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Tonix Pharmaceuticals Expedites Fibromyalgia and Chronic Migraine Programs

Streamlining Phase 3 Fibromyalgia and Phase 2 Chronic Migraine Trials by Eliminating Interim Analyses

Topline Results Expected for Both Programs in Fourth Quarter 2023

CHATHAM, N.J., April 13, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced that it is eliminating the interim analyses in its registration-enabling, confirmatory Phase 3 RESILIENT study of TNX-102 SL for fibromyalgia and its Phase 2 PREVENTION study of TNX-1900 for chronic migraine. The modifications to the RESILIENT and PREVENTION studies are designed to streamline the trials and to provide topline data for both programs in 2023. Target enrollment for the core TNX-102 SL fibromyalgia study remains approximately 470 participants while target enrollment for the TNX-1900 chronic migraine study will be reduced from approximately 300 participants to approximately 150 participants, to accommodate the new topline timing.

“In an effort to expedite and deliver on clinical timelines, we are modifying the designs of our confirmatory, registration-enabling Phase 3 trial in fibromyalgia and our Phase 2 trial in chronic migraine,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “By eliminating the interim analyses, we remove the statistical penalties associated with this type of analysis, conserve resources, and can plan on topline results for each of these studies in the fourth quarter of 2023. Fibromyalgia and migraine each affect millions of people, and we remain committed to aligning our operational and scientific efforts on these core CNS programs. We are excited to progress these programs closer to FDA approval, upon achieving positive topline data.”

Key Anticipated 2023 Milestones

Updated Guidance

- Eliminating interim analysis of Phase 3 RESILIENT study of TNX-102 SL (sublingual cyclobenzaprine tablets) for fibromyalgia.
- Eliminating interim analysis of Phase 2 PREVENTION study of TNX-1900 (intranasal potentiated oxytocin) for chronic migraine; topline results now expected in the fourth quarter of 2023.

Unchanged Guidance

- Topline results of Phase 3 RESILIENT study of TNX-102 SL (sublingual cyclobenzaprine tablets) for fibromyalgia in the fourth quarter of 2023.
- Topline results of Phase 2 PREVAIL study of TNX-102 SL for fibromyalgia-type Long COVID in the third quarter of 2023.
- Interim analysis results of Phase 2 UPLIFT study of TNX-601 ER (tianeptine hemioxalate extended-release tablets) for major depressive disorder in the fourth quarter of 2023.
- Initiate enrollment in a potentially pivotal Phase 2 study of TNX-1300 (recombinant double-mutant cocaine esterase for injection) for the treatment of cocaine intoxication in the second quarter of 2023.
- Initiate enrollment in a Phase 1 study of TNX-1500 (anti-CD40L monoclonal antibody) for the prophylaxis of rejection in kidney transplantation in the second quarter of 2023.
- Initiate enrollment in a Phase 1 study of TNX-801 (live virus vaccine for percutaneous administration), a potential vaccine to protect against smallpox and mpox (formerly known as monkeypox), in the second half of 2023.
- Continue development of TNX-2900 (intranasal potentiated oxytocin), a small peptide for the treatment of hyperphagia in Prader-Willi syndrome (PWS), for which the FDA has granted Orphan Drug designation.

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 topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth 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 second 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 TNX-801, a vaccine in development to prevent smallpox and mpox, for

which a Phase 1 study is expected to be initiated in the second half of 2023. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

*All of Tonix's product candidates are investigational new drugs (IND) or biologics and have not been approved for any indication. TNX-801, TNX-1500, TNX-2900, TNX-3900 and TNX-4000 are in pre-IND stage of development 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. 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, 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.

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