

June 17, 2015



# **Tonix Pharmaceuticals Announces Conditional Acceptance of Tonmya as Proposed Brand Name for Cyclobenzaprine HCl Sublingual Tablets, 2.8 mg**

NEW YORK, June 17, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) ("Tonix") today reported that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proposed trade name Tonmya™ (*ton-MY-ah*) for TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, for the management of fibromyalgia. Tonix recently launched the Phase 3 AFFIRM study of Tonmya in fibromyalgia, from which top-line results are expected to be reported in the second half of 2016.

A request for proprietary name review for Tonmya will be submitted once the fibromyalgia New Drug Application (NDA) is submitted. FDA's final approval of Tonmya is subject to NDA approval. Tonix has applied to the U.S. Patent and Trademark Office to obtain federal registration of the Tonmya mark.

## **About Tonix Pharmaceuticals Holding Corp.**

Tonix is dedicated to the development of next-generation medicines for common yet challenging disorders of the central nervous system, characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. Tonix's Tonmya is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 for episodic tension-type headache was recently initiated. To learn more, please visit [www.tonixpharma.com](http://www.tonixpharma.com).

Tonmya, TNX-102 SL, and TNX-201 are Investigational New Drugs and have not been approved for any indications.

## **Cautionary Note on 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" 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 filed with the SEC on February 27, 2015 and future periodic reports filed with the Securities and Exchange Commission. 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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