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Tonix Pharmaceuticals Presents at EULAR Results of a Retrospective Analysis from the Phase 2b BESTFIT Clinical Study of TNX-102 SL in Fibromyalgia

NEW YORK, June 09, 2016 (GLOBE NEWSWIRE) -- [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia (FM) and post-traumatic stress disorder (PTSD), announced that today the company presented results from a retrospective analysis from its Phase 2b BESTFIT clinical study further supporting TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 2.8 mg for the treatment of fibromyalgia. Data were featured in a poster presentation at the European League Against Rheumatism ([EULAR](#)) Scientific Congress being held June 8-11, 2016 in London, England. The poster, titled, "*TNX-102 SL for the Treatment of Fibromyalgia: Comparison of 30% Pain Responder Analysis with OMERACT Draft Composite Responder Endpoint Analyses*," is available on Tonix's website at www.tonixpharma.com.

Response rates were evaluated in this retrospective analysis of the Phase 2b BESTFIT trial results using the two preferred response definitions proposed by the Outcome Measures in Rheumatology (OMERACT) FM subcommittee as alternative methods by which to assess efficacy. The two responder definitions proposed by the OMERACT committee are the FM30 Short, which defines a responder as $\geq 30\%$ reduction in pain, $\geq 10\%$ improvement in physical function plus a $\geq 30\%$ improvement in either sleep or fatigue, and the FM30 Long, which defines a responder as $\geq 30\%$ reduction in pain, $\geq 10\%$ improvement in physical function plus $\geq 30\%$ improvement in any two of the following measures: sleep, fatigue, depression, anxiety, or cognition.

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. Topline results from BESTFIT were first reported in September 2014.

Seth Lederman, M.D., chairman and CEO of Tonix, stated, "The retrospective analysis clearly demonstrates improvements in the key domains of fibromyalgia and shows that TNX-102 SL has broad activity confirmed by different experimental responder analyses. Given that, we are very pleased with the results from this analysis as it gives us further confidence as we look forward to the outcome of our ongoing Phase 3 study. Most importantly, we believe Tonix will have the potential to provide a meaningful treatment alternative to fibromyalgia patients."

Results of the analysis showed that TNX-102 SL improved multiple domains of fibromyalgia, including sleep, pain, and physical function. Applying composite responder criteria developed by the OMERACT committee to the results of this study gave results consistent with the conclusions of BESTFIT; namely that the improvements in fibromyalgia symptoms seen with TNX-102 SL treatment are not limited only to an analgesic response, since these composite criteria require improvement in other somatic and functional symptoms. The proposed OMERACT response criteria provide an additional method by which to assess clinical benefit in fibromyalgia clinical trials.

The table below shows the comparison of a pain responder analysis ($\geq 30\%$ improvement in pain based on daily diary) to the alternative composite responder definitions proposed by OMERACT.

Responder Definition/ Result (pain based on diary)	Physical Function Measure	Additional Symptom Measures	Result
30% Pain Responder	None	None	34.0% vs. 20.6%; p=0.033
FM30 Short Ver 1	SF-36 physical function	1	23.3% vs. 11.8%; p=0.038
FM30 Short Ver 2	SF-36 PCS score	1	25.2% vs. 11.8%; p=0.015
FM30 Long Ver 1	SF-36 physical function	2	21.4% vs. 9.8%; p=0.031
FM30 Long Ver 2	SF-36 PCS score	2	23.3% vs. 9.8%; p=0.011

1: either FIQ sleep or FIQ energy; 2: any 2 out of FIQ sleep, FIQ energy, FIQ depression, or FIQ anxiety FIQ, Fibromyalgia Impact Questionnaire; PCS, Physical Component Summary; SF, Short Form; Ver, version

Additional improvements noted over placebo included: FIQ-R total score (-17.2 vs. -9.1, p = 0.015), Patient Global Impression of Change response rate (30.1% vs. 16.7%, p = 0.025), Patient-Reported Outcomes Measurement Information System sleep disturbance (-9.5 vs -6.1, p = 0.004), sleep based on daily diary (change from baseline to week-12, 1.9 vs. -1.0; p<0.001) and FIQ-R sleep item (-2.9 vs. -1.2; p <0.0001). Systemic adverse events reported for TNX-102 SL were similar to placebo (somnolence, 1.9 v. 6.9%; dry mouth, 3.9 v. 4.0%; back pain, 4.9 v. 3.0%; nausea, 4.9 v. 2.0%; sinusitis, 3.9 v. 3.0%). The most common local adverse event was transient tongue or mouth numbness occurring in 44% of patients taking TNX-102 SL and 2% taking placebo.

TNX-102 SL is currently being evaluated in a randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial in fibromyalgia. The AFFIRM study is designed to evaluate the efficacy of TNX-102 SL for the management of patients with fibromyalgia. Participants are treated with TNX-102 SL 2.8 mg, sublingually once daily at bedtime for 12 weeks. The primary outcome assessment for the study will be an FDA-accepted pain responder analysis, defined as the proportion of patients who report at least a 30 percent reduction in pain from baseline at the end of the 12-week treatment period. The AFFIRM study is being conducted at 35 U.S. clinical sites, and enrollment has surpassed the 500-patient goal per protocol. Tonix expects to report top line AFFIRM data in the third quarter of 2016.

TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

About EULAR 2016

The European League Against Rheumatism (EULAR) is the organization which represents the patient, health professional and scientific societies of rheumatology of all the European nations. EULAR endeavors to stimulate, promote, and support the research, prevention, treatment and rehabilitation of rheumatic diseases. In line with UEMS, EULAR defines rheumatology as including rheumatic diseases of the connective tissue, locomotor and musculoskeletal systems.

The aim of the 2016 scientific congress is to provide a forum of the highest standard for scientific (both clinical and basic), educational and social exchange among professionals involved in rheumatology, liaising with patient organizations, in order to achieve progress in the clinical care of people with rheumatic and musculoskeletal diseases.

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, nonrestorative 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.

About TNX-102 SL

TNX-102 SL is designed to deliver cyclobenzaprine to the bloodstream rapidly via sublingual (under the tongue) absorption and to bypass first-pass hepatic metabolism. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is under clinical development for the treatment of fibromyalgia and PTSD and is intended to provide broad spectrum improvement by targeting sleep and the stress response. Tonix is developing TNX-102 SL 2.8 mg for daily bedtime administration for the treatment of fibromyalgia and TNX-102 SL 5.6 mg for daily bedtime administration for the treatment of PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. 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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