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

Dissecting the Immune Response to SARS-CoV-2 in Healthy Recovered or Asymptomatic Volunteers May Lead to Biomarkers for Tailoring COVID-19 Vaccines and Therapeutics

Potential for Human Monoclonal Antibody COVID-19 Therapeutics to be Developed as a Result of the Collaboration

NEW YORK, July 16, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has entered into a research collaboration and option agreement with Columbia University focused on studying the immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were asymptomatic. The research collaboration will focus on T cell and antibody responses to SARS-CoV-2 (CoV-2), the virus that causes COVID-19 at the cellular level including human monoclonal antibodies and anti-idiotypes. The research is designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation upon which to target vaccines and therapeutics to appropriate individuals by 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's project will study 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 CoV-2. The project, directed by Dr. Trakht, has the potential to lead to the isolation and characterization of therapeutically relevant fully human monoclonal antibodies to CoV-2. Dr. Rudchenko's project will generate DNA aptamer-based anti-idiotypes to certain of the monoclonal antibodies identified by Dr. Trakht. Such aptamers have the potential to identify biomarkers for protective CoV-2 immunity and to lead to accelerated precision medicine-driven vaccines designed to protect against COVID-19.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals, said, "We expect that more than one COVID-19 vaccine will ultimately be approved by the Food and Drug Administration (FDA), and a challenge for future research will be to determine which vaccine is appropriate for each individual. Data from this collaboration will provide a roadmap and tools to potentially guide these recommendations. This work may also guide the selection of appropriate individuals for COVID-19 vaccine trials, such as for Tonix's TNX-

1800, based on a live replicating vector platform, which is designed to confer durable T cell immunity. It is also possible that new COVID-19 vaccines can designed which will be tailored to individuals by precision medicine. We are excited to work with our collaborators at Columbia University on these precision medicine technologies and also to potentially develop new monoclonal antibody therapeutics."

Dr. Trakht said, "T cell responses to SARS-CoV-2 have only recently been reported, so there is much that we hope to learn and to contribute to the understanding of the systemic immune response to COVID-19. We are excited to exploit our fully human monoclonal antibody system to characterize the antibody response to SARS-CoV-2 infection and the potential for developing antibody-based immunotherapeutics."

Dr. Rudchenko said, "The anti-idiotype aptamer tools that we plan to develop will characterize the immune responses in healthy people who have recovered or were asymptomatic from SARS-CoV-2 infection, which are relevant for developing therapeutics and vaccines. A goal for future research will be to use these tools to distinguish SARS-CoV-2-specific immunity in COVID-19 patients who suffered poor outcomes. My colleague, Dr. Trakht's system to make human monoclonal antibodies is particularly well suited to evaluate individuals' antibody responses at a high level of detail in the context of accelerating precision medicine approaches to vaccines and therapeutics."

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 central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, 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 expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix is also developing TNX-2300*, a second live replicating vaccine candidate for the prevention of COVID-19, but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth quarter of 2020. 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 life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain.

Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor) , a new molecular entity being developed as a treatment for PTSD; 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-1800, TNX-801, TNX-2300, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs 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, 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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