November 30, 2022

Tonix Pharmaceuticals Announced Data from its Fully Human anti-SARS-CoV-2 Monoclonal Antibody Platform in an Oral Presentation at the World Antiviral Congress

Research Being Conducted in Collaboration with Scientists at Columbia University

SARS-CoV-2 Variants have Evaded Antibody Therapeutics Previously Granted FDA Emergency Use Authorization, but which are No Longer Recommended for Use by the NIH COVID-19 Guidelines Panel

Immunocompromised Individuals, Including Organ Transplant Recipients, are at Increased Risk of Severe COVID-19 and Poor Outcomes

Therapeutic Antibody Platform Leverages Tonix's Expanding Internal Development and Manufacturing Capabilities for Biologics

CHATHAM, N.J., Nov. 30, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced data from its fully human anti-SARS-CoV-2 monoclonal antibody platform in an oral presentation delivered by Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals, at the World Antiviral Congress 2022 in San Diego, Calif. The project is part of a broader research collaboration and option agreement with scientists at Columbia University designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation upon which to target vaccines and therapeutics to appropriate individuals by precision medicine. A copy of the presentation is available under the Scientific Presentations tab of the Tonix website atwww.tonixpharma.com.

The presentation titled, *"Platform for Generating Fully Human anti-SARS-CoV-2 Spike Therapeutic Monoclonal Antibodies"* highlights the need for a broad array of monoclonal antibodies (mAbs) which can be scaled up quickly and potentially combined with other mAbs to treat or prevent COVID-19.

"We believe that the development of these fully human mAbs strengthens our pipeline of next-generation therapeutics to treat Covid-19," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Immunocompromised individuals, including organ transplant recipients, are at increased risk of severe COVID-19 and bad outcomes[1]. Although five mAb products, containing 7 distinct mAbs, have received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for either treatment

or prophylaxis of COVID-19, only a single product, Evusheld® is still recommended for use as a prophylaxis by the NIH COVID Guidelines panel or FDA[2,3]. Moreover, concerns have been raised about the ongoing ability of Evusheld® to serve as a prophylaxis against COVID-19 in the face of new variants[4]. For these reasons, we believe there is a need for second generation mAb treatments and prophylactics for COVID-19[5]. Generating fully human mAbs starting from recovered patient blood samples has the potential to reduce the time required to create novel therapeutics in response to newly identified COVID-19 variants."

Ilya Trakht, Ph.D., Associate Research Scientist at Columbia and principal investigator of the sponsored research agreement said, "We are excited to work with Tonix because of their commitment to developing therapeutics to COVID-19. As new variants emerge, anti-spike mAbs that were highly effective against older variants of SARS-CoV-2, may quickly lose their place in the treatment landscape. To protect immunocompromised people, we are committed to assembling a diverse inventory of monoclonal antibodies to keep pace with circulating mix of SARS-CoV-2 variants. Our proprietary technology is based on CD40-ligand promoted B-cell expansion and the MFP-2S human hybridoma system"

Seth Lederman added, "This potential therapeutic antibody platform leverages our expanding internal development and manufacturing capabilities for biologics."

[1]Haidar G, Mellors JW. Improving the Outcomes of Immunocompromised Patients With Coronavirus Disease 2019. *Clin Infect Dis*. 2021;73(6):e1397-e1401. Doi:10.1093/cid/ciab397

[2]https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/ - accessed Nov 3, 2022

[3]"FDA Updates on Bebtelovimab" – "This information shows that bebtelovimab is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1." – www.fda.gov/drugs/drug-safety-and-availability/fda-updates-bebtelovimab- Accessed Nov 4, 2022

[4]Wu, K.J. October 29, 2022. The Atlantic. "The End of Evusheld: If you're immunocompromised, this … isn't great. www.theatlantic.com/health/archive/2022/10/covid-variants-antibody-treatments-immunocompromised/671929/

[5]Madison Muller, M. November 16, 2022 Bloomberg. "Doctors Are Running Out of Antibody Drugs to Treat Covid as Virus Mutates." www.bloomberg.com/news/articles/2022-11-16/covid-s-mutations-leave-doctors-with-far-fewer-antibody-drugs-to-treat-virus?

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study

launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the second quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the fourth quarter of 2022. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes 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 and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the first half of 2023. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. Tonix's lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform.

**All of Tonix's product candidates are investigational new drugs or biologics and have 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 the 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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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