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Tonix Pharmaceuticals Announces Issuance of U.S. Patent for Use of TNX-1700, a Stabilized Recombinant Form of Trefoil Factor 2 (TFF2), for Treating Gastric and Pancreatic Cancers

CHATHAM, N.J., Nov. 15, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the U.S. Patent and Trademark Office issued U.S. Patent No. 11,167,010 on November 9, 2021. The patent, entitled "Trefoil Family Factor Proteins and Uses Thereof," includes claims directed to an isolated polypeptide comprising a carboxy-terminal (CTP) domain of the beta subunit of the human chorionic gonadotropin (hCG) fused to a TFF2 protein (TFF2-CTP). This patent, excluding possible patent term extensions, is expected to provide U.S. market exclusivity until April 2, 2033.

TNX-1700* is a stabilized recombinant modified form of Trefoil Family Factor 2, or rTFF2, which Tonix licensed from Columbia University in 2019. Tonix is developing the biologic to treat gastric and pancreatic cancers. TFF2 is a small, secreted protein, expressed in gastrointestinal mucosa where it functions to protect and repair mucosa. TFF2 is also expressed at low levels in splenic immune cells and is now appreciated to have intravascular roles in spleen and in the tumor microenvironment. In gastric cancer, TFF2 is epigenetically silenced, therefore, TFF2 is suggested to be protective against cancer development through several mechanisms.

In 2020, data from a preclinical study were presented which investigated the role of PD-L1 in colorectal tumorigenesis and evaluated the utility of targeting myeloid-derived suppressor cells (MDSCs) with TFF2-CTP in combination with PD-1 blockade in mouse models of colorectal cancer. The data showed that anti-PD-1 monotherapy was unable to evoke anti-tumor immunity in this model of colorectal cancer, but TFF2-CTP augmented the efficacy of anti-PD-1 therapy. Anti-PD-1 in combination with TFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice.

**TNX-1700 is an investigational new biologic at the pre-IND stage of development and has 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 therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of immunology and central

nervous system (CNS) product candidates. Tonix's immunology portfolio includes COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL¹ (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300² is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800³, is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is developing TNX-2100⁴, an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study in the fourth quarter of 2021, pending IND clearance. TNX-3500⁵ (sangivamycin, i.v. solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

¹TNX-102 SL is an investigational new drug and has not been approved for any indication.

²TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.

³TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.

⁴TNX-2100 is an investigational new biologic and has not been approved for any indication

⁵TNX-3500 is an investigational new drug at the pre-IND stage of development 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, the risks related to intellectual property rights and protections related to TNX-1700, 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, 2020, as filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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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