September 28, 2020

Tonix Pharmaceuticals Completes Purchase of Facility to House Advanced Development Center (ADC) for Vaccine Programs

Facility Addresses the Shortage of Vaccine Production Capacity in the U.S.

When Fully Operational the ADC Is Expected to be Capable of Manufacturing Clinical Trial Quality Vaccines, Including Vaccines Under Development for COVID-19

CHATHAM, N.J., Sept. 28, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, completed the purchase a 40,000 square foot facility in Massachusetts to house its new *Advanced Development Center* (ADC) for accelerated development and manufacturing of vaccines, including vaccines for COVID-19.

Tonix expects the facility to be operational within 24 months with single-use bioreactors and purification suites with equipment for Good Manufacturing Practice production of vaccines for clinical trials, including when fully operational, the capability of producing sterile vaccines in glass bottles. In addition, research, development and supporting analytical capabilities are planned.

Tonix currently is developing potential COVID-19 vaccines based on two live viral vector platforms: horsepox and bovine parainfluenza (BPI) virus. Four potential COVID-19 vaccines in development are based on the horsepox vector and two potential vaccines based on the BPI vector. Before year end the company expects to report results from an efficacy study of its lead COVID-19 candidate based on horsepox platform, TNX-1800, in which non-human primates are being challenged with SARS-CoV-2, the virus that causes COVID-19. The TNX-1800 vaccine is based on horsepox which is believed to be similar to the live attenuated single dose smallpox vaccine developed by Dr. Edward Jenner more than 200 years ago, which led to the eradication of smallpox. TNX-1800 is designed to express the SARS-CoV-2 spike protein and to elicit a predominately T cell response in order to provide long term immunity and prevent forward transmission.

“We are excited to have taken the first step in vertically integrating more of our development activities, but, even more importantly, adding a manufacturing capability for clinical trial quality vaccines. We believe this provides Tonix with a competitive advantage, especially in the current COVID-19 environment in which more domestic development and manufacturing capacity is needed,” commented Seth Lederman, M.D., Tonix’s President and Chief Executive Officer. “As a nation, we have a mandate to reduce our reliance on off-shore resources and we hope our plans become a siren call for others to join in fulfilling this

objective. We expect that the U.S. government will maintain a sustained interest in pandemic preparedness based on the devastating effect of COVID-19 on the health of the U.S. population, on education and on the economy."

The facility is located in the New Bedford Business Park, but the facility is in a section of the park that is actually located in the Town of Dartmouth, Massachusetts. The two municipalities work together to accommodate businesses located in the Dartmouth portion of the park as the roads are inaccessible through Dartmouth and municipal services are provided by the City of New Bedford.

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* and TNX-2600*, live replicating vaccine candidates 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. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). Both programs are Phase 2 ready, and the AAD program has FDA Fast Track designation. 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-2600, 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Elizabeth Isherwood (media)
Moore & Isherwood Communications, Inc.
eisherwood@micomm.com
(508) 996-3946

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.