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Tonix Pharmaceuticals Acquires Exclusive License to University of Geneva Technology for Oxytocin-Based Treatments for Treating Insulin Resistance, Diabetes and Obesity, Expanding Proprietary Uses for TNX-1900 (Intranasal Potentiated Oxytocin)

University of Geneva Technology Covers Broad Applications for Cardiometabolic Syndromes

CHATHAM, N.J., Dec. 22, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby Tonix has acquired the exclusive license to the University of Geneva's technology for using oxytocin to treat insulin resistance and related syndromes, including obesity, from privately held Katana Pharmaceuticals, Inc. This license allows Tonix to expand its intranasal potentiated oxytocin development program, TNX-1900, into cardiometabolic syndromes, which include insulin resistance, impaired glucose tolerance, and obesity. The patents covering the technology are expected to provide Tonix with freedom to operate in these indications as well as market exclusivity in the U.S. and Europe through 2031, upon its approval, independently of other Tonix-held patents covering the formulation and potentiation technologies related to TNX-1900.

The University of Geneva technology is based on the discovery that oxytocin administration in an animal model of obesity improved lipid metabolism by increasing lipolysis and fatty acid-β-oxidation in adipose tissue accompanied by improvements in glucose intolerance and insulin resistance, independent of food intake[1].

"The important new technology from University of Geneva will allow Tonix to develop intranasal oxytocin on a broader platform to treat both central nervous system (CNS) and cardiometabolic conditions. We believe that TNX-1900 has the potential to be a safe, natural, non-addictive, and easy to administer treatment alternative for a number of CNS disease states. Our lead indication for TNX-1900 is for the treatment of migraine," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals.

"Subsequent to the University of Geneva inventions, a number of studies have shown that intranasal oxytocin has effects on insulin resistance and weight[2-4]," continued Dr. Lederman.

"Intranasal oxytocin has been reported to improve glucose homeostasis, improve pancreatic β-cell responsivity, decrease energy-induced and reward-induced eating, and support cognitive control of food choices.[2-9] The effects of intranasal oxytocin on improving peripheral insulin sensitivity, pancreatic function and lipid metabolism encourage us to develop TNX-1900 as a potential therapeutic in obesity, insulin resistance, diabetes management and related metabolic complications."

In June 2020, Tonix acquired its potentiated oxytocin technology and development program from Trigemina, Inc., and assumed licenses for certain related technologies from Stanford University. TNX-1900 has demonstrated activity in several non-clinical studies in CNS disease models. In addition, prior to the acquisition from Trigemina, TNX-1900 was studied in the U.S. under a physician-requested Investigational New Drug Application .

[1]Deblon N, et al. (2011) *PLoS ONE* 6(9): e25565. doi:10.1371/journal.pone.0025565
[2]Lawson EA. (2017) *Nat Rev Endocrinol.* 13(12):700-709. doi: 10.1038/nrendo.2017.115. PMID: 28960210
[3]Olszewski PK, et al. (2017) *Curr Opin Endocrinol Diabetes Obes*. 24(5):320-325. doi: 10.1097/MED.0000000000000351. PMID: 28590323.
[4]Ding C, et al. (2019) *Obes Rev*. 2019 Jan;20(1):22-40. doi: 10.1111/obr.12757. PMID: 30253045.
[5]Lawson EA, et al. (2015) *Obesity*. 23:950–956. DOI: 10.1002/oby.21069 PMID: 25865294
[6]Klement, J et al. (2017) Diabetes 66(2) 264-271; DOI: 10.2337/db16-0569
[7]Ott V, et al. (2013) *Diabetes*. 62:3418–3425. DOI: 10.2337/db13-0663 PMID: 23835346
[8]Thienel M, et al. (2016) *Int J Obes*. 40(11):1707-1714. DOI: 10.1038/ijo.2016.149 PMID: 27553712
[9]Striepens N, et al. (2016) *Human Brain Mapp*. 37(12):4276–4285. DOI: 10.1002/hbm.23308 PMID: 27381253

About TNX-1900 (Intranasal Potentiated Oxytocin)*

TNX-1900, Tonix's proprietary intranasal oxytocin is currently being studied as a candidate for prophylaxis of chronic migraine. TNX-1900 is in the pre-Investigational New Drug (IND) stage and has not been approved for any indication. It is based on a proprietary formulation of oxytocin and is being developed first for the treatment of migraine. Oxytocin is a naturally-occurring human hormone that acts as a neurotransmitter in the brain. It is approved by the U.S. Food and Drug Administration (FDA) 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 withdrawn and the New Drug Application (NDA) has been discontinued. In clinical and preliminary research, it has been observed that low oxytocin levels in the body can lead to increase in headache frequency, and that increased oxytocin levels can relieve headaches. Oxytocin, when delivered via the nasal route, results in enhanced binding of oxytocin to receptors on neurons in the trigeminal system, inhibiting transmission of pain signals. Intranasal oxytocin has been well tolerated in several clinical trials in adults and children. Intranasal oxytocin has been shown to block calcitonin gene-related peptide (CGRP) release in animals, a pathway known to be critical to the pathogenesis of migraine attacks. TNX-1900 is believed to interrupt pain signals at the trigeminal ganglia by suppressing electrical impulses, a potentially different activity than

drugs that just block CGRP. Migraine attacks are caused, in part, by the release of CGRP from pain-sensing nerve cells that are part of the trigeminal system. Targeted delivery results in low systemic exposure and lower risk of non-nervous system, off-target effects which could potentially occur with systemic CGRP antagonists. For example, CGRP has roles in dilating blood vessels in response to ischemia, including in the heart. Tonix believes targeted delivery of oxytocin could translate into selective blockade of CGRP release in the trigeminal ganglion and not throughout the body, which could be a potential safety advantage over systemic CGRP inhibition.

*TNX-1900 is in the pre-IND phase and has not been approved for any indication.

Pitocin® is a trademark of Par Pharmaceutical, Inc.

Syntocinon® is a trademark of BGP Products Operations GmbH

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL**, is in mid-Phase 3 development for the management of fibromyalgia since positive data on the RELIEF Phase 3 trial were recently reported. The Company expects topline data for a 2nd Phase 3 study, RALLY, in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800***, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

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

***TNX-1800 and TNX-801 are investigational new biologics and have 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 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 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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