

July 1, 2024



# **Tonix Pharmaceuticals Awarded Up to \$34 Million U.S. Department of Defense Contract for Accelerated Development of Broad-Spectrum Antiviral Program**

**Defense Threat Reduction Agency (DTRA) contract is expected to advance development of Tonix's broad-spectrum oral antiviral program TNX-4200 for medical countermeasures**

CHATHAM, N.J., July 01, 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 it has been awarded an Other Transaction Agreement (OTA) with a potential for up to \$34 million over five years by the Defense Threat Reduction Agency (DTRA), an agency within the U.S. Department of Defense (DoD). The objective of the contract is to develop small molecule broad-spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments.

Tonix's program will focus on optimization and development of its TNX-4200 program, to develop an orally available CD45 antagonist, with broad-spectrum efficacy against a range of viral families through preclinical evaluation. The program is expected to establish physicochemical properties, pharmacokinetics, and safety attributes to support an Investigational New Drug (IND) submission and to fund a first-in-human Phase 1 clinical study.

"Through our agreement with DTRA, our broad-spectrum antiviral research program will address the DoD's goal of protecting U.S. Joint Forces in the event biological weapons are introduced onto the battlefield," said Seth Lederman, M.D., President, and Chief Executive Officer of Tonix. "The DoD announced in December 2022 that they are moving beyond a 'one bug, one drug' approach and are seeking broad-spectrum drugs since one cannot predict which or how many viruses may be deployed.<sup>1</sup> This funding provides important validation for our ongoing research and current in-house capabilities, and will enable Tonix to advance its antiviral discovery program."

The \$34 million five-year contract will help fund and accelerate the development of the Company's broad-spectrum antiviral program, which has the potential to reduce viral load and 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, specifically compounds that target CD45, to optimize lead compounds for

therapeutic intervention of biothreat agents and provide the government with a complete and cost-effective solution for a broad-spectrum medical countermeasure. Tonix's premise is that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations, a lower dose, and a better safety profile.

Tonix will utilize 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.

<sup>1</sup> "Approach for Research, Development, and Acquisition of Medical Countermeasure and Test Products." 2022. Chemical and Biological Defense Program. U.S. Department of Defense. <https://media.defense.gov/2023/Jan/10/2003142624/-1/-1/0/APPROACH-RDA-MCM-TEST-PRODUCTS.PDF> (accessed March 5, 2024)

### **About Defense Threat Reduction Agency (DTRA)**

The Defense Threat Reduction Agency (DTRA), an agency within the United States Department of Defense (DoD) is both a Defense Agency and Combat Support Agency with two distinct yet highly integrated roles countering Weapons of Mass Destruction (WMD) and emerging threats. Its origins stretch back to World War II and the Manhattan Project, but today the agency encompasses a wide variety of strategic and operational functions that deter, prevent, and ultimately prevail against these unique threats. DTRA enables the Department of Defense (DoD), the United States Government and international partners to counter and deter weapons of mass destruction (WMD) and emerging threats. DTRA provides cross-cutting solutions to enable the Department of Defense, the United States Government, and international partners to deter strategic attack against the United States and its allies; prevent, reduce, and counter WMD and emerging threats; and prevail against WMD-armed adversaries in crisis and conflict. DTRA's continued effort to enhance the combat support mission also advances public health services by developing innovative technologies that protect against biological threats. For more information, visit [www.dtra.mil](http://www.dtra.mil).

### **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 development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for Tonmya<sup>1</sup>, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction as well as fibromyalgia-type Long COVID. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic 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<sup>®</sup>

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 and have not been approved for any indication.

<sup>1</sup>Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has 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](http://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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