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Tonix Pharmaceuticals Joins the Alliance for Biosecurity

NEW YORK, Oct. 15, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today that it has joined the Alliance for Biosecurity (the Alliance). The Alliance is a coalition of biopharmaceutical companies and laboratory/academic partners that promotes a strong public-private partnership to ensure medical countermeasures are available to protect public health and enhance national health security. The Alliance advocates for public policies and funding to support the rapid development, production, stockpiling, and distribution of critically needed medical countermeasures.

“We are excited to join the Alliance as it helps build and strengthen partnerships between biopharmaceutical companies and the government,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “Tonix has two programs in development to improve biodefense by potentially providing safe and effective countermeasures against possible biological and radiological threats.”

Anthony Macaluso, Ph.D., Tonix’s Executive Vice President of Strategic Development, added, “Tonix is developing innovative products that are designed to potentially protect the public from attacks with biological agents and radioactive materials. Our lead biodefense program is TNX-801, a potential smallpox-preventing vaccine. The U.S. maintains a stockpile of smallpox vaccines to protect the public in the event of malicious re-introduction of variola by terrorists or rogue states. We look forward to working with the Alliance on advocating for medical countermeasures.”

"The Alliance for Biosecurity is pleased to welcome Tonix to our team,” said Chris Frech, Co-Chair of the Alliance for Biosecurity. “As a voice for industry, the addition of Tonix helps amplify the Alliance's stance for preparedness against the threats of chemical and biological warfare. Our goal has always been to communicate with policymakers and highlight how our public-private partnerships must stay ahead of those who wish to do harm.”

About TNX-801

TNX-801, live virus vaccine for percutaneous (scarification) administration, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus. It is currently in the pre-Investigational New Drug (IND) application stage of development. TNX-801 demonstrated the ability to protect against lethal vaccinia infection in a mouse model which may be indicative of vaccine protection in humans.

About the Alliance for Biosecurity

The Alliance for Biosecurity promotes a stronger, more effective partnership between

government, the biopharmaceutical industry, and other stakeholders in order to advance their shared goal of developing critically needed medical countermeasures. The Alliance also seeks to develop sound public policy proposals that could bolster national efforts to rapidly develop, produce, stockpile, and distribute medical countermeasures.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix has two other programs in the pre-Investigational New Drug (IND) application stage of development for PTSD, but with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate) and TNX-1600, a triple reuptake inhibitor. Tonix is also developing TNX-102 SL as a bedtime treatment for the chronic pain condition fibromyalgia, which is in Phase 3 development. Tonix has two programs for addiction conditions: TNX-102 SL is in the pre-IND application stage for alcohol use disorder program and TNX-1300** (double-mutant cocaine esterase) is in Phase 2 development for the treatment of cocaine intoxication. Tonix's preclinical pipeline includes two programs to improve biodefense through potential medical counter-measures, a program to prevent and treat organ transplant rejection and finally a program to treat gastric and pancreatic cancers.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL for the treatment of PTSD. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has 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 failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2018, as filed with the

Securities and Exchange Commission (the “SEC”) on March 18, 2019, 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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