEC") on March 14, 2022, 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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