December 23, 2020

Tonix Pharmaceuticals Plans Commercial Scale Vaccine Manufacturing Facility

Hamilton, MT Facility Is Planned to Manufacture Vaccines at Commercial Scale, Including Vaccines Under Development for COVID-19

CHATHAM, N.J., Dec. 23, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has completed the purchase of an approximately 44-acre site in Hamilton, Montana, for the construction of a vaccine development and commercial scale manufacturing facility. In September 2020, Tonix completed the purchase of a 40,000 square foot facility in Massachusetts to house its new Advanced Development Center (ADC) for accelerated development and manufacturing of vaccines for clinical trials. Both the Montana and Massachusetts facilities are intended to support the development and production of Tonix's vaccine candidates, which are led by modified horsepox vaccines, TNX-1800, a potential COVID-19 vaccine and TNX-801, a potential smallpox and monkeypox vaccine.

"The COVID-19 pandemic exposed weaknesses in the U.S. domestic vaccine development and manufacturing capabilities," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "Tonix seeks to be a leader in the re-domestication of American vaccine development and production. We believe it is critical to bring these capabilities and high-tech jobs back to the U.S. both to finish the fight against the COVID-19 pandemic and to prepare for potential future pandemics. After the pandemic, we believe it is likely that COVID-19 will become endemic. That means humans will have to co-exist with COVID-19 and it will be a constant threat that can only be managed by maintaining a vaccinated population. To manage COVID-19 in the future, we need a next-generation COVID-19 vaccine that can be part of the standard childhood immunizations, like MMR for mumps, measles and rubella. We expect that such a vaccine will be a live-virus vaccine, because of their potential to provide durable protection and block forward transmission."

Dr, Lederman continued, "The planned Montana facility reflects our commitment to the development of our vaccines and, along with the recent announcement of our new ADC in Massachusetts, takes us a step closer to controlling and vertically integrating more of our development and manufacturing activities. While we applaud the recent successes and Emergency Use Authorizations of the first-generation COVID-19 vaccines, we believe that Tonix's live replicating viral vector vaccine technology in development remains an important initiative given all of the unanswered questions about those vaccines due to the novelty of their underlying technology and the expedited timelines allowed for emergency use authorization. Specifically, it is unknown whether the first-generation vaccines provide durable protection (for example a year after vaccination), protect against death, or block forward transmission. Tonix's lead COVID-19 vaccine candidate TNX-1800, is based on the backbone of the smallpox vaccine developed by Edward Jenner more than 200 years ago,

which led to the eradication of smallpox. TNX-1800 has been designed to have several important features including one shot dosing, ability to elicit a 'take' biomarker for T cell protection, stability during transport and storage, and scalability of manufacturing."

U.S. Senators Jon Tester and Steve Daines and Governor-elect Greg Gianforte have shown broad support of Montana's bioscience industry.

"Good news for Hamilton! It's great to see Montana leading in the bioscience industry which will help support Montana jobs and end our reliance on other countries for critical vaccines and prescription drugs," said Senator Steve Daines.

Senator Jon Tester echoed the sentiment, noting, "Montanans are hard workers and I am pleased to see more manufacturing jobs come to our state. The growing bioscience industry in Montana is good for our economy and will improve our public health."

Tonix joins the U.S. National Institutes of Health's Rocky Mountain Laboratories (RML) in Hamilton, which is an internationally recognized leader in vaccine development and virology research. GlaxoSmithKline (GSK) also has a vaccine manufacturing facility in Hamilton.

"It's no surprise that the bioscience industry is thriving in Montana," said Governor-elect Gianforte. "We have an unmatched work ethic. We're problem solvers. And we do it all from one of the most beautiful places in the world."

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. The Company's lead vaccine, TNX-1800, is based on the horsepox vector[1]. Horsepox 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: the only viral disease ever eradicated. Recently, it was shown that horsepox has 99.7% colinear identity with a circa 1860 U.S. smallpox vaccine[2]. TNX-1800 is expresses the SARS-CoV-2 spike protein after vaccination and is believed to elicit a predominantly T cell response which is expected to provide long term immunity and prevent forward transmission. Tonix expects to report efficacy data from animal challenge studies of TNX-1800 in the first quarter of 2021.

About TNX-801*

TNX-801 is a live virus vaccine based on synthesized horsepox[1]. Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. Molecular analysis of archaic smallpox vaccines shows that horsepox is closer than modern smallpox vaccines in DNA sequence to the vaccine discovered and disseminated by Dr. Edward Jenner, including the recent report that horsepox shares 99.7% co-linear identity with a U.S. smallpox vaccine from circa 1860[2]. The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[3]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[1]. Tonix's TNX-801 vaccine candidate is administered percutaneously using a two-pronged, or "bifurcated" needle. The major cutaneous reaction or "take" to vaccinia vaccine was described by Dr. Edward Jenner in 1796 and has been used since then as a biomarker for protective immunity to smallpox, including in the World Health Organization's (WHO) accelerated

smallpox eradication program that successfully eradicated smallpox in the 1960's. The "take" is a measure of functional T cell immunity validated by the eradication of smallpox, a respiratory-transmitted disease caused by variola. Tonix's proprietary horsepox vector is believed to be more closely related to Jenner's vaccinia vaccine than modern vaccinia vaccines, which appear to have evolved by deletions and mutations to a phenotype of larger plaque size in tissue culture and greater virulence in mice. TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge[4].

About TNX-1800**
TNX-1800 is a live modified horsepox virus vaccine for percutaneous administration that is designed to express the Spike protein of the SARS-CoV-2 virus and to elicit a predominant T cell response. TNX-1800 is based on a horsepox vector, which is a live replicating, attenuated virus that elicits a strong immune response. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been explored as platforms for vaccine development because they possess; (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) readily manufacturable at scale, and (7) ability to provide direct antigen presentation. Relative to vaccinia, horsepox has substantially decreased virulence in mice[1]. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, that can be manufactured using conventional cell culture systems, with the potential for mass scale production and packaging in multi-dose vials. Like TNX-801, Tonix's TNX-1800 vaccine candidate is administered percutaneously using a two-pronged, or "bifurcated" needle. Tonix recently reported that immunization with a single dose of TNX-1800 induced "takes" and neutralizing anti-SARS-CoV-2 antibodies in non-human primates.

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 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 since positive data on the RELIEF Phase 3 trial were recently reported. The Company expects topline data in the Phase 3 RALLY study in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. 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 efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

*TNX-801 is in the pre-IND stage and has not been approved for any indication.
**TNX-1800 is in the pre-IND stage and has not been approved for any indication.
***TNX-102 SL is an investigational new drug and has not been approved for any indication.

[1]Noyce RS, et al. (2018) PLoS One. 13(1):e0188453

[2]Brinkmann A et al, (2020) Genome Biology 21:286https://doi.org/10.1186/s13059-020-02202-0

[3]Trindale GS et al. Viruses (2016) (12). pii: E328. PMID:27973399

[4]Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

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
(862) 904-8182

Olipriya Das, Ph.D. (media)
Russo Partners
Olipriya.Das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)
Westwicke

peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.