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Tonix Pharmaceuticals Presents Non-Clinical Data on TNX-2900 for the Potential Treatment of Hyperphagia in Adolescents and Young Adults with Prader-Willi Syndrome at the Rare Disease Innovation and Partnership Summit

CHATHAM, N.J., March 23, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced that Herbert Harris, M.D., Ph.D., Executive Vice President, Translational Medicine of Tonix Pharmaceuticals, delivered an oral presentation on March 23, 2023, at the Rare Disease Innovation and Partnership Summit being held as a hybrid event in Philadelphia, Pa. A copy of the presentation is available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com. Additional information can be found on the Rare Disease Innovation and Partnership Summit website here.

The oral presentation, titled, *"TNX-2900 (Intranasal Potentiated Oxytocin) in Development for the Treatment of Hyperphagia in Adolescents and Young Adults with Prader-Willi Syndrome,"* includes data showing the enhancing effects of magnesium (Mg^{2+}) on the activation of oxytocin receptors. The Mg^{2+} enhanced formulation of intranasal oxytocin is the basis for TNX-2900, in development to treat hyperphagia, or pathological over-eating, in adolescent and young adult patients with Prader-Willi syndrome (PWS), and for TNX-1900 in development to prevent migraine headaches in chronic migraineurs. TNX-2900 has been granted Orphan Drug designation from the U.S. Food and Drug Administration for the treatment of PWS. There is no treatment currently approved for PWS-related hyperphagia.

"PWS is a rare genetic disorder characterized by failure to thrive in infancy, but leads to hyperphagia in childhood, resulting in PWS being the most common genetic syndromic cause of obesity," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Tonix is excited to develop TNX-2900, a Mg^{2+}-enhanced formulation of intranasal oxytocin, as a treatment for hyperphagia in adolescents and young adults with this rare disease."

"Hyperphagia is more than just insatiable appetite. It leads to extreme behavioral and metabolic effects. Consequences around this abnormal food behavior can be life-threatening, particularly obesity and cardiovascular disease, the latter of which is a leading cause of death in people with PWS," said Dr. Harris. "Oxytocin is an anorexigenic hormone that reduces appetite and signals fullness. The oxytocin receptor requires magnesium ions

for the high-affinity conformation for signaling satiety. TNX-2900 combines oxytocin with magnesium for improved receptor binding and potentially improved therapeutic action."

Tonix licensed the technology to treat PWS from Inserm Transfert, the private subsidiary of Inserm (the French National Institute of Health and Medical Research). In addition, Tonix has entered into a sponsored research agreement with Aix-Marseille Université to study oxytocin in the genetically engineered mouse model of PWS. In adults, hyperphagia in PWS can lead to obesity and other complications associated with significant mortality. In newborns, PWS causes a deficiency in suckling, which has been shown to be normalized by oxytocin treatment.

About Prader-Willi Syndrome

Prader-Willi syndrome is recognized as the most common genetic cause of life-threatening childhood obesity[1] and affects males and females with equal frequency and all races and ethnicities. The hallmarks of Prader-Willi syndrome are lack of suckling in infants and, in children and adults, severe hyperphagia, an overriding physiological drive to eat, leading to severe obesity and other complications associated with significant mortality. There is currently no approved treatment for either the suckling deficit in babies or the obesity and hyperphagia in older children associated with Prader-Willi syndrome.

[1]Foundation for Prader-Willi Research (fpwr.org).

About TNX-2900 and Tonix's Potentiated Oxytocin Platform

TNX-2900 is based on Tonix's patented intranasal potentiated oxytocin formulation intended for use by adults and adolescents. Tonix's patented potentiated oxytocin formulation is believed to increase specificity for oxytocin receptors relative to vasopressin receptors as well as to enhance the potency of oxytocin. Tonix is also developing a different intranasal formulation and device, designated TNX-1900, for prophylaxis of chronic migraine and for the treatment of insulin resistance and related conditions. Oxytocin is a naturally occurring human hormone that acts as a neurotransmitter in the brain. It was originally approved by the U.S. Food and Drug Administration as Pitocin®*, an intravenous infusion or intramuscular injection drug, for use in pregnant women to induce labor. An intranasal form of oxytocin was marketed in the U.S. by Novartis to assist in the production of breast milk as Syntocinon®** (oxytocin nasal 40 units/ml), but the product was discontinued, and the New Drug Application was withdrawn.

**Pitocin® is a trademark of Par Pharmaceutical, Inc.*

***Syntocinon® is a trademark of BGP Products Operations GmbH.*

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 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, for which a Phase 2 study was initiated in the third quarter of 2022. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is currently enrolling with interim data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation of tianeptine 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, a class of broad-spectrum small molecule oral antivirals.

**All of Tonix's product 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. 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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