

September 27, 2021



## Tonix Pharmaceuticals Announces Oral Presentation at the American College of Rheumatology Convergence 2021

CHATHAM, N.J., Sept. 27, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announces the acceptance and details of an oral presentation at the American College of Rheumatology (ACR) Convergence 2021. The ACR Convergence 2021 is being held virtually November 5-9, 2021. A copy of the presentation will be made available under the IR Events tab of the Investors section of the Tonix website following the presentation at [www.tonixpharma.com](http://www.tonixpharma.com). The oral presentation details are as follows:

Title      TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia in the RELIEF Study: Positive Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Efficacy and Safety Trial

Abstract 0477

No.

Presn      1815778

ID

Date      November 6, 2021

Time      11:45 a.m. – 12:00 p.m. ET

### **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 immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes a COVID-19 platform of product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to COVID-19. Tonix's lead vaccine candidate for COVID-19, TNX-1800<sup>1</sup>, 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 reported positive efficacy data from animal studies of TNX-1800 in the first quarter of 2021 and expects to start a Phase 1 study in humans in the first half of 2022. TNX-3500<sup>2</sup> (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-Investigational New Drug (IND) stage of development. TNX-102 SL<sup>3</sup> (cyclobenzaprine HCl sublingual tablets) is a small molecule drug being developed to treat Long COVID, a chronic condition, and is also in the pre-IND stage. Finally, Tonix is developing TNX-2100, an *in vivo* diagnostic to measure the presence of functional T cell immunity to COVID-19. Tonix intends to initiate a first-in-human clinical study of TNX-2100<sup>4</sup> in the fourth quarter of 2021,

pending IND clearance. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases. The Company'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<sup>3</sup>, is in mid-Phase 3 development for the management of fibromyalgia.

<sup>1</sup>*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.*

<sup>2</sup>*TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.*

<sup>3</sup>*TNX-102 SL is an investigational new drug and has not been approved for any indication.*

<sup>4</sup>*TNX-2100 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](http://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, the 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, 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 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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Source: Tonix Pharmaceuticals Holding Corp.