

March 7, 2017



# Tonix Pharmaceuticals to Present Breakthrough Therapy Designated-PTSD Program and Corporate Update at the 29th Annual ROTH Conference

*TNX-102 SL, a Phase 3 drug candidate, Recently Granted Breakthrough Therapy Designation by the FDA*

*Pivotal Study in Military-related PTSD to Begin this Quarter*

NEW YORK, March 07, 2017 (GLOBE NEWSWIRE) -- [Tonix Pharmaceuticals Holding Corp.](#) (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced today that it will present at the 29<sup>th</sup> Annual ROTH Conference, being held March 12-15, 2017 in Dana Point, CA.

Seth Lederman, M.D., president and chief executive officer of Tonix, will provide a corporate update and an overview of Tonix's posttraumatic stress disorder ([PTSD](#)) clinical program. TNX-102 SL\* was recently granted Breakthrough Therapy designation by the U.S. Food and Drug Administration for the treatment of PTSD. Tonix will commence in this quarter the "HONOR" study, a 12-week Phase 3 clinical study evaluating TNX-102 SL, 5.6 mg, in military-related PTSD. The interim analysis of the HONOR study is expected in the first half of 2018 and topline results are expected in the second half of 2018. Additional details of the HONOR study are available at [www.thehonorstudy.com](http://www.thehonorstudy.com) or <http://bit.ly/2lrMZ1H>.

In his podium presentation, Dr. Lederman will also provide details of Tonix's recently expanded therapeutic pipeline in PTSD and the new development program in a potential smallpox-preventing vaccine containing a live form of horsepox virus (HPXV).

**Event:** 29<sup>th</sup> Annual ROTH Conference

**Date:** Tuesday, March 14, 2017

**Time:** 12:30 pm PST

**Location:** PINK Room - Salon 5, The Ritz Carlton, Dana Point, CA

The presentation will be webcast live and remain available for 90 days following the presentation. To access the webcast, please visit the [Events](#) tab of the [Investor Relations](#) section of Tonix's website at [www.tonixpharma.com](http://www.tonixpharma.com).

\*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is developing innovative pharmaceutical products to address current and emerging public health challenges, with two programs focusing on PTSD. TNX-102 SL is ready to start Phase 3 clinical trials and TNX-601 is in pre-IND (Investigational New Drug application) stage of development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options especially for military-related PTSD and overall high utilization of healthcare services creating significant economic burden. TNX-102 SL was recently granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of PTSD. Other development efforts include TNX-601, an IND drug candidate designed for daytime use for the treatment of PTSD, and TNX-801, a potential smallpox-preventing vaccine containing a live form of HPXV that has been demonstrated to have protective vaccine activity in mice.

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, substantial competition; 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. 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 hereof.*

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