September 30, 2024

Tonix Pharmaceuticals Announces Participation in Endpoints Panel at the Long COVID Workshop and RECOVER TLC Workshop Convened by the Foundation for the National Institutes of Health (FNIH) and the National Institute of Allergy and Infectious Diseases (NIAID)

Tonix's CEO Dr. Lederman shared perspectives from the development of TNX-102 SL for fibromyalgia and the proof-of-concept Phase 2 study of TNX-102 SL for Fibromyalgia-type Long COVID

CHATHAM, N.J., Sept. 30, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that Seth Lederman M.D., Chief Executive Officer of Tonix Pharmaceuticals, participated in the "Endpoints" panel at the *RECOVER Treating Long COVID (TLC) – Navigating the Pathway Forward* workshop hosted by the Foundation for the National Institutes of Health (FNIH) and National Institute of Allergy and Infectious Diseases (NIAID), held September 23-25, 2024, in Bethesda, Md.

The panel, titled "Endpoints," focused on clinical trial endpoints that could provide meaningful data to support regulatory approval of potential Long COVID therapeutics.

"We were honored to be invited to participate in the Long COVID workshop to discuss the progress of the RECOVER study and to plan the path forward for developing drugs to treat Long COVID," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We welcomed the opportunity to share lessons from our development of TNX-102 SL for Fibromyalgia-type Long COVID, and also for fibromyalgia for which we expect to submit the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in October. Given the urgency of the Long COVID situation, I recommended that the RECOVER-TLC team dialogue with FDA about validating Patient Global Impression of Change (PGIC) as a primary endpoint for therapeutics trials in the context of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)-type Long COVID."

Dr. Lederman continued, "FDA has already recognized PGIC as a potential endpoint in their recent draft guidance on patient-reported outcomes (PROs). I believe the development of

Long COVID drugs should emulate the highly successful regulatory pathway established for cancer drugs. I believe PGIC has the potential to be for Long COVID, what Progression-Free Survival (PFS) has been for new cancer drugs. There are several conceptual similarities that lead me to believe PGIC also could be an appropriate endpoint for accelerated approvals for CFS/ME and Long COVID drugs."

About the RECOVER Initiative

Millions of Americans suffer from Long COVID. This disease affects each person differently, so no single research study can provide all the answers to Long COVID for everyone. The National Institutes of Health (NIH) created the RECOVER Initiative to find answers across many different types of research studies.

RECOVER brings together clinicians, scientists, caregivers, patients, and community members to understand, treat, and prevent Long COVID. RECOVER has created the world's most comprehensive and diverse group of Long COVID study participants. For more information can be found at www.recovercovid.org.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders, and its priority is to submit a New Drug Application (NDA) to the FDA in October 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of 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 rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years in an Other Transaction Agreement (OTA) to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD, instrumental in progressing this development. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

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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; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the “SEC”) on April 1, 2024, 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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