August 2, 2021

Tonix Pharmaceuticals Announces Groundbreaking Ceremony for Massachusetts R&D Facility to House the Advanced Development Center (ADC) for Vaccine Programs

The ADC is Expected to Accelerate Development and Clinical Manufacturing of Vaccines, Including Vaccines for COVID-19, When Fully Operational

CHATHAM, N.J., Aug. 02, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it will hold a groundbreaking ceremony at the Company's planned 45,000 square foot clinical scale manufacturing facility in the New Bedford Business Park in Massachusetts on August 3, 2021 at 11:00 a.m. ET. The new facility is expected to house Tonix's Advanced Development Center (ADC) for accelerated research, development and analytical capabilities, as well as the production of clinical trial quality vaccines for infectious diseases, including COVID-19. The ceremony marks the formal start of site construction. Tonix expects the facility to be operational in the first half of 2022.

Plans for the ADC include single-use bioreactors and purification suites with equipment for Good Manufacturing Practice (GMP) production of vaccines for clinical trials, including when fully operational, the capability of producing sterile vaccines in glass bottles. The ADC is intended to be Biosafety Level 2 (BSL-2). At full capacity, the facility can employ up to 70 researchers, scientists, manufacturing and technical support staff.

U. S. Representative Bill Keating is expected to attend the event, along with Massachusetts Housing and Economic Development Secretary, Mike Kennealy, the mayor of New Bedford, Jon Mitchell, and Seth Lederman, M.D., President and Chief Executive Officer of Tonix.

"The South Coast is fast becoming a significant player in biotech in Massachusetts, and Tonix Pharmaceuticals' decision to open the Advanced Development Center within the New Bedford Business Park is a positive indicator of future economic growth throughout the region," said Congressman Bill Keating. "Tonix Pharmaceuticals is bringing good jobs to our region, and I look forward to watching their growth as the local economy continues to benefit from increased investment on the South Coast, including in South Coast Rail. The research, development, and manufacturing planned to take place in the new ADC has the potential to improve lives all over the world, and that is something we can all be proud of."

“We welcome Tonix Pharmaceuticals to the New Bedford Business Park as they strive to develop important solutions that address the health challenges of today and tomorrow,” said Jon Mitchell, mayor of the City of New Bedford.

“The ADC is expected to greatly enhance our internal capacity for development activities, but, even more importantly, add a manufacturing capability for clinical trial quality vaccines. We at Tonix are grateful to the Town of Dartmouth for their support. We also thank the City of New Bedford for its cooperation with the Town of Dartmouth on this project,” stated Dr. Lederman. “The initiation of construction is a significant milestone in ultimately adding to our competitive advantage in responding quickly to emerging infectious diseases utilizing our growing range of vaccine technologies and protein-based therapeutic platforms.”

The facility is located in the New Bedford Business Park in a section of the park that is 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.

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 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], is in mid-Phase 3 development for the management of fibromyalgia. 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[2], 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[2], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox. TNX-3500[3] (sangivamycin) is a small molecule antiviral drug in the pre-IND stage of development.

[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.

[2]TNX-1800 and TNX-801 are investigational new biologics and have not been approved for any indication.

[3]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 and operation of the ADC, 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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