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# **Tonix Pharmaceuticals Announces FUJIFILM Diosynth Biotechnologies to be Manufacturing Partner for COVID-19 Vaccine Candidate TNX-1800**

**Collaboration includes Development of Manufacturing Processes and to Supply Clinical Trial Material to Support Tonix's Development of TNX-1800**

NEW YORK, June 01, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby FUJIFILM Diosynth Biotechnologies (FDB) will provide contract manufacturing and development services to support the manufacturing of Tonix's COVID-19 vaccine candidate, TNX-1800, for clinical trial supply.

"Tonix is proud to partner with FUJIFILM Diosynth Biotechnologies, a leader in pharmaceutical manufacturing and development," said Seth Lederman, M.D., President and Chief Executive Officer. "Live replicating orthopoxvirus vaccines have the potential for scalability to supply very large markets because the projected dose of vaccine (2.5-12.5 x 10<sup>5</sup> PFU) is relatively low and it is typical to provide the vaccines with 100 doses in each glass vial as is the case for licensed smallpox vaccine. This collaboration allows Tonix to benefit from FUJIFILM Diosynth Biotechnologies' leading technical expertise in process development and commercial cGMP production to have a meaningful impact in the fight against this pandemic."

Under the agreement, FUJIFILM Diosynth Biotechnologies will develop a manufacturing process, manufacture, and stock a supply of TNX-1800 at FDB's College Station, Texas site for Tonix's clinical development. FDB's manufacturing site in College Station, Texas is a state-of-the-art facility designed to operate as a flexible, responsive contract manufacturing facility to support production on multiple scales as candidates move through the clinical process from clinical stages into commercialization.

"FUJIFILM Diosynth Biotechnologies is excited to be Tonix's manufacturing partner for TNX-1800, their potential vaccine for COVID-19," said Martin Meeson, President and Chief Executive Officer. "We believe that our team's expertise with vaccinia manufacturing may apply directly to manufacturing horsepox-based vaccines. FUJIFILM Diosynth Biotechnologies is capable of providing large scale production of viral vaccines to support the demands required in this pandemic."

In February, Tonix announced a strategic collaboration with Southern Research to support

the development of TNX-1800\* (live modified horsepox virus vaccine for percutaneous administration) to protect against the new coronavirus disease, COVID-19, based on Tonix's proprietary horsepox vaccine platform. Tonix is developing TNX-801 (live horsepox virus vaccine for percutaneous administration) as a potential smallpox preventing vaccine for the U.S. strategic national stockpile and as a monkeypox preventing vaccine. The Company believes that its proprietary horsepox virus has the potential to serve as a vector for vaccines to protect against other infectious agents.

### **About TNX-801\* and TNX-1800\***

TNX-801 is a live virus vaccine based on synthesized horsepox<sup>1,2</sup>. TNX-1800 is a modified horsepox virus that is designed to express a protein from the virus that causes COVID-19, which is known as SARS-CoV-2. Molecular analysis suggests that TNX-801 has relatively "complete" left and right inverted terminal repeats (ITRs) while different vaccinia isolates have a variety of deletions in the left and right ITRs. Therefore, TNX-801 has additional genes, relative to vaccinia vaccines, that may play roles in host immune interactions and one or more of such proteins may serve as antigens for protective immunity. Molecular analysis also shows that horsepox is closer than modern vaccines in DNA sequence to the vaccine discovered and disseminated by Dr. Edward Jenner<sup>2,3,4</sup>. No new gene elements were added to the natural isolate and the small plaque size in culture appears identical to the U.S. Centers for Disease Control publication of the natural isolate<sup>5</sup>. Relative to vaccinia, horsepox has substantially decreased virulence in mice<sup>1</sup>. TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge<sup>6</sup>.

<sup>1</sup>Noyce RS, et al. (2018) *PLoS One*. 13(1):e0188453

<sup>2</sup>Tulman ER, et al. (2006) *J Virol*. 80(18):9244-58.PMID:16940536

<sup>3</sup>Schrick L et al. *N Engl J Med*. (2017) 377:1491.

<sup>4</sup>Qin et al. *J. Virol*. 89:1809 (2015).

<sup>5</sup>Trindale GS et al. *Viruses* (2016) (12). pii: E328. PMID:27973399

<sup>6</sup>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>)

\*TNX-801 and TNX-1800 are in the pre-IND stage and have not been approved for any indication.

### **About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. In 2020, Tonix announced a program to develop a potential vaccine, TNX-1800\* (live modified horsepox virus vaccine for percutaneous administration) to protect against the novel coronavirus disease emerging in 2019, or COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform and is molecularly designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. TNX-801\* (live horsepox virus

vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL\*\*, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in September of 2020 and topline data in the first quarter of 2021. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya\*\*\*) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second 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 in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. Tonix's preclinical pipeline includes 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-1200\* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

\*TNX-1800, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.

\*\*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

\*\*\*Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

### **About FUJIFILM Diosynth Biotechnologies (FDB)**

FDB is an industry-leading biologics contract development and manufacturing organization with locations in Teesside, UK; Research Triangle Park, North Carolina; College Station, Texas; and Hillerød, Denmark. FDB has over 30 years of experience in the development and manufacturing of recombinant proteins, vaccines, monoclonal antibodies, among other large molecules, viral products and medical countermeasures expressed in a wide array of microbial, mammalian, and host/virus systems. The company offers a comprehensive list of

services from cell line development using its proprietary pAVEway™ microbial and Apollo™X cell line systems to process development, analytical development, clinical and FDA-approved commercial manufacturing. FDB is a partnership between FUJIFILM Corporation and Mitsubishi Corporation. For more information, go to [www.fujifilmdiosynth.com](http://www.fujifilmdiosynth.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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