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Tonix Pharmaceuticals Announces Exclusive License of Potential Therapeutic or Preventative Humanized anti-SARS-CoV-2 Monoclonal Antibodies from Curia Global, Inc.

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

SARS-CoV-2 has Mutated to Evade the Existing EUA-Approved Therapeutic Monoclonal Antibody Therapies

CHATHAM, N.J., Dec. 12, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced that it has obtained an exclusive license from Curia Global, Inc., a leading contract research, development and manufacturing organization, for the development of three humanized murine monoclonal antibodies (mAbs) for the treatment or prophylaxis of SARS-CoV-2 infection. SARS-CoV-2 is the cause of COVID-19.

“We believe that the licensing of these 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 poor clinical outcomes[1]. Although five monoclonal antibody products, containing seven distinct monoclonal antibodies, 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 National Institutes of Health COVID-19 Treatment Guidelines Panel or FDA[2,3]. Moreover, concerns have been raised about the ongoing ability of Evusheld® to prophylax in the face of new variants[4]. We believe there is a need for second generation mAb treatments and prophylactics for COVID-19[5]. To date, the EUA-approved products have been derived from the blood of COVID-convalescent patients or a humanized mouse[6,7]. The Company believes that humanized murine monoclonal antibodies discovered by Curia and licensed by Tonix represent a potential new approach to treating SARS-CoV-2 infection. The Company believes that murine monoclonal antibodies have the potential for neutralizing a broader spectrum of SARS-CoV-2 variants and may be harder for SARS-CoV-2 to evade as we face a ‘variant soup’ from both convergent and divergent evolution.”[8]

Brian Zabel, Ph.D., Senior Director at Curia said, “We are excited to work with Tonix because of their commitment to developing therapeutics to COVID-19. Murine monoclonal antibodies represent a different approach and one that has the potential to generate high affinity antibodies that recognize different epitopes on the SARS-CoV-2 spike protein. Mice have a different repertoire of antibodies and the Curia technology for generating antibodies optimizes the selection of appropriate B cells by the timing of immunization, harvesting approach and screening platform.”

Seth Lederman added, “The potential therapeutic antibodies licensed leverage our expanding internal development and manufacturing capabilities for biologics. These murine monoclonal antibodies and their humanized counterparts build on a base of knowledge from the fully human monoclonal antibody platform, TNX-3600, which we are developing with Columbia University.”

[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 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?

[6]Hansen J et al. *Science*. 2020 Aug 21;369(6506):1010-1014. Doi: 10.1126/science.abd0827

[7] Asdaq, S.M.B. et al. A Patent Review on the Therapeutic Application of Monoclonal Antibodies in COVID-19. *Int. J. Mol. Sci.* 2021, 22, 11953. https://doi.org/10.3390/ijms222111953

[8]Callaway, E. Oct 28 2022. *Nature (News)*. COVID ‘variant soup’ is making winter surges hard to predict: Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6

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 first quarter of 2023. 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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