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Tonix Pharmaceuticals Plans Massachusetts R&D Facility to Accelerate Clinical Development of Vaccines and Protein-Based Therapeutics

Tonix's *Advanced Development Center* Will House Laboratories Dedicated to Process and Analytical Development

NEW YORK, July 07, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced its intent to purchase an approximately 40,000 square foot facility in Massachusetts to use as laboratories to enable R&D functions associated with its expanding portfolio of immunology candidates, including vaccines for COVID-19 and biological products for other disorders.

Tonix's Advanced Development Center is expected to expand and strengthen the Company's capabilities in process and analytical development. Tonix will continue working collaboratively in certain cases with outside partners, such as its current collaborations with Southern Research for preclinical testing and with FUJIFILM Diosynth Biotechnologies for the manufacturing of the TNX-801 and TNX-1800 vaccines for smallpox and COVID-19, respectively. Both vaccines utilize Tonix's proprietary live replicating virus platform, which is designed to potentially elicit a predominately T cell response, believed to be essential in conferring long-term vs. temporary immunity. Preclinical results from the TNX-1800 COVID-19 study in small animals and non-human primates are expected in the fourth quarter of this year. The R&D facility is expected to be operational in 2022.

"The Federal Government's 'Operation Warp Speed' for COVID-19, while critically important, has commandeered a large portion of America's biologics contract research and manufacturing facilities. As a country, the U.S. needs more domestic onshore capacity, and as a company Tonix needs more control over the speed with which we can make vaccines and biologics products suitable for clinical studies," said Seth Lederman, M.D., Chief Executive Officer of Tonix.

Dr. Lederman continued, "This is a significant step that we believe will add to our competitive advantage in responding quickly to emerging infectious diseases utilizing our growing range of vaccine technologies and protein-based therapeutic platforms. We view having our own in-house facilities for R&D as a strategic capability and we foresee a potential scarcity of available domestic capacity. In addition, R&D resources in foreign countries may not fit with our strategy to develop products related to emerging biodefense threats or critical public health needs."

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 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 2020. 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's lead CNS candidate, TNX-102 SL** (cyclobenzaprine HCl sublingual tablets), 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 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-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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