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Tonix Pharmaceuticals Describes Emerging Research on the Incidence of Multi-Site Pain Symptoms in Long COVID Patients During Event Titled, “Long COVID: What Will it Take to Accelerate Therapeutic Progress?”

Symptoms of Long COVID, Like Multi-Site Pain, Fatigue and Insomnia, are the Hallmarks of Chronic Pain Syndromes Like Fibromyalgia and Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)

Event Co-Hosted by the Biotechnology Innovation Organization (BIO) and Solve M.E., an Advocacy Group for CFS/ME

CHATHAM, N.J., Feb. 22, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that during a virtual event co-hosted by BIO and Solve M.E. titled, “Long COVID: What Will it Take to Accelerate Therapeutic Progress?”, Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals, presented emerging research describing the role of infections in triggering fibromyalgia or CFS/ME and other fibromyalgia-type illnesses, and discussed Tonix’s ongoing Phase 2 study of TNX-102 SL in fibromyalgia-type Long COVID. Symptoms of Long COVID, like multi-site pain, fatigue and insomnia, are the hallmarks of chronic pain syndromes like fibromyalgia and CFS/ME.

“The U.S. Department of Health and Human Services *National Research Action Plan on Long COVID*[1], released in August 2022, addresses the overlap of Long COVID with CFS/ME, which, like fibromyalgia, is one of the overlapping chronic pain syndromes with central sensitization,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Furthermore, a recent survey[2] found comparable pain, fatigue and function between Long COVID, fibromyalgia and CFS/ME.”

Enrollment continues in the Phase 2 PREVAIL study of TNX-102 SL as a potential treatment for patients with Long COVID syndrome whose symptoms overlap with fibromyalgia. PREVAIL is a randomized, double-blind, placebo-controlled study in the U.S. that is expected to enroll approximately 470 patients. One unblinded interim analysis is anticipated based on the first 50% of randomized participants.

Dr. Lederman’s presentation is available under the Presentations tab of the Tonix website at

www.tonixpharma.com.

[1]Department of Health and Human Services, Office of the Assistant Secretary for Health. 2022. National Research Action Plan on Long COVID, 200 Independence Ave SW, Washington, DC 20201.

[2]Haider S, et al. Pain. 2023;164(2):385-401.

About Solve M.E.

Solve M.E. is a non-profit organization that serves as a catalyst for critical research into diagnostics, treatments, and cures for CFS/ME, Long COVID and other post-infection conditions.

About BIO

BIO is the world's largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries.

About Long COVID or Post-Acute Sequelae of SARS-CoV-2 (PASC)

Although most people recover from COVID-19 within weeks of the acute illness, a substantial portion develop a chronic syndrome called Long COVID. These individuals experience a constellation of symptoms long past the time of recovery from acute COVID-19. Most Long COVID patients who have been studied appear to have cleared the SARS-CoV-2 virus from their systems. The symptoms of Long COVID can include fatigue, sleep disorders, pain, fevers, shortness of breath, cognitive impairment described as "brain fog" or memory disturbance, gastrointestinal symptoms, anxiety, and depression. Long COVID can persist for months and can range in severity from mild to incapacitating. Several cohort studies have reported that persistence of symptoms following SARS-CoV-2 infection occurs in approximately 19% of people who recover from COVID.[1] While typically associated with moderate or severe COVID-19, Long COVID can occur after mild COVID-19 or even after asymptomatic SARS-CoV-2 infection. Patients with Long COVID are sometimes referred to as "long-haulers". Long COVID is a chronic disabling condition that is expected to result in a significant global health and economic burden.[2] In response to the urgent need for therapies that address Long COVID, Congress awarded $1.15 billion to the National Institutes of Health to study Long COVID in December 2021.[3] While the vaccines available in the U.S. under Emergency Use Authorization have been shown to prevent acute COVID, their ability to prevent Long COVID is unknown. There is currently no approved drug for the treatment of Long COVID."

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. 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 second quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is being studied in a potential pivotal Phase 2 study that initiated enrollment in the first quarter of 2023 and for which interim data is expected in the fourth 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 second quarter 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; and a class of broad-spectrum small molecule oral antivirals, TNX-3900. 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 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.*

[1]*https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220622.htm – Accessed Feb. 21, 2023*

[2]*Briggs, Andrew, and Anna Vassall. "Count the cost of disability caused by COVID-19." (2021): 502-505.*

[3]*The NIH provision of Title III Health and Human Services, Division M--Coronavirus Response and Relief Supplemental Appropriations Act, 2021, of H.R. 133, The Consolidated Appropriations Act of 2021. The bill was enacted into law on 27 December 2020, becoming Public Law 116-260.*

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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