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# **Tonix Pharmaceuticals Appoints Zeil Rosenberg, M.D., M.P.H., as Executive Vice President, Medical for Infectious Disease Programs**

## **Dr. Rosenberg Will Lead Clinical Development of Tonix's Vaccine and Antiviral Programs**

CHATHAM, N.J., Jan. 04, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the appointment of Zeil Rosenberg, M.D., M.P.H. as its new Executive Vice President, Medical. In this role, Dr. Rosenberg will be responsible for leading Tonix's clinical development efforts for vaccines and antivirals. Dr. Rosenberg will be based in the Company's Chatham, N.J. headquarters, and as part of his role will oversee the clinical development of Tonix's vaccine for smallpox and monkeypox, TNX-801, the vaccine for COVID-19, TNX-1850, and the antiviral anti-SARS-CoV-2 spike protein monoclonal antibodies, TNX-3600 and TNX-3800, to protect immunocompromised individuals from severe COVID-19.

"We are pleased to welcome Dr. Rosenberg to Tonix's clinical team to lead the development of our infectious disease programs at a time when Tonix continues to make meaningful progress in the clinical development of multiple programs within its robust pipeline," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals.

"Dr. Rosenberg brings to our team expertise as an infectious disease drug developer and we are fortunate to have someone with Dr. Rosenberg's skills, vision and operational expertise join at a pivotal time in the evolution of our infectious disease product portfolio, with our vaccine candidate for monkeypox, TNX-801, expected to enter clinical testing in 2023, and TNX-3600 and TNX-3800 moving ahead in pre-clinical development to address the need for anti-SARS-CoV-2 monoclonal antibodies for immune-compromised individuals," said Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals. "At Becton, Dickinson and Company (BD), Dr. Rosenberg worked on the development of the BD Bifurcated Needle, a safety-engineered improved bifurcated needle device for the percutaneous administration of live virus vaccinia vaccines, as well as BD VaxiNet™, a data monitoring system to improve patient safety in smallpox vaccine mass immunization efforts, which we believe have direct relevance to our recombinant poxvirus (RPV) platform."

"I am thrilled to join Tonix's executive management team and lead the clinical development of its infectious disease portfolio," said Dr. Rosenberg. "I look forward to working together with the talented Tonix team to advance the Company's portfolio of promising vaccines and

antiviral therapies and help bring them to as many appropriate patients as possible."

Dr. Rosenberg was most recently at PPD, part of Thermo Fisher Scientific, serving as Executive Director, Biotech and as Therapeutic Area Head for Vaccines at its Accelerated Enrollment Solutions Group, where he provided leadership on multiple successful COVID-19 vaccine clinical trials. At BD he was Worldwide Business Leader and Medical Director for Immunization, and was Vice President for Medical Affairs at Admera Health, a medical diagnostics company focused on precision medicine. He was key to the launch of a global public private partnership, including UNICEF and WHO, to help eliminate maternal and neonatal tetanus through immunization, resulting in the significant reduction of neonatal mortality. He served as National Immunization Advisor to the Indonesian Ministry of Health in Jakarta, sponsored by the U.S. Agency for International Development (USAID), and as Chief Technical Officer for Immunization at USAID, Washington, D.C.

Dr. Rosenberg received his B.A. with Honors and Distinction at Stanford University, earned his M.D. at the University of California, San Francisco and completed his internship and residency at Mount Sinai and Cornell University Medical College, respectively. He holds a Masters of Public Health from Columbia University. Dr. Rosenberg is an elected Fellow of both the American College of Preventive Medicine and the New York Academy of Medicine, and Specialty Fellow of the American Academy of Pediatrics. He has served as AAS Science, Engineering and Diplomacy Fellow.

### **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 third 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 includes a vaccine in development to prevent smallpox and monkeypox, TNX-801, a next-generation vaccine to prevent COVID-19, TNX-1850, a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600, and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800, recently licensed from Curia. 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 second half of 2023.

*\* 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](http://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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