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Tonix Pharmaceuticals Presents Additional Data From Phase 2b BESTFIT Clinical Study at EULAR

– Results Further Illustrate Efficacy and Tolerability Profile of TNX-102 SL in Fibromyalgia –

– TNX-102 SL Currently Being Evaluated in a Phase 3 Study in Fibromyalgia –

NEW YORK, June 11, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) ("Tonix"), a clinical-stage company developing next-generation medicines for fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache, today presented additional data from its Phase 2b BESTFIT clinical study further supporting TNX-102 SL (cyclobenzaprine HCl sublingual tablets) as a promising treatment candidate for patients with fibromyalgia. TNX-102 SL is a eutectic sublingual formulation of very low dose cyclobenzaprine designed for chronic daily use at bedtime to treat fibromyalgia.

TNX-102 SL 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 study will be 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. In the Phase 2b BESTFIT study, in which this analysis was a pre-specified secondary outcome measure, TNX-102 SL resulted in a statistically-significantly higher responder rate as compared to placebo.

Additional Data from the BESTFIT Study

The BESTFIT results were presented at the European League Against Rheumatism Annual Congress (EULAR 2015) in Rome, Italy, in two posters entitled:

- "TNX-102 SL for Treatment of Fibromyalgia: Approaches to Pain Measurement" (abstract no. THU0322); and

- "TNX-102 SL for the Treatment of Fibromyalgia: Role of Nonrestorative Sleep on Pain Centralization" (abstract no. THU0325).

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

"In the 12-week randomized, double-blinded and placebo controlled BESTFIT study, TNX-102 SL treatment led to significant improvements across the spectrum of symptoms suffered by fibromyalgia patients as well as on measures of the impact of this disorder on patients' lives," said Daniel J. Clauw, M.D., professor of anesthesiology, medicine (rheumatology) and psychiatry and director of the Chronic Pain and Fatigue Research Center at the University of

Michigan, study chair of BESTFIT, a study co-author and a consultant to Tonix. "Levels of clinical improvement achieved with TNX-102 SL during the study were generally sustained, and in some cases, were continuing to become greater at the Week 12 study endpoint. Notably, TNX-102 SL demonstrated excellent tolerability in the study, which likely contributed to the high rate of study completion. I believe these encouraging results are an important step forward in the development of TNX-102 SL as a meaningful treatment candidate for individuals suffering from fibromyalgia."

Seth Lederman, M.D., chairman and CEO of Tonix, stated, "The drugs that are currently approved for fibromyalgia are limited by certain shortcomings, including their adverse event profiles. TNX-102 SL was well tolerated in the 12-week BESTFIT study, and systemic adverse events were very infrequent. These results are consistent with our treatment strategy to provide broad symptom relief with a medication that is well-tolerated, particularly in a population with heightened sensitivity to sensory input."

Dr. Lederman concluded, "Our scientific and clinical teams have pioneered and validated the importance of sleep quality as a therapeutic target for treatment of fibromyalgia. Following our encouraging results from the BESTFIT study, we are expediting the clinical development and registration process of TNX-102 SL for patients living with fibromyalgia. If approved by the FDA, TNX-102 SL will represent an effective and well-tolerated treatment option that works differently from the currently approved products. We are looking forward to the outcome of our ongoing Phase 3 AFFIRM study."

TNX-102 SL is designed to improve sleep quality in patients with fibromyalgia. The importance of poor quality, or nonrestorative, sleep in the pathophysiology of fibromyalgia suggests that treatments that improve sleep quality may broadly improve fibromyalgia symptoms by a mechanism distinct from that of the currently approved products. Nonrestorative sleep has been linked to central sensitization, a process in which there are changes in the way the brain processes and interprets pain.

The Phase 2b BESTFIT study was designed to evaluate the efficacy of TNX-102 SL, 2.8 mg, taken daily at bedtime in improving pain, sleep quality, function, and other clinical measures, as well as safety. The study also used a variety of approaches to evaluate changes in patient-reported symptoms. In BESTFIT, 205 patients were randomized to TNX-102 SL (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 intent-to-treat (ITT) population, treatment with TNX-102 SL decreased mean pain on the Numeric Rating Scale (NRS, 0-10) by 1.50 points from baseline to Week 12, as compared to a decrease of 0.97 point with placebo, a positive trend (p=0.086; mixed-effect model repeated measure (MMRM) analysis, daily pain diary). According to a responder analysis, in which responders are defined as patients who achieve at least a 30% reduction in pain on the daily diary from baseline to Week 12, treatment with TNX-102 SL led to a 34.0% response rate, which was statistically-significant compared to a 20.6% response rate in the placebo group (p=0.033). Pain reported during clinic visits was also significantly improved with TNX-102 SL (7 day recall NRS, -1.65 vs. -0.96, p=0.033) as was the Fibromyalgia Impact Questionnaire-Revised (FIQ-R) pain item (7 day recall, -1.80 vs. -0.72, p=0.004).

Sleep quality was significantly improved in the TNX-102 SL arm by all measures, including

the Patient Reported Outcomes Measurement Information System (PROMIS) sleep instrument (p=0.004), the daily sleep diary (p<0.001), and the FIQ-R sleep item (p<0.001). Sleep quality improvements were observed to occur early with TNX-102 SL and generally preceded improvements in other outcome measures, a finding that supports nonrestorative sleep as the principal target of TNX-102 SL therapy.

At Week 12, the Patient Global Impression of Change (PGIC) response rate in the TNX-102 SL arm was significantly higher than that in the placebo arm (30.1% vs. 16.7%, p=0.025), and the differences in PGIC response rates between the two arms increased over time, starting in Week 2. A "PGIC Responder" is defined as the patient rating their overall fibromyalgia "Much Improved" or "Very Much Improved". The PGIC is a patient rating of overall improvement and is a standard assessment in pain treatment trials, including fibromyalgia.

At Week 12, the improvement from baseline in the FIQ-R Total Score in the TNX-102 SL arm was significantly higher than that in the placebo arm (-15.6 vs. -9.1, p=0.014), and the differences in FIQ-R Total Score improvement between the two arms increased over time, starting in Week 4. In a continuous responder analysis performed on Week 12 FIQ-R Total Score data, the proportion of participants achieving a reduction in the FIQ-R Total Score was greater in the TNX-102 SL arm at all levels of improvement from baseline in the FIQ-R Total Score. The FIQ-R measures the impact of fibromyalgia on patients' daily lives and is a standard assessment in fibromyalgia clinical trials.

TNX-102 SL was very 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 local adverse event was intermittent tongue or mouth numbness, which occurred in 42% of patients in the active treatment arm. This adverse event had been previously observed in pharmacokinetic studies conducted in healthy volunteers, and in those studies the effect was noted to be transient and to resolve within 45 minutes or less. Whether patients reported any oral numbness did not appear to lead to significant differences in efficacy as determined by several outcome measures, including the change in mean pain score at Week 12 as well as in the 30% pain responder analysis at Week 12. Of patients randomized to TNX-102 SL, 86% completed the 12-week study vs. 83% in the placebo group.

Interim Update on Open-Label Extension Study

Tonix also today announced an update on Study F203, an ongoing, 12-month, open-label extension study of TNX-102 SL taken daily at bedtime. Patients who successfully completed the BESTFIT study could optionally enroll into this open-label study. Of the 174 patients who completed BESTFIT, 158 (91%) enrolled into Study F203. Of these 158 patients, 108 (68%) completed at least six months in Study F203. This study is expected to complete in August 2015.

About Fibromyalgia

Fibromyalgia is a prevalent central nervous system disorder that is thought to result from amplified sensory and pain signaling. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep (poor sleep quality), and fatigue. As a result of these symptoms, individuals suffering from fibromyalgia struggle with normal daily activities, have

impaired quality of life, and frequently are disabled. It is estimated that five to 15 million Americans are afflicted with fibromyalgia.

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 TNX-102 SL is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia and 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 will begin in the second quarter of 2015. This press release and further information about Tonix can be found at www.tonixpharma.com.

TNX-102 SL and TNX-201 are Investigational New Drugs and are not 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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