January 3, 2024

Tonix Pharmaceuticals to Present at Two Upcoming Investor Conferences in January: Focus is on TNX-102 SL for the Management of Fibromyalgia Following Positive Topline Results in Second Pivotal Phase 3 Trial

TNX-102 SL is a Non-Opioid Analgesic that Demonstrated Daily Pain Reduction Over Placebo (Primary Endpoint, p = 0.00005) and Showed Positive Effects Across All Six Key Secondary Endpoints in Recently Reported Phase 3 Trial

Company Plans to Submit a New Drug Application (NDA) to the FDA in the Second Half of 2024

CHATHAM, N.J., Jan. 03, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a biopharmaceutical company with marketed products and a pipeline of development candidates, announced today that Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals, will present and host investor meetings at the following January investor conferences:

7th Annual Neuroscience Innovation Forum by Sachs Associates
Date: Sunday, January 7, 2024
Place: Marines Memorial Club, San Francisco, Calif.
Time: 3:50 p.m. PT

2024 Biotech Showcase
Date: Monday, January 8, 2024
Place: Hilton San Francisco Union Square, San Francisco, Calif.
Room: Yosemite C (Ballroom Level)
Time: 2:00 p.m. PT

Investors interested in arranging a meeting with the Company's management during these conferences should contact the respective conference coordinators. Replays of both webcasts of the Company's presentations at the Neuroscience Innovation Forum and the 2024 Biotech Showcase will be available under the IR Events tab of the Tonix website at www.tonixpharma.com following each presentation.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's development portfolio is focused on central nervous system disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA for TNX-102 SL (cyclobenzaprine HCl sublingual tablet), which has completed two positive Phase 3 studies for the management of fibromyalgia. Tonix intends to meet with the FDA in the first half of 2024 and submit an NDA for the approval of TNX-102 SL for the management of fibromyalgia in the second half of 2024. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition, and topline results from a proof-of-concept study were reported 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 2024. Tonix's rare disease development portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome (PWS). TNX-2900 has been granted Orphan Drug designation by the FDA and an investigational new drug (IND) application has been cleared to support a Phase 2 study in PWS patients. Tonix's immunology development 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 rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases, including TNX-1800, in development as a vaccine to protect against COVID-19. During the fourth quarter of 2023, TNX-1800 was selected by the U.S. National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) Project NextGen for inclusion in Phase 1 clinical trials. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated 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.*

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statement that are predictive in nature. 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, statements about the expected closing of the offering; anticipated gross proceeds from the offering; 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, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2023, 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.

Investor Contact

Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Peter Vozzo
ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505

Media Contact

Ben Shannon
ICR Westwicke
ben.shannon@westwicke.com
(919) 360-3039

Source: Tonix Pharmaceuticals Holding Corp.