May 19, 2020

Tonix Pharmaceuticals Announces Appointment of Herbert Harris, M.D., Ph.D., as Executive Vice President, Translational Medicine

NEW YORK, May 19, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the appointment of Herbert Harris, M.D., Ph.D., as its new Executive Vice President, Translational Medicine, effective May 15, 2020. In this role, Dr. Harris will focus on advancing Tonix's pre-clinical pipeline, including the potential COVID-19 vaccine into the clinic, as well as participate in Tonix's ongoing clinical programs.

Dr. Gregory Sullivan, Chief Medical Officer of Tonix said, "The recruitment of Dr. Harris to our management team is opportune, arriving at a time Tonix has launched its COVID-19 program and expanded its pipeline of clinical candidates including those in addiction, mood disorders, and geriatric psychiatry. Dr. Harris' career has exemplified the translational tradition of bringing bench to bedside, with extensive training and research in our Nation's premier academic and National Institutes of Health (NIH) intramural programs. Moreover, he has applied that expertise to pharmaceutical drug development in industry for many years, and thus brings to Tonix a wealth of experience advancing therapeutics in critical underserved areas that align well with our mission. He will be an asset to both our management team and to the development of our pipeline as Tonix advances its therapeutics, with the goal of ultimately delivering much needed therapeutics for the benefit of patients."

"It's exciting to join a company with such an experienced management team and sense of purpose towards finding treatments for underserved populations," said Dr. Harris. "Developing the COVID-19 vaccine is particularly exciting because T cell immunity has been a great interest since my doctoral work. I believe T cell immunity, and particularly TH1 type immunity, will be important in protecting against serious COVID-19 disease and in clearing the virus. Clearing the virus, which I believe requires CD8 T cell immunity in similar viral illnesses, will be important to decreasing forward transmission. I look forward to offering my capabilities and strategic mindset to the Tonix team as the company continues to grow and progress its pipeline."

Dr. Harris earned his M.D. and Ph.D. degrees from the University of Pittsburgh. Dr. Harris' Ph.D. work in immunology involved the regulation of cell surface expression and turnover of Class I MHC antigens, which are the targets of CD8 T cells. Class I MHC proteins play a crucial role in directing T cell-mediated immune responses in transplantation and antiviral immunity. The regulation of these proteins by cytokines was a central focus of this work. Dr.

Harris completed residency training in psychiatry at Yale University. He performed postdoctoral research on the neurobiology of addiction in the laboratory of Dr. Eric Nestler, M.D., Ph.D. After the completion of clinical training, Dr. Harris served as Senior Staff Fellow at the National Institute on Aging, a division of the NIH, where his research focused on the mechanisms of programmed cell death in neurons. He subsequently served as Chief of the Geriatric Psychopharmacology Program and Chief of the Adult Psychopathology Branch at the National Institute of Mental Health. He also served as scientific liaison to the Neuropharmacology Division of the U.S. Food and Drug Administration. Dr. Harris subsequently joined industry and has devoted more than two decades to drug discovery and development at companies that include Merck, Cephalon, GlaxoSmithKline, and Jazz Pharmaceuticals. In addition, he has served as Tonix's Chief Medical Officer from 2009 to 2011 and for other early-stage companies that include Vela Pharmaceuticals, Validus Pharmaceuticals. Dr. Harris served on the Scientific Advisory Board of Tonix for approximately 10 years until his appointment as Tonix's Executive Vice President, Translational Medicine.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. Tonix is developing four potential vaccines, based on the horsepox viral vector platform to protect against the novel coronavirus disease emerging in 2019, or COVID-19: TNX-1800, TNX-1810, TNX-1820 and TNX-1830*. TNX-1800 is designed to express the Spike protein of the SARS-CoV-2 and to a predominant T cell response. TNX-1810, TNX-1820 and TNX-1830 are designed to express different proteins from SARS-CoV-2 and to elicit almost pure T cell responses. TNX-801* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL**, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in September of 2020 and topline data in the first quarter of 2021. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya***) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second quarter of 2020. 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 in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. Tonix's

preclinical pipeline includes 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-1200* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-1800, TNX-1810, TNX-1820, TNX-1830, TNX-801, TNX-1200 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.

***Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

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.

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Source: Tonix Pharmaceuticals Holding Corp.