September 6, 2016

Tonix Pharmaceuticals Reports Topline Results from Phase 3 AFFIRM Study of TNX-102 SL in Fibromyalgia and Provides Corporate Update

Following Completion of AFFIRM, Tonix to Prioritize Resources for Advancing Posttraumatic Stress Disorder (PTSD) Program into Phase 3

TNX-102 SL Generally Well Tolerated; No New Safety Signals Observed

NEW YORK, Sept. 06, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix) announced preliminary topline results from its Phase 3 clinical study, AFFIRM, designed to evaluate the safety and efficacy of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, in patients with fibromyalgia. AFFIRM was a 12-week randomized, double-blind, placebo-controlled trial of TNX-102 SL taken daily at bedtime, in which 519 participants were enrolled at 35 centers in the U.S. Fibromyalgia is a multi-symptom disorder that originates in the central nervous system and is characterized by widespread pain, non-restorative sleep, fatigue, and disability.

The AFFIRM data did not achieve statistical significance in the primary efficacy endpoint: the proportion of patients who reported a 30 percent or greater reduction in pain from baseline to the end of the 12-week treatment period based on the pre-specified primary analysis ($p=0.095$, Table 1). However, TNX-102 SL did show statistically significant effects on pain when analyzed by other standard statistical approaches (Table 1). TNX-102 SL activity in fibromyalgia was cross-validated by two additional endpoints, Patient Global Impression of Change (PGIC) and Fibromyalgia Impact Questionnaire-Revised (FIQ-R) (Table 2). These endpoints assess global improvement and a range of fibromyalgia symptoms and function. TNX-102 SL showed strong effects on improving sleep quality by the daily diary and the PROMIS sleep disturbance scale (Table 2). The internal consistency of these results provides clear evidence of beneficial effect of TNX-102 SL for the treatment of fibromyalgia.

Seth Lederman, M.D., president and chief executive officer of Tonix, commented, "TNX-102 SL showed broad beneficial effects across key fibromyalgia symptoms and was well-tolerated in the AFFIRM study. Despite achieving clinically meaningful results from AFFIRM, we have greater clarity on the regulatory path forward in our PTSD program. We will therefore discontinue the fibromyalgia program in order to fully focus Tonix's resources on advancing our potential breakthrough PTSD program to Phase 3. We owe it to our investors, and to patients who are waiting for meaningful clinical innovation, to steward our resources effectively." Dr. Lederman continued, "We thank those who contributed to the AFFIRM trial,

from the clinical teams to the patients and their families. They helped us evaluate this potential new therapy and their involvement provided valuable clinical and scientific information."

An unexpected imbalance in patient discontinuations for reasons unrelated to efficacy or tolerability (for example, a patient relocating away from the clinical site) (Table 3), created a negative bias in the primary responder analysis because any patient who left the study, for any reason prior to completion, was labeled a non-responder despite their results up to that point. Another standard statistical method for assessing the 30 percent responder analysis that considers the reason for discontinuation showed statistical significance in the primary pain data (Table 1, P=0.012).

Overall, TNX-102 SL was well-tolerated in the AFFIRM study and the adverse events reported were similar to those seen in other TNX-102 SL clinical studies (Table 4). There were seven serious adverse events (SAEs) reported during the study: four in the placebo group and three in the active group. No new safety signals were observed; multiple causal factors were involved in each SAE, and all were resolved quickly and without sequelae.

Table 1. Primary and Other Standard Analyses of Pain

Analysis Method	Imputation	Result
30% Responder Analysis Pre-specified	BOCF all discontinuations	P=0.095
30% Responder Analysis	BOCF for LOE and AE; LOCF for others	P=0.012
ANCOVA; MCFB	Multiple imputation; LOE, AE and ID considered MNAR	P=0.009
ANCOVA; MCFB	Multiple imputation; all MNAR except LTF	P=0.042
MMRM of MCFB	None	P<0.001
50% Responder Analysis	BOCF all discontinuations	P=0.035

AE- Adverse Event; ANCOVA- Analysis of Covariance; BOCF- Baseline Observation Carried Forward; ID- Investigator Decision; LOCF- Last Observation Carried Forward; LOE- Lack of Efficacy; LTF- Lost to Follow-up; MCFB- Mean Change from Baseline; MMRM- Mixed Models Repeated Measures; MNAR- Missing Not at Random

Table 2. Key Secondary Efficacy Data

Measure	Analysis Method	Imputation	Result
PGIC	Responder Analysis	BOCF	0.038
FIQ-R Total Score	MMRM of MCFB	None	<0.001
FIQ-R Symptom Domain	MMRM of MCFB	None	<0.001
FIQ-R Function Domain	MMRM of MCFB	None	<0.001
Clinic 7-day pain recall	MMRM of MCFB	None	0.003
FIQ-R Pain Item	MMRM of MCFB	None	<0.001
PROMIS Fatigue	MMRM of MCFB	None	<0.001
Daily Sleep Quality Diary	MMRM of MCFB	None	<0.001
PROMIS Sleep Disturbance	MMRM of MCFB	None	<0.001
FIQ-R Sleep Quality Item	MMRM of MCFB	None	<0.001

Table 3. Reasons for Patient Dropouts/Discontinuations

Reason	TNX-102 SL	Placebo
Occurrence of an Adverse Event	20 (7.6%)	11 (4.3%)
Withdrawal of Consent	15 (5.7%)	3 (1.2%)
Investigator Decision	6 (2.3%)	0 (0%)
Lack of Efficacy	6 (2.3%)	5 (1.9%)
Lost to Follow-up	11 (4.2%)	15 (5.8%)
Other	1 (0.4%)	1 (0.4%)
Total	59 (22.5%)	35 (13.6%)

Among subjects randomized to the TNX-102 SL and control arms, 77.5 percent and 86.4 percent, respectively, completed the 12-week dosing period. As observed in other TNX-102 SL clinical studies, the rate of tongue numbness was higher in the active treatment group (40.2 percent vs. 0.8 percent). Transient tongue numbness, the most frequent adverse reaction, is a local effect related to TNX-102 SL sublingual administration and it did not appear to bias efficacy results. The most common systemic adverse reactions occurring in greater than or equal to 3 percent of patients in TNX-102 SL group and greater than placebo, are listed in Table 4.

Table 4. Most Common Systemic Adverse Reactions Occurring in≥ 3% of Patients in the TNX-102 SL Group and Greater than Placebo

Preferred term	TNX-102 SL (N = 261)*	Placebo (N=257)*
Fatigue	15 (5.7%)	6 (2.3%)
Somnolence	8 (3.1%)	4 (1.6%)

*Safety Population = 518 patients

About PTSD

PTSD affects approximately 8.5 million Americans and is a chronic and debilitating condition, in which patients experience nightmares and disturbed sleep, and which is associated with depression and suicide. Individuals who suffer from PTSD experience impaired social functioning, occupational disability, intense anxiety and avoidance, emotional numbness, intense guilt or worry, agitation and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable or violent behaviors, additional reasons that make it a critical public health concern. PTSD can develop from witnessing or experiencing a traumatic event in which there was the threat or actual occurrence of grave physical harm.

About TNX-102 SL

TNX-102 SL is an Investigational New Drug and has not been approved for any indication. 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 PTSD and is intended to provide broad spectrum improvement by targeting sleep quality and the stress response. Tonix is developing 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, with its lead program focusing on PTSD. This disorder is 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.

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 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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Source: Tonix Pharmaceuticals Holding Corp.