May 19, 2016

Tonix Pharmaceuticals Reports Positive Topline Results from Phase 2 AtEase Study of TNX-102 SL in Post-Traumatic Stress Disorder (PTSD)

- *Conference Call and Webcast Today at 8:00 a.m. ET*
- *Successfully-executed Dose-finding Study Identified 5.6 mg as the Efficacious and Well-tolerated Dose for Registration Studies*
- *Plan to Meet with the U.S. Food and Drug Administration (FDA) to Finalize Phase 3 Clinical Program*
- *Topline Data will be Presented at the American Society of Clinical Psychopharmacology Annual Meeting in Scottsdale, Arizona on May 31, 2016*

NEW YORK, May 19, 2016 (GLOBE NEWSWIRE) --Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), today announced topline results of the Phase 2 dose-finding clinical study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in military-related PTSD (AtEase Study).

The goal of the AtEase Study was to evaluate the potential clinical benefit of using TNX-102 SL to treat military-related PTSD at a dose of 2.8 mg or 5.6 mg. In a randomized, placebo-controlled study of 231 patients with PTSD at 25 U.S. clinical sites, a bedtime sublingual dose of 2.8 mg TNX-102 SL (n=90) or 5.6 mg TNX-102 SL (n=49) was compared to placebo (n=92) for the treatment of military-related PTSD. The retention rate was higher than typical for a PTSD clinical trial, since 73% completed the study on placebo, 79% on TNX-102 SL 2.8 mg and 84% on TNX-102 SL 5.6 mg. The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with TNX-102 SL and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the gold standard in research for measuring the symptom severity of PTSD.

This dose-finding study was designed to evaluate whether a 2.8 mg dose would be an efficacious dose and to provide an opportunity for this study to be one of the pivotal efficacy studies. Although the 2.8 mg dose trended in the direction of a therapeutic effect, it did not reach statistical significance on the primary endpoint. In contrast, the 5.6 mg dose had a therapeutic effect as assessed by the CAPS-5, which was statistically significant by analysis of covariance (ANCOVA) (p-value = 0.038), even though this arm of the study was designed to include half the number of patients of the 2.8 mg arm. The AtEase Study successfully demonstrated a dose-response relationship on multiple efficacy and safety measurements.

TNX-102 SL 2.8 mg and 5.6 mg were well tolerated as evidenced by the high overall completion rate in the active treatment groups, which exceeded the completion rate in the placebo group. The three treatment arms were well balanced on demographic characteristics.

There were four distinct serious adverse events (SAEs); three were in the placebo group, and one (proctitis/peri-rectal abscess), in the TNX-102 SL group, was reported to be unrelated to TNX-102 SL.

Seth Lederman, M.D., president and chief executive officer of Tonix, stated, "TNX-102 SL 5.6 mg taken sublingually at bedtime demonstrated efficacy (reduction in CAPS-5 score) and safety for the treatment of military-related PTSD compared to placebo. We are pleased to have established a dose-response relationship of TNX-102 SL in this Phase 2 PTSD study and identified the 5.6 mg dose as appropriate for Phase 3 development. We plan to meet with the FDA to discuss the clinical program to support the registration of TNX-102 SL 5.6 mg for the treatment of PTSD."

Jonathan R.T. Davidson, M.D., emeritus professor in the Department of Psychiatry and Behavioral Sciences at Duke University Medical Center and former Director of the Anxiety and Traumatic Stress Program, and consultant to Tonix, commented, "There is a continuing need to develop effective and well-tolerated treatments for people whose daily living is impaired by PTSD. I am encouraged by the results that have emerged from this well-designed and carefully executed study and look forward to seeing this drug treatment advance into a registration clinical program."

Dr. Lederman added, "In the last decade, there has been little activity in the recruitment of military-related PTSD patients to participate in industry-sponsored, large-scale randomized controlled clinical studies of experimental medicines. We were successful in recruiting a relevant patient population. The AtEase Study evaluated the dose-response relationship of TNX-102 SL and identified the 5.6 mg dose as a clinically effective and well-tolerated dose for registration studies. The results of the AtEase Study not only support the development of TNX-102 SL 5.6 mg towards commercialization, but also help to better understand PTSD, a serious and disabling condition affecting many veterans who have served our country. We are grateful to the participants and their families for supporting this study."

Summaries of the preliminary efficacy and safety results are provided in the following tables:

Table 1. Preliminary Efficacy of TNX-102 SL in the AtEase Study

Assessment	Domain	Analysis	p Values	
			2.8 mg (N=90)	5.6 mg (N=49)
CAPS-5	Total	MMRM[1] with Multiple Imputation	0.211	0.031*
	Total	ANCOVA	0.090	0.038*
	Arousal and Reactivity	MMRM	0.141	0.048*
	Sleep E6 Item	MMRM	0.185	0.010*
	Startle E4 Item	MMRM	0.336	0.015*
CGI-I[2]		Responder	0.240	0.041*

PGIC[3]		MMRM	0.075	0.035*
Sheehan Disability Scale	Total	MMRM	0.174	0.079
	Work/school Item	MMRM	0.123	0.050*
	Social/leisure Item	MMRM	0.198	0.031*
	Family life/home responsibilities Item	MMRM	0.375	0.524

[1]MMRM = Mixed Model Repeated Measures
[2]CGI-I = Clinician Global Impression-Improvement
[3]PGIC = Patient Global Impression of Change
*$p \leq 0.05$

Table 2. Preliminary Adverse Events Reported in > 5% of Subjects in Any Treatment Arm

		TNX-102 SL		
	Placebo (N=94)	**2.8 mg (N=93)**	**5.6 mg (N=50)**	**Total TNX-102 SL (N=143)**
Local Administration Site Conditions				
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)	54 (37.8%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)	17 (11.9%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)	6 (4.2%)
Systemic Adverse Events				
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)	19 (13.3%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)	12 (8.4%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)	11 (7.7%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)	10 (7.0%)
Sedation	1 (1.1%)	2 (2.2%)	6 (12.0%)	8 (5.6%)
Upper respiratory infection	5 (5.3%)	3 (3.2%)	2 (4.0%)	5 (3.5%)
Abnormal dreams	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)
Weight increased	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)

Tonix's chief medical officer, Gregory Sullivan, M.D., will present topline data from the AtEase Study at the American Society of Clinical Psychopharmacology Annual Meeting to be held in Scottsdale, Arizona on May 31, 2016.

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

Conference Call and Webcast Information

Tonix will host a conference call today at 8:00 a.m. ET to review the topline results from the Phase 2 study of TNX-102 SL. To participate in the call, please dial +1 (877) 481-7178 (domestic) or +1 (929) 387-3796 (international) and reference the access code 2193496. A replay of the conference call may be accessed through June 18, 2016 by dialing +1 (855) 859-2056 (domestic) or +1 (404) 537-3406 (international) and by using the access code 2193496. The conference call also will be webcast live on the Investors section of Tonix's website, www.tonixpharma.com, and will be archived until June 18, 2016.

About Post-Traumatic Stress Disorder

PTSD can develop from witnessing or experiencing a traumatic event or ordeal in which there was the severe threat of or actual occurrence of grave physical harm. PTSD affects approximately 8.4 million Americans and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of intrusive memories, flashbacks, and nightmares. PTSD is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and sometimes associated with clinical depression and suicidal thinking. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable violent or suicidal behaviors. It is estimated that 20 percent of the over 2.5 million US military personnel returning from tours of duty in the recent conflicts in Iraq and Afghanistan suffer from PTSD[1].

[1]Source: Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD. Cumulative from 1st Qtr FY 2002 through 1st Qtr FY 2014.

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 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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