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Tonix Pharmaceuticals Enters into Exclusive Worldwide Licensing Agreement with OyaGen to Develop Antiviral SARS-CoV-2 Inhibitor, TNX-3500, for the Treatment of COVID-19

Early Studies Show TNX-3500 Significantly Inhibits SARS-CoV-2, the Cause of COVID-19, and Potentiates Remdesivir

CHATHAM, N.J., April 19, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, and OyaGen, Inc. (OyaGen), a pre-clinical biotechnology research company, announced today an exclusive worldwide licensing agreement for an antiviral inhibitor of SARS-CoV-2, TNX-3500 (sangivamycin, formerly OYA1), for the treatment of COVID-19 and potentially other viral disorders. The active ingredient of TNX-3500 has been studied for safety in humans in prior studies on cancer patients at the U.S. National Cancer Institute but has not been approved for marketing in any jurisdiction.

“We are excited to expand our pipeline and we look forward to developing TNX-3500 as a potential treatment for COVID-19 and emerging variants,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “TNX-3500 is in the pre-Investigational New Drug (IND) phase of development with encouraging early data from cell culture infectivity studies with SARS-CoV-2. We believe that its potency on SARS-CoV-2 inhibition in tissue culture and its tolerability in humans from prior studies suggests that TNX-3500 may qualify for expedited clinical development.”

Harold Smith, PhD, Chief Executive Officer and founder of OyaGen and professor of biochemistry and biophysics at the University of Rochester, School of Medicine and Dentistry said, “TNX-3500 has shown strong dose-dependent antiviral activity against live SARS-CoV-2 virus in cell culture infectivity studies. TNX-3500 was demonstrated to be approximately 65 times more potent in head to head comparisons at inhibiting SARS-CoV-2 than remdesivir, the active ingredient of Veklury®. In addition, combining TNX-3500 and remdesivir has demonstrated additive activity against SARS-CoV-2 in cell culture infectivity studies. These studies are from unpublished results from OyaGen’s collaborative research with the National Institutes of Allergy and Infectious Diseases Integrated Research Facility (NIAID-IRF), part of the National Institutes of Health. TNX-3500 inhibits the replication of SARS-CoV-2 and may have other mechanisms of action that affect viral particle release from infected cells.”

Dr. Smith continued, “We’re delighted to partner with Tonix on the development of TNX-3500 because we believe Tonix to be ideally capable to bring this program to the clinic and position it for worldwide commercialization in the rapidly evolving and highly competitive area of SARS-CoV-2 inhibitors.”

Under the terms of the agreement, Tonix has been granted an exclusive license from OyaGen for technology and patents related to TNX-3500 and other related compounds. Tonix will conduct further studies to test the safety and efficacy of TNX-3500 in treating COVID-19 as necessary to support regulatory approval.

About TNX-3500

TNX-3500 (sangivamycin) has demonstrated broad-spectrum antiviral activity in laboratory-based assays against the coronaviruses SARS-CoV-2 and MERS-CoV. Sangivamycin also demonstrated that it acts as a dual target specific antiviral against filoviruses such as Ebola virus in cell culture infectivity studies. TNX-3500 was studied in the U.S. at the National Cancer Institute (NCI), part of NIH, as an investigational new drug for treating cancer in the 1960s. Studies at that time demonstrated safety in nonhuman primates and human adults when dosed daily or weekly. TNX-3500 was demonstrated in studies in mice to persist in tissues for greater than 12 days following a single dose. Its long half-life in tissues suggests that a single dose or weekly dosing may be sufficient for antiviral treatments.

About OyaGen, Inc.

OyaGen is a privately held biotechnology company located in Rochester, New York. OyaGen is focused on the identification and early development of novel therapeutics for the treatment of viral diseases, such as those caused by HIV, coronavirus, and Ebola virus.

Further information about OyaGen can be found at www.oyageninc.com.

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 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], is in mid-Phase 3 development for the management of fibromyalgia, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY, in the third quarter of 2021[2] and topline data in the fourth quarter of 2021. Tonix’s immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix’s lead vaccine candidate, TNX-1800[3], 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. TNX-801[3], a live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.
[2]Pending agreement from FDA on statistical analysis plan.
[3]TNX-1800 and TNX-801 are investigational new biologics 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; 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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