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Tonix Pharmaceuticals Announces Data from an in vitro Study of the Impact of Oxytocin on Human Neurons at Neuroscience 2022, the Annual Meeting of the Society for Neuroscience

CHATHAM, N.J., Nov. 16, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced data describing the impact of oxytocin on isolated human sensory neurons, presented at *Neuroscience 2022*, the annual meeting of the Society for Neuroscience. A copy of the poster is available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com.

“This study of the effects of oxytocin on isolated human sensory neurons adds to the growing evidence that oxytocin plays a key role in pain modulation. The potential for intranasal oxytocin to be used as a non-opioid analgesic warrants further investigation,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “To that end, we look forward to initiating our Phase 2 study of intranasal oxytocin in chronic migraine by the end of 2022.”

Professor David Yeomans, Director of Pain Research at Stanford said, “The poster, titled*In Vitro Impact of Oxytocin on Human Sensory Neurons*, is the first to show that oxytocin receptors are present on human sensory neurons and that inflammation drives expression of oxytocin receptors on these neurons. The study also showed that oxytocin inhibits these neurons, suggesting a mechanism by which oxytocin can produce analgesia. The study also showed the critical contribution of magnesium to this analgesia, as the impact of oxytocin on the sensory neurons was dramatically enhanced in the presence of supraphysiologic levels of this ion, and are consistent with prior work which demonstrated that magnesium ions (Mg2+) bind to a pocket in the oxytocin receptor, enhancing the activity of oxytocin at its receptor. The results of this study are consistent with data from animal models and provide support for the use of oxytocin agonists for the treatment of pain.”

In late 2021, Tonix received Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) to support the initiation of a Phase 2 study of TNX-1900 (intranasal potentiated oxytocin) for the prevention of migraine headache in chronic migraineurs. The Company expects to begin enrollment in the Phase 2 study during the fourth quarter of 2022.

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 a new Phase 3 study launched in the second quarter of 2022 and 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. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the second 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 first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the fourth quarter of 2022. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first 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 first half of 2023. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. Tonix's lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform.

> [*] *All of Tonix's product candidates are investigational new drugs or 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 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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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