June 16, 2022

Tonix Pharmaceuticals Announces Ribbon-Cutting Ceremony for its Advanced Development Center (ADC) for Vaccine Programs in Massachusetts

The ADC is Expected to Accelerate Clinical-Scale Manufacturing of Live Virus Vaccines, Including Vaccines for Monkeypox, Smallpox and COVID-19

Internal Manufacturing Capabilities Expected to Support U.S. Pandemic Preparedness

CHATHAM, N.J., June 16, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it will hold a ribbon-cutting ceremony at the Company's 45,000 square foot clinical-scale manufacturing facility in the New Bedford Business Park in North Dartmouth, Massachusetts on June 21, 2022 at 1:00 pm ET. The new facility houses 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 monkeypox, smallpox and COVID-19 as well as other infectious diseases for pandemic preparedness. The ceremony marks the formal opening of the New Bedford site.

U.S. Representative Bill Keating; the mayor of New Bedford, Mass., Jon Mitchell; Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals; and other prominent community members and employees plan to attend the event.

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

"Tonix Pharmaceuticals is making good on their promise to bring jobs to the New Bedford area, and we should be proud to host this new facility that has the potential to impact lives all over the world," said Congressman Bill Keating. "Thanks to the hard work of Tonix, the town of Dartmouth and City of New Bedford, this facility opening further cements the role that the South Coast is playing in biotech. The continued private and public sector investments in our region are paying dividends, and the ribbon-cutting for this facility serves as yet another positive indicator of continued economic growth on the South Coast."

"The addition of Tonix Pharmaceuticals to the growing biotech community in Greater New Bedford is a strong indicator of the quality of the region's workforce. We have the talent to compete in a variety of sectors," said Jon Mitchell, Mayor of the City of New Bedford.

“The opening of our new manufacturing facility in the New Bedford Business Park is a significant milestone for Tonix and we are excited to be part of the growing biotech industry in the South Coast region of Massachusetts,” stated Dr. Lederman. “The ADC greatly enhances our ability to progress our pipeline of vaccines for infectious diseases, including monkeypox, smallpox and COVID-19. We believe that the recombinant pox virus platform technology underlying our key vaccines in development, TNX-801, TNX-1840 and TNX-1850, coupled with our capabilities at the Tonix R&D Center (RDC) for research and development, will be rapidly deployable for addressing potential novel or emerging pathogens, with simplified distribution and administration, relative to modified mRNA-based vaccines. Our goal is to be able to design and test new recombinant pox virus vaccines against novel pathogens within the 100 days of recognition of a potential emerging pandemic threat, consistent with the criteria set forth by the White House Office of Science and Technology Policy. With high quality people, systems and processes, we intend to be a center of excellence for vaccine development.”

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.[1]

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix’s portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’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 (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the second quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that Phase 2 ready and has been granted Breakthrough Therapy Designation by the FDA. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the second half of 2022. Tonix’s rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan-Drug Designation by the FDA. Tonix’s immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500 which is a humanized monoclonal antibody targeting CD40-ligand being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second half of 2022. Tonix’s infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. Tonix’s lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850, which are live virus vaccines based on Tonix’s recombinant pox live virus vector vaccine platform.

[1]*All of Tonix's product candidates are investigational new drugs or 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 the 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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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Source: Tonix Pharmaceuticals Holding Corp.