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Tonix Pharmaceuticals Announces Publication of Paper on Antiviral SARS-CoV-2 Inhibitor, TNX-3500, in JCI Insight

Early Studies in vitro Show that TNX-3500 is a Potent Antiviral Against Multiple Variants of SARS-CoV-2, the Cause of COVID-19, and Potentiates Remdesivir

CHATHAM, N.J., Nov. 22, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the publication of "*Sangivamycin is highly effective against SARS-CoV-2 in vitro and has favorable drug properties,*" in *JCI Insight*. The paper includes *in vitro* studies that show sangivamycin, the active pharmaceutical ingredient in the Company's (TNX-3500) product candidate, is a potent antiviral against SARS-CoV-2, the cause of COVID-19, and suppresses viral replication in tissue culture with greater efficacy than remdesivir, the active pharmaceutical ingredient of Gilead Sciences, Inc.'s Veklury®. When tested in combination with remdesivir, both drugs had additive rather than competitive effect against SARS-CoV-2. The new data show that TNX-3500 has similar low nanomolar antiviral activity in laboratory-based assays against multiple variants of SARS-CoV-2, including the Delta variant. The article can be accessed at https://insight.jci.org/articles/view/153165.

"We are excited to have the results of this study published, as it demonstrates Tonix's commitment to helping fight COVID-19 and other viral disorders," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix. "We believe that TNX-3500's potency on SARS-CoV-2 inhibition in tissue culture and its tolerability in humans from prior clinical studies support the pursuit of TNX-3500 for further clinical development as a potential COVID-19 therapeutic."

In April 2021, Tonix entered into an exclusive worldwide licensing agreement with OyaGen, Inc. (www.oyageninc.com) to develop TNX-3500 for the treatment of COVID-19 and potentially other viral infections. OyaGen, Inc. discovered sangivamycin's broad-spectrum antiviral effect against Ebola virus, Lassa virus and orthopoxviruses (https://doi.org/10.3390/v13010052) through a collaborative research agreement with National Institute of Allergy and Infectious Disease/National Institute of Health (NIAID/NIH) Integrated Research Facility (IRF-Frederick) at Fort Detrick, Maryland, and the recent findings on SARS-CoV-2 are a product of this collaboration.

Dr. Harold Smith, President and CEO of OyaGen, Inc. stated, "The findings reported in our paper are exciting and reveal significant new understanding of the broad-spectrum antiviral activity of sangivamycin and its *in vitro* activity. Given the rapid global spread of the Delta variant of SARS-CoV-2, we are encouraged that the high potency of sangivamycin against

multiple variants of SARS-CoV-2 may provide a much-needed medical countermeasure against current and future variants of coronaviruses. The data produced through a collaborative research agreement with the IRF-Frederick together with prior safety studies in cancer clinical trials suggest that TNX-3500 may be effective in clinical settings and perhaps may enhance the efficacy of other therapeutics through combination antiviral therapy. We are excited to be working with Tonix on the development of TNX-3500 for the treatment of COVID-19."

Tonix intends to conduct further nonclinical animal studies prior to submitting an Investigational New Drug application (IND) and initiating a Phase 1 clinical study.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics 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 COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. 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 SL[1] (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300[2] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800[3], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is also developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study. TNX-3500[5] (sangivamycin, i.v. solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.
[2]TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.
[3]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. TNX-801 is an investigational new biologic and has not been approved for any indication.
[4]TNX-2100 is an investigational new biologic and has not been approved for any indication
[5]TNX-3500 is an investigational new drug at the pre-IND stage of development 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 the development of TNX-3500, 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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