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Tonix Pharmaceuticals Announces Research Agreement with the French National Institute of Health and Medical Research (Inserm) to Study the Mechanism of Oxytocin-Mediated Improvement of Eating Behaviors in Prader-Willi Mice

Tonix is Developing TNX-2900 (Intranasal Potentiated Oxytocin) for the Treatment of Prader-Willi in Adolescents and Adults with Hyperphagia or Excessive Eating

Planned Studies in Prader-Willi Mice Will Focus on Oxytocin-Mediated Normalization of Suckling in Newborns

CHATHAM, N.J., Feb. 28, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has entered into a sponsored research agreement with Inserm Transfert, the private subsidiary of Inserm, on behalf of Inserm (the French National Institute of Health and Medical Research) and Aix-Marseille Université to study oxytocin in the genetically engineered mouse model of Prader-Willi syndrome, a rare genetic disorder that causes distinct, but related pathological eating disorders in adults and newborns. In adults, Prader-Willi causes hyperphagia, or pathological over-eating, which leads to obesity and other complications associated with significant mortality. In newborns, Prader-Willi causes a deficiency in suckling, which has been shown to be normalized by oxytocin treatment.

“Tonix is excited to enter into this new research collaboration, which we hope will expand our understanding of oxytocin’s potential to treat Prader-Willi syndrome,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Currently, there is no approved treatment for Prader-Willi syndrome. With this new research collaboration, our goal is to learn how oxytocin-based pharmacological treatment improves and normalizes feeding behavior in infancy.”

Tonix is developing TNX-2900* (intranasal potentiated oxytocin) for the treatment of Prader-Willi Syndrome in adults and adolescents. A related intranasal potentiated oxytocin product candidate, TNX-1900*, is under development for the treatment of chronic migraine and is expected to enter a Phase 2 clinical trial for the prevention of migraine headache in chronic migraineurs in the second half of 2022.

The proposed research, directed by Professor Françoise Muscatelli at the Institut de Neurobiologie de la Méditerranée (INMED-Inserm UMR1249/Aix-Marseille Université), will

involve *in vitro* and *in vivo* studies designed to characterize the mechanism by which oxytocin normalizes the suckling and maturation of feeding behavior during infancy in mice that have been genetically modified to recapitulate part of the genetic alterations underlying Prader-Willi in humans. The results of this work are expected to increase the understanding of the mechanism by which oxytocin regulates feeding behavior in a mouse model of Prader-Willi.

In 2021, Tonix licensed technology for treating Prader-Willi syndrome from Inserm, Aix Marseille Université and Centre Hospitalier Universitaire of Toulouse. The patents covering the technology are expected to provide market exclusivity for the co-licensees in the U.S. and Europe through 2031, which exclusivity could be extended after marketing authorization by a Supplemental Protection Certificate in Europe or a Patent Term Extension in the U.S., independent of other Tonix-held patents covering the formulation and oxytocin potentiation technologies for intranasal administration. Additionally, Tonix has submitted an application to the FDA for orphan drug designation.

**TNX-2900 and TNX-1900 are investigational new drugs and have not been approved for any indication.*

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*

About Inserm Transfert

Inserm Transfert, the private subsidiary of the French National Institute of the Health and Medical Research (Inserm), is responsible for value creation of Inserm and its academic partners' innovations in human health and promotes long-term technology transfers in line with international best practices. Inserm Transfert SA was founded in 2000, and manages, under a Public Service Management Contract (Délégation de Service Public), the entire promotion and transfer of knowledge emerging from the Inserm research laboratories to the industrial world, from invention disclosure to industrial partnerships and startups incorporation. Inserm Transfert also offers services relating to setting up and managing national, European and international projects, as well as supporting the technology transfer of clinical research and health data/databases. In 2009, Inserm Transfert and Inserm established an investment fund to finance proofs of concept. In 2005, Inserm Transfert Initiative, a dedicated seed money fund for life sciences, was created. Since 2017 a pathway for pre-entrepreneurship supports researchers/inventors that aspire to become involved in entrepreneurship. www.inserm-transfert.com

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of infectious disease, central nervous system (CNS) and immunology product candidates. Tonix's infectious disease portfolio of product candidates includes next-generation vaccines to prevent COVID-19, an antiviral to treat COVID-19, and a potential treatment for Long COVID. The portfolio also includes a vaccine in development to prevent smallpox. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. The immunology portfolio includes biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate for COVID-19, TNX-1800[1], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. TNX-3500[2] (sangivamycin, i.v. solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL[3] (cyclobenzaprine HCl sublingual tablets), is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition. Tonix expects to initiate a Phase 2 study in Long COVID in the first half of 2022. Tonix's lead CNS candidate, TNX-102 SL, is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study expected to start in the first half of 2022. TNX-1300[4] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the first quarter of 2022.

[1]TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.

[2]TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.

[3]*TNX-102 SL is an investigational new drug and has not been approved for any indication.*

[4]*TNX-1300 is an investigational new biologic and has not been approved for any indication.*

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 development of TNX-2900, 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, 2020, as filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2021, 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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