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Tonix Pharmaceuticals Presents Additional Data on Tonmya(TM) Demonstrating Improvements in Sleep, Pain, and Other Outcomes in Fibromyalgia at 2015 ACR/ARHP Annual Meeting

Phase 2b BESTFIT Clinical Study Results Reveal Correlations Between Sleep Quality and Key Clinical Measures

NEW YORK, Nov. 10, 2015 (GLOBE NEWSWIRE) --Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) ("Tonix"), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, today presents additional results from its completed 12-week, 205-patient Phase 2b BESTFIT clinical study of Tonmya (TNX-102 SL; cyclobenzaprine HCl sublingual tablets, 2.8 mg) for the treatment of fibromyalgia. Tonmya is designed for chronic daily use at bedtime to treat fibromyalgia.

Tonmya is currently being evaluated in the 500-patient Phase 3 AFFIRM study in fibromyalgia. As accepted by the U.S. Food and Drug Administration, the primary outcome measure for this Phase 3 study is a pain responder analysis, defined as the proportion of patients who report at least a 30% reduction in pain from baseline at the end of the 12-week treatment period. Tonix expects to report top-line data from the AFFIRM trial in the third quarter of 2016.

"Our new analyses of the BESTFIT data show that those patients who reported the greatest improvement in sleep quality were the most likely to experience pain relief," said Seth Lederman, M.D., Tonix's chairman and CEO. "We also observed that the group treated with Tonmya was approximately twice as likely as placebo-treated patients to be in the top third of reported sleep quality improvement. Among all patients in BESTFIT who ranked highest in reported sleep quality improvement, twice as many Tonmya-treated patients experienced at least a 30% improvement in their pain as compared to those treated with placebo."

Of the 174 patients who completed the BESTFIT study, 172 were evaluable for the analyses described in this paragraph. Of these 172, 88 patients were treated with Tonmya ("Tonmya group"), and 84 were treated with placebo ("placebo group"). According to a tertile analysis of reported sleep quality improvement, the 54 of these 172 patients who reported the greatest improvement in sleep quality, or top sleep tertile, were examined in further detail. Of those in the Tonmya group, 36, or 41%, were in the top sleep tertile compared to 18 of the 84 patients, or 21%, in the placebo group. Of the 42 patients in the top sleep tertile who experienced at least a 30% improvement in their pain from baseline, 28, or 67%, had

received Tonmya, compared to 14, or 33%, who had received placebo.

In other analyses, the relationships between reported sleep quality and several standard measures of fibromyalgia were evaluated. According to each of the three different assessments of sleep quality used in BESTFIT, improvement in patient-reported sleep quality was found to significantly correlate with improvement in pain as well as broader measures of fibromyalgia symptoms and impact.

These findings from BESTFIT may support the hypothesis that improving sleep quality facilitates pain improvement over time, and is consistent with the growing recognition of a reciprocal relationship between sleep and chronic, widespread pain. Nonrestorative sleep has been linked to altered processes in the brain that are thought to be responsible for certain fibromyalgia symptoms.

These results are included within a larger body of data being presented today at the 2015 American College of Rheumatology / Association of Rheumatology Health Professionals Annual Meeting in San Francisco, CA, in three posters entitled:

- "Relationship of Sleep Quality and Fibromyalgia Outcomes in a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study of Bedtime, Rapidly Absorbed, Sublingual Cyclobenzaprine (TNX-102 SL)." (abstract no. 2307);
- "Responder Compared to Mean Change Analyses in a Fibromyalgia Phase 2b Clinical Study of Bedtime Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL)." (abstract no. 2308); and
- "Bedtime, Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Fibromyalgia: Results of a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study." (abstract no. 2309).

The posters are available on Tonix's website at www.tonixpharma.com.

About the BESTFIT Study

The Phase 2b BESTFIT study was designed to evaluate the efficacy of Tonmya taken daily at bedtime in improving pain, sleep quality, and other clinical measures of fibromyalgia, as well as safety and tolerability. In BESTFIT, 205 patients were randomized to Tonmya (n=103) or placebo (n=102) for 12 weeks. The study was conducted at 17 sites in the U.S. Top-line results from BESTFIT were first reported in September 2014. In the BESTFIT study, in which a 30% pain responder analysis was a pre-specified secondary outcome measure, Tonmya resulted in a response rate at week 12 that was statistically-significantly higher than placebo (p=0.033). In addition, Tonmya resulted in statistically-significant improvements at week 12 in the pre-specified secondary analyses of the Patient Global Impression of Change, or PGIC (p=0.025) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R (p=0.014). The study showed statistically-significant improvements with Tonmya on measures of sleep quality at week 12, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, instrument for Sleep Disturbance (p=0.005). Tonmya was well tolerated in the BESTFIT study. All of the reported systemic adverse events occurred in less than five percent of treated participants, and no serious adverse events were reported. The most common adverse events were local and related to sublingual administration. Mild and transient tongue or mouth numbness occurred in 44% of participants on Tonmya vs. 2% on placebo, and bitter taste in 8% on Tonmya compared to

none on placebo. Among subjects randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period.

About Fibromyalgia

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, non-restorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled. To learn more, please visit www.affirmstudy.com.

About Tonix Pharmaceuticals Holding Corp.

Tonix is dedicated to the invention and development of novel pharmaceutical products that it believes will have broad societal impact, since they address medical conditions that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's lead product candidate 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 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at www.tonixpharma.com.

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

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" 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, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and November 6, 2015, respectively, 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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