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Tonix Pharmaceuticals Posted Results from Pharmacokinetic Analyses of TNX-102 SL and TNX-601 CR in Advance of Virtual Poster Presentations at the American Society of Clinical Psychopharmacology

NEW YORK, May 21, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, posted two posters for the American Society of Clinical Psychopharmacology (ASCP) 2020 Annual Meeting to be held online virtually on May 29-30, 2020. The posters can be found on the Scientific Presentations page of Tonix's website.

A poster, titled "Pharmacokinetic Results of Dose Proportionality and Food Effect Study of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL)" includes pharmacokinetic (PK) analyses of TNX-102 SL that is being developed as a bedtime treatment for fibromyalgia, posttraumatic stress disorder (PTSD), agitation in Alzheimer's disease (ADD) and alcohol use disorder (AUD). Sixteen healthy subjects, ages 18-65, were randomized in a 3-way crossover to receive a single dose of TNX-102 SL 2.8 mg fasted, TNX-102 SL 5.6 mg fasted, and TNX-102 SL 5.6 mg fed using a standardized high-fat meal.

A poster, titled "Phase 1 Pharmacokinetic Study of a Once-Daily Formulation of TNX-601 CR (Tianeptine Oxalate Controlled-Release) Tablets," includes PK analyses of TNX-601 CR which is being developed as a once-daily treatment of major depressive disorder (MDD), PTSD and corticosteroid-induced cognitive dysfunction. In this single-center, open-label, multiple sequential period study, a single cohort of 12 male and female healthy volunteers were administered in successive periods: tianeptine sodium 12.5 mg (Stablon®[1]), tianeptine oxalate 13.1 mg (TNX-601), tianeptine oxalate CR (TNX-601 CR) 39.4 mg in a fasted state; and TNX-601 CR in a fed state using a standardized high-fat meal.

Dr. Gregory Sullivan, Chief Medical Officer of Tonix said, "Based on the PK results of the study with TNX-102 SL, the rate and extent of absorption of CBP increased in a dose-proportional manner from 2.8 mg to 5.6 mg of CBP. No food effect was observed for CBP for TNX-102 SL 5.6 mg. The absence of a food effect is consistent with transmucosal absorption after sublingual administration, and this is expected to provide more predictable plasma levels compared to oral swallowed forms of CBP."

Dr. Sullivan continued, “Based on the PK results of the TNX-601 CR study, TNX-601 CR 39.4 mg demonstrated PK appropriate for once-daily dosing with minimal food effect. TNX-601 CR was well-tolerated, without unexpected side effects, and with profiles consistent with the ex-U.S.-marketed sodium salt form of tianeptine dosed three times a day. We believe these findings support further development of TNX-601 CR, the once-daily formulation of tianeptine, in MDD, PTSD and corticosteroid-induced cognitive dysfunction.”

[1]Stablon is a registered trademark of Les Laboratoires SERVIER (France).

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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