October 8, 2024

Tonix Pharmaceuticals Announces AI Collaboration with X-Chem to Develop Broad-Spectrum Antivirals

AI (Artificial Intelligence) and ML (Machine Learning) drug discovery collaboration will accelerate the development of small molecules as orally available host-targeted broad-spectrum medical countermeasures

Host-directed antiviral drugs have the potential to enhance the immune response to viruses from a range of viral families

Tonix was awarded a contract with the U.S. Department of Defense for up to $34 million for the accelerated development of its host-directed broad-spectrum antiviral program TNX-4200

CHATHAM, N.J., Oct. 08, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that it has entered into an AI and ML research collaboration with X-Chem, Inc. (X-Chem), a leader in small molecule drug discovery, to accelerate development of Tonix's oral broad-spectrum antivirals.

Tonix's TNX-4200 antiviral program focuses on the development of oral CD45 phosphatase inhibitors, with broad-spectrum activity against a range of viral families. As previously disclosed, Tonix entered into a contract with the U.S. Department of Defense's Defense Threat Reduction Agency (DTRA) for up to $34 million to advance the development of Tonix's TNX-4200 broad-spectrum oral antiviral program for medical countermeasures, including an Investigational New Drug (IND) submission and a first-in-human Phase 1 clinical study.

"We are excited to enter into this research collaboration with X-Chem, which we believe will expand our capabilities, and deepen our understanding of host-targeted small molecule therapeutics for a variety of targets," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "With the support of X-Chem's drug discovery AI/ML technology, we expect to optimize the physicochemical properties, pharmacokinetics, and safety attributes of our drug candidates."

"We are excited to partner with Tonix in their pursuit of such important programs in human health, at the intersection of laboratory and *in silico* technology. This collaboration highlights how integrative work continues to leverage the creation of target-specific high-quality data to drive AI drug discovery," said Erin Davis, Ph.D., Chief Technology Officer of X-Chem."

The DTRA contract awarded to Tonix is expected to help fund and accelerate the development of the Company's lead oral host-directed TNX-4200 broad-spectrum antiviral program. The TNX-4200 program aims to reduce viral load and to allow the adaptive immune system to alert the other arms of the immune system to mount a protective response. Tonix plans to leverage previous research on phosphatase inhibitors to optimize lead compounds for therapeutic intervention of biothreat agents.

For the oral broad-spectrum antiviral programs, including TNX-4200, Tonix is utilizing its state-of-the-art research laboratory capabilities, including a Biosafety Level 3 (BSL-3) lab and an Animal Biosafety Level 3 (ABSL-3) facility at its research and development center (RDC) located in Frederick, Md., as well as experienced personnel in-house. The RDC is located in Maryland's 'I-270 biotech corridor' and is close to the center of the U.S. biodefense research community.

About X-Chem, Inc.

X-Chem, Inc. is a leader in small molecule drug discovery services for pharmaceutical and biotech companies. As pioneers of DNA-encoded chemical library (DEL) technology and its integration with proprietary AI technology and computational sciences, X-Chem can accelerate all steps in the discovery process. The company leverages its unique AI/ML approach, market-leading DEL platform, and computationally-driven medicinal chemistry expertise to discover novel small molecule leads against challenging, high-value therapeutic targets. Integrated with X-Chem's extensive chemistry and computational technologies, project teams can deliver clinical candidates with unmatched speed. X-Chem also provides libraries, reagents, and informatic tools to allow DEL operators to get the most of their DEL platform. X-Chem empowers its partners to effectively build drug pipelines from target to clinical candidate, enhanced with AI and extensive data packages.

Further information about X-Chem can be found at www.x-chemrx.com.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in October of 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL was generally well tolerated in the Phase 3 program. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years to develop TNX-4200 small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. The company's Good Manufacturing Practice (GMP)-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801 and the GMP suites are ready to be reactivated in case of a national or international emergency. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has

Breakthrough Therapy designation. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease and infectious disease. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

* Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

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; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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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