

Tonix Pharmaceuticals Announces New Board Member, R. Newcomb Stillwell

CHATHAM, N.J., Feb. 23, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the appointment of R. Newcomb Stillwell to its Board of Directors, to be effective as of March 15, 2023.

"We are pleased to welcome Newcomb to our Board of Directors," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix. "Mr. Stillwell brings nearly four decades of experience in corporate law, having practiced exclusively at Ropes & Gray LLP, where he was the Co-Managing Partner of the Boston office. His extensive advisory experience on numerous transactions in the life science and healthcare sectors will add meaningful value to Tonix's Board."

Mr. Stillwell said, "I'm excited to join the Board of Tonix, and to work with its dynamic management team and other Board members. I look forward to providing strategic guidance and insights to help the Company continue its advancement of numerous product candidates throughout the drug development process."

Mr. Stillwell was a partner at Ropes & Gray LLP, an international law firm, where he spent approximately 38 years, principally advising private equity firms on acquisitions and related matters, including life science and healthcare investments. In addition, he served as the first chair of the firm's Private Equity Group. Mr. Stillwell received a J.D., *cum laude*, from Harvard Law School and an A.B., *magna cum laude*, from Princeton University.

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. 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. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is being studied

in a potential pivotal Phase 2 study that initiated enrollment in the first guarter of 2023 and for which interim data is expected in the fourth guarter of 2023. 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 guarter 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 guarter of 2023. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801; a next-generation vaccine to prevent COVID-19, TNX-1850; a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600; and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800; and a class of broad-spectrum small molecule oral antivirals, TNX-3900. 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 the second half of 2023.

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

^{*}All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.

only as of the date thereof.

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