June 22, 2020

Tonix Pharmaceuticals Announces Results from Preclinical Study of TNX-1700 Presented in a Poster at AACR Virtual Annual Meeting 2020

TNX-1700 (Stabilized Recombinant Trefoil Factor 2) (rTFF2-CTP) Enhances Anti-tumor Activity of PD-1
blockade in Mouse Models of Colorectal Cancer

NEW YORK, June 22, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that preclinical results of TNX-1700 are being presented in a poster at the American Association of Cancer Research (AACR) Virtual Annual Meeting II. The meeting is being held online June 22-24, 2020. The poster can be found on the Scientific Presentations page of Tonix's website.

A poster, titled "Stabilized recombinant trefoil factor 2 (TFF2-CTP) enhances anti-tumor activity of PD-1 blockade in mouse models of colorectal cancer," includes data from a preclinical study which investigated the role of PD-L1 in colorectal tumorigenesis and evaluated the utility of targeting myeloid-derived suppressor cells (MDSCs) in combination with PD-1 blockade in mouse models of colorectal cancer. The data show 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. Tonix is developing TNX-1700 (rTFF2-CTP) for the treatment of gastric, colon and pancreatic cancers under a license from Columbia University. The studies conducted were performed by scientists at Columbia University under the direction of Timothy Wang, M.D., Chief of the Division of Digestive and Liver Diseases at Columbia University Irving Medical Center.

"Colorectal cancer is notoriously unresponsive to anti-PD1 treatment, which has revolutionized the treatment of other cancers and is known as immuno-oncology. Much research has been focused on trying to turn anti-PD1 unresponsive tumors into anti-PD1 responsive tumors," said Seth Lederman, M.D., Chief Executive Officer of Tonix.

"The data from this preclinical trial demonstrate that TNX-1700 treatment converted anti-PD1 non-responsive colorectal tumors into anti-PD1 responsive tumors," said Dr. Wang. "In addition, it was shown that TNX-1700 inhibits the MDSCs which contribute to the toxic element of the tumor microenvironment. Therefore, whether a tumor is anti-PD1 non-responsive or responsive may relate to the tumor microenvironment rather than the tumor itself."

“We believe these data warrant additional work to learn if TNX-1700 modifies the toxic tumor microenvironment in humans and will make colorectal cancer responsive to anti-PD-1 therapy,” added Dr. Lederman.

About TNX-1700

TNX-1700 is a stabilized recombinant version of Trefoil Factor 2 (TFF2). TFF2 is a small secreted protein, encoded by the TFF2 gene in humans that is 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, and TFF2 is suggested to be protective against cancer development through several mechanisms.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix’s portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead vaccine candidate, TNX-1800*, is based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix’s lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the first quarter of 2021. 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 another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix’s preclinical pipeline includes TNX-1600 (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD, 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-1800, TNX-801 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.

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; 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.