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Tonix Pharmaceuticals Doses Participants in Phase 1 Study Evaluating TNX-601 for the Daytime Treatment of Posttraumatic Stress Disorder

NEW YORK, Sept. 04, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today that participants were dosed in a Phase 1 study evaluating the safety, tolerability and pharmacokinetics (PK) of TNX-601 (tianeptine oxalate) for the daytime treatment of posttraumatic stress disorder (PTSD). Topline data from this study investigating new modified release formulations are expected later this year.

“We are excited to leverage our expertise in PTSD and further our development of TNX-601 as a potential daytime treatment for PTSD,” said Seth Lederman, M.D., Tonix’s President and Chief Executive Officer. “TNX-601 is one of three drug candidates we are developing for PTSD. Our most advanced is TNX-102 SL, which is in Phase 3 development. We look forward to topline results from the TNX-601 Phase 1 study later this year and to selecting a formulation of TNX-601 for further development.”

This open-label Phase 1 formulation study will compare the bioavailability and safety of TNX-601, immediate release and modified release tablets, with a reference product, Les Laboratoires SERVIER (France) Stablon® (tianeptine sodium), in 12 healthy male and female volunteers. The study will also evaluate the PK profile of TNX-601 and its metabolite, MC5, using immediate and modified release tablets. Secondary objectives include the evaluation of the safety and tolerability of single doses of TNX-601. The study is being conducted outside of the U.S. using Quotient Sciences’ integrated Translational Pharmaceutics® platform.

Gregory M. Sullivan, M.D., Chief Medical Officer, Tonix Pharmaceuticals Holdings Corp., commented, “TNX-601 is notable in that it addresses the stress response related to PTSD, as opposed to a deficit in memory processing. We believe the memory processing deficits in PTSD are a downstream manifestation of the derangements in the stress response system. Therefore, TNX-601 may work closer to the genesis of the PTSD neuropathology than drugs designed to help recovery from the memory processing deficits. The amorphous sodium salt of tianeptine is a well-described antidepressant with activity against severe stress-induced sequelae within the central nervous system. For that reason, TNX-601, the crystalline oxalate salt of tianeptine in a once-daily dosing formulation may improve global symptoms in individuals with PTSD. Initiating this clinical trial represents another step in our ongoing development program of novel therapeutic approaches for treating PTSD.”

The decision to advance TNX-601 into clinical development is supported by recent work performed by several groups that identified genetically-defined subgroups of PTSD patients who may be more responsive to this treatment, such as those with particular polymorphisms in the stress response system. In response, Dr. Sullivan commented, “These data call for consideration of an individual’s genetic makeup during the development of future therapies for this devastating condition. We believe that Tonix is poised to utilize these findings and employ this type of precision medicine in future clinical trials of its drug candidates, including TNX-601.”

About TNX-601

TNX-601 is a novel oral formulation of tianeptine designed for daytime dosing that is in the pre-IND (Investigational New Drug) stage of development. Tianeptine’s reported pro-cognitive and anxiolytic effects as well as its ability to attenuate the neuropathological effects of excessive stress responses suggest that it may be used to treat PTSD by a different mechanism of action than TNX-102 SL. Tonix discovered a novel salt and polymorph of tianeptine that may provide improved stability, consistency, and manufacturability as compared to known forms of tianeptine. Currently there is no tianeptine-containing product approved in the U.S., though tianeptine sodium (amorphous) has been available for decades in Europe, Asia, and Latin America for the treatment of depression, first approved in France in 1987. Tianeptine modulates the glutamatergic system indirectly and reverses the neuroplastic changes that are observed during periods of stress and elevated corticosteroid exposure. Tianeptine is a weak mu-opioid receptor (MOR) agonist, but does not have significant affinity for other known neurotransmitter receptors. Tianeptine sodium has an established safety profile from decades of use as an antidepressant in Europe, Asia, and Latin America. Several published studies support the potential of tianeptine as a treatment for PTSD. TNX-601 is being developed under Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act (FDCA) as a potential treatment for PTSD and neurocognitive dysfunction associated with corticosteroid use.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions, to improve biodefense through potential medical counter-measures and to prevent and treat organ transplant rejection. Tonix’s lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia, agitation in Alzheimer’s disease and alcohol use disorder, to be developed under separate Investigational New Drug applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development, the agitation in Alzheimer’s program is Phase 2 ready and the alcohol use disorder program is in the pre-IND application stage. TNX-1300** (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. Tonix has two other programs in the pre-IND application stage of development for PTSD, but with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate) and TNX-1600***, a triple reuptake inhibitor. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted

outside of the U.S. TNX-801 (live virus vaccine for percutaneous (scarification) administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. Finally, TNX-1500 is being developed to prevent and treat organ transplant rejection, as well as to treat autoimmune conditions, and is in the pre-IND application stage.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL for the treatment of PTSD. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

****TNX-1600* ((2*S*,4*R*,5*R*)-5-(((2-aminobenzo[*d*]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2*H*-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine), or a "triple reuptake" inhibitor.

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; 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, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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