September 29, 2014

Tonix Pharmaceuticals Reports Top Line Results From Phase 2b BESTFIT Trial of TNX-102 SL in Patients With Fibromyalgia

Conference Call Today at 8:30 a.m. ET

NEW YORK, Sept. 29, 2014 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) today announced top line results of the Phase 2b BESTFIT (BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy) study of TNX-102 SL as a chronic bedtime treatment for fibromyalgia.

While the study did not achieve statistical significance in the primary efficacy endpoint of change in average daily pain score at week 12 (p=0.086 by mixed-effect model repeated measure analysis, p=0.172 by jump-to-control, multiple imputation analysis), it did demonstrate that TNX-102 SL had a statistically significant effect on pain by a 30 percent responder analysis of the primary pain data (p=0.030). BESTFIT also showed statistically significant improvements with TNX-102 SL in the key secondary analyses of the Patient Global Impression of Change (PGIC, p=0.025) and the Fibromyalgia Impact Questionnaire-Revised (FIQ-R) total score (p=0.014). The study showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the PROMIS Sleep Disturbance instrument (p=0.003). In addition, statistically significant improvements with TNX-102 SL were observed on several FIQ-R items (pain, sleep quality, anxiety, stiffness, and sensitivity) as well as on the overall symptom subdomain.

Seth Lederman, M.D., president and chief executive officer of Tonix, commented, "TNX-102 SL showed broad activity across key fibromyalgia symptoms in the BESTFIT study, and the treatment was well tolerated. While the study did not achieve statistical significance on the primary endpoint, this is a very supportive study for the Phase 3 clinical program. Also, these findings validate our approach to develop a differentiated drug that acts beyond analgesia to improve multiple symptom domains of a complex condition. The activity of TNX-102 SL was cross-validated by two endpoints, FIQ-R and PGIC, which assess a range of fibromyalgia symptoms and global improvement. The internal consistency of these results is strongly supportive of the activity of TNX-102 SL to treat fibromyalgia, which manifests with several different symptoms." Dr. Lederman continued, "We plan to meet with the Food and Drug Administration to review the BESTFIT data and to design an acceptable Phase 3 program." Dr. Lederman concluded, "These results also support the potential clinical benefit of TNX-102 SL for the treatment of post-traumatic stress disorder (PTSD). We are confident that addressing disturbed sleep will provide a new treatment option for those suffering with PTSD and the BESTFIT data show that TNX-102 SL has strong positive effects on sleep quality."

A summary of preliminary efficacy results is given in the following table:

Outcome Measure at Week 12	Intent-to-Treat Analysis	P value (1)
Pain		
Daily Pain Diary, NRS	Mean Change (2)	0.086 / 0.172 (JTC)
Daily Pain Diary, NRS	Proportion of Patients Achieving 30% Improvement (3)	0.030* (LR)
Clinic NRS 7-day pain recall	Mean Change	0.029*
FIQ-R Pain Item	Mean Change	0.004*
Sleep		
Daily Sleep Quality Diary, NRS	Mean Change	<0.001*
PROMIS Sleep Disturbance	T-score Change	0.003* / 0.004* (JTC)
FIQ-R Sleep Quality Item	Mean Change	<0.001*
Fibromyalgia-Related		
Patient Global Impression of Change	Responder Analysis	0.025* (LR)
FIQ-R Total Score	Mean Change	0.014* / 0.015* (JTC)
FIQ-R Symptom Domain	Mean Change	0.004*
FIQ-R Function Domain	Mean Change	0.060
FIQ-R Anxiety Item	Mean Change	0.015*
FIQ-R Sensitivity Item	Mean Change	0.017*
FIQ-R Stiffness Item	Mean Change	0.039*

JTC = Jump to Control, Multiple Imputation; LR = Logistic Regression; NRS = Numeric Rating Scale

** p < 0.05*

(1) Analysis by Mixed-Effect Model Repeated Measure unless otherwise indicated.

(2) Primary endpoint for FDA approvals of Lyrica® and Cymbalta® in fibromyalgia.

(3) Primary endpoint for FDA approval of Savella® in fibromyalgia.

In the BESTFIT study, TNX-102 SL was well tolerated. Among subjects randomized to the active and control arms, 86.4 percent and 83.3 percent, respectively, completed the 12-week dosing period. No serious adverse events were reported in the study. As expected, based on Phase 1 sublingual study results, rates of tongue numbness (41.7 percent vs. 1.0 percent) and abnormal taste (7.8 percent vs. 0.0 percent) were higher in the active treatment group. Tongue numbness is a local effect related to dose administration and was transient in almost all occurrences. Efficacy results did not appear to be biased by these local effects. Systemic treatment-emergent adverse events that occurred at a rate of 3.0 percent or greater in the overall trial population are listed in the following table:

Systemic	TNX-102 SL (N=103)		Placebo (N=101)		Total (N=204)	
Adverse Event	N	%	N	%	N	%
Somnolence	2	1.9	7	6.9	9	4.4
Dry Mouth	4	3.9	4	4.0	8	3.9
Back Pain	5	4.9	3	3.0	8	3.9

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, and Study Chair of the BESTFIT study, said, "Based on the clinical improvement and safety profile demonstrated by TNX-102 SL in this study, I believe this is a promising treatment because patients with fibromyalgia want a well-tolerated drug that addresses non-restorative sleep in addition to pain. Together, the broad activity of TNX-102 SL and its particularly strong effect on sleep are supportive of the hypothesis that targeting non-restorative sleep is a path to a new class of therapeutics for fibromyalgia."

BESTFIT was a randomized, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of TNX-102 SL (cyclobenzaprine HCl 2.8 mg sublingual tablets) in patients diagnosed with fibromyalgia. In the trial, 205 participants were enrolled at 17 centers in the United States, of whom 204 received at least one dose of study medication. Trial participants were randomized to 12 weeks of TNX-102 SL (N=103) or placebo (N=102), and were instructed to take their study medication at bedtime. The primary efficacy endpoint of BESTFIT was the change from baseline of the average of the daily pain scores assessed at week 12. Secondary efficacy analyses included the Fibromyalgia Impact Questionnaire-Revised, Patient Global Impression of Change, daily sleep diary, and the PROMIS Sleep Disturbance instrument.

Conference Call and Webcast Information

Tonix will host a conference call today at 8:30 a.m. ET to review the top line results from BESTFIT. To participate in the call, please dial +1 (888) 771-4371 (domestic) or +1 (847) 585-4405 (international) and reference the access code 38094192. A replay of the conference call may be accessed through October 29, 2014 by dialing +1 (888) 843-7419 (domestic) or +1 (630) 652-3042 (international) and by using the access code 38094192. The conference call also will be webcast live on the Investor section of Tonix's website, www.tonixpharma.com, and will be archived until October 29, 2014.

About Fibromyalgia

Fibromyalgia is a chronic syndrome characterized by widespread pain, non-restorative sleep, and other symptoms. Fibromyalgia is debilitating and interferes with daily activities, and affects millions of adult Americans. It is not known what causes fibromyalgia.

About Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals develops innovative prescription medicines for patients who suffer from common central nervous system disorders. The company's clinical candidates target disorders for which current treatment options are unsatisfactory and healthcare utilization is considerable. Tonix's lead candidate, TNX-102 SL, is intended to be a first-line treatment for fibromyalgia and for PTSD. A Phase 2b trial of TNX-102 SL in fibromyalgia (BESTFIT) has been completed, and a Phase 2 trial in PTSD is expected to begin in the fourth quarter of 2014. Tonix plans to enter its second product candidate, TNX-201, into clinical development for patients with episodic tension-type headache in the first quarter of 2015. To learn more, please visit www.tonixpharma.com.

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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 March 28, 2014 and future periodic reports filed with the Securities and Exchange Commission. All of the Company'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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Source: Tonix Pharmaceuticals Holding Corp.