

March 9, 2016



Tonix Pharmaceuticals Presents Pharmacokinetic Data on TNX-102 SL as a Potential Treatment for the Management of Fibromyalgia and Treatment of Post- Traumatic Stress Disorder at the ASCPT 2016 Annual Meeting

- TNX-102 SL is a sublingual formulation of cyclobenzaprine designed for bedtime administration currently under development for the long-term management of fibromyalgia and treatment of post-traumatic stress disorder-

- TNX-102 SL pharmacokinetic data demonstrated increased plasma levels of 338% during the first hour and 83% during the first two hours after administration compared with immediate-release cyclobenzaprine oral tablet-

NEW YORK, March 09, 2016 (GLOBE NEWSWIRE) -- [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) (Tonix), today announced that it is presenting data from its TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) program for the management of fibromyalgia and treatment of post-traumatic stress disorder (PTSD) in a poster presentation at the [American Society for Clinical Pharmacology and Therapeutics 2016 Annual Meeting](#) in San Diego, CA.

Tonix is currently evaluating TNX-102 SL in a randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial in fibromyalgia and a randomized, double-blind, placebo-controlled, registration-quality Phase 2 AtEase clinical trial in military-related PTSD. Tonix expects to report top-line AFFIRM data in the third quarter of 2016 and top-line AtEase data in the second quarter of 2016. TNX-102 SL is designed for bedtime administration and the long term management of fibromyalgia and treatment of PTSD.

The poster entitled, “*Rapid Sublingual Absorption on Cyclobenzaprine (CBP) with Basifying Agents: Prospect for Bedtime Treatment of Fibromyalgia Syndrome (FM)*,” is being presented by Bruce Daugherty, PhD, Chief Scientific Officer of Tonix.

Tonix’s recent research confirms that their proprietary cyclobenzaprine (CBP) sublingual formulation has a differentiated pharmacokinetic profile from the oral immediate release (IR) CBP tablet. The results are encouraging because by design TNX-102 SL has the desirable pharmacokinetic properties as a potential bedtime medication for fibromyalgia or PTSD. The pharmacokinetic data demonstrated the following:

- TNX-102 SL shows evidence of rapid delivery of CBP across the sublingual mucosal membrane into plasma resulting in 12 times faster onset of absorption relative to the oral CBP IR tablet;
- TNX-102 SL increased plasma levels of 338% during the first hour and 83% during the first two hours after administration compared with oral CBP IR tablet;
- The relative bioavailability of cyclobenzaprine is 154% with TNX-102 SL compared to the oral CBP IR tablet;
- The active metabolite, norcyclobenzaprine, is reduced by 48% with TNX-102 SL; and
- The most frequent adverse event reported in this single-dose comparative bioavailability/pharmacokinetic study was transient numbness in the oral cavity, which was experienced in 50% of the TNX-102 SL subjects and resolved within 30-45 minutes.

The poster LB-026 highlighting the pharmacokinetic properties of TNX-102 SL as a potential bedtime medication for fibromyalgia and PTSD is available on Tonix's website at www.tonixpharma.com.

The United States Food and Drug Administration (FDA) has conditionally accepted "Tonmya" as the proposed trade name of TNX-102 SL for fibromyalgia. TNX-102 SL 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, including fibromyalgia and post-traumatic stress disorder. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

Safe Harbor / 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 possible 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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