January 3, 2017



## Tonix Pharmaceuticals to Present Breakthrough Therapy Designated-PTSD Program and Corporate Update at 9th Annual Biotech Showcase 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, Jan. 03, 2017 (GLOBE NEWSWIRE) -- <u>Tonix Pharmaceuticals Holding Corp.</u> (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for PTSD, announced today that it will present at the 9<sup>th</sup> Annual Biotech Showcase Conference being held January 9-11, 2017 in San Francisco, CA.

Seth Lederman, M.D., president and chief executive officer of Tonix, will provide a corporate update and an overview of Tonix's <u>PTSD</u> clinical program. Tonix recently announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to TNX-102 SL\* for the treatment of PTSD. In August 2016, Tonix held a successful End-of-Phase 2/Pre-Phase 3 meeting with the FDA based on positive data from its 12-week randomized, double-blind, placebo-controlled Phase 2 AtEase clinical trial evaluating TNX-102 SL in military-related PTSD. Tonix intends to commence its 12-week Phase 3 HONOR study, evaluating TNX-102 SL, 5.6 mg, in military-related PTSD, in the first quarter of 2017, upon FDA acceptance of the protocol and proposed interim analysis plan.

Event:9th Annual Biotech Showcase ConferenceDate:Tuesday, January 10, 2017Time:9:30 am (PT)Room 7 (Ballroom Level), Parc 55 Hotel, San Francisco,Location:CA

The presentation will be webcast live and remain available for 90 days following the presentation. To access the webcast, please visit the <u>Events</u> tab of the <u>Investor</u> <u>Relations</u> section of Tonix's website at<u>www.tonixpharma.com</u>.

\*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 next-generation medicines for common disorders of the central nervous system, with its lead program focusing on posttraumatic stress disorder. This disorder is a

serious condition characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. TNX-102 SL was recently granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. This press release and further information about Tonix can be found at <u>www.tonixpharma.com</u>.

## **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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