UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): June 11, 2015

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

509 Madison Avenue, Suite 306, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

Copy of correspondence to:

Marc J. Ross, Esq.
James M. Turner, Esq.
Sichenzia Ross Friedman Ference LLP
61 Broadway
New York, New York 10006
Tel: (212) 930-9700 Fax: (212) 930-9725

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On June 11, 2015, Tonix Pharmaceuticals Holding Corp. (the "Company") announced additional data from its Phase 2b BESTFIT (Bedtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy) study presented in two posters entitled "TNX-102 SL for the Treatment of Fibromyalgia: Role of Nonrestorative Sleep on Pain Centralization" and "TNX-102 SL for Treatment of Fibromyalgia: Approaches to Pain Measurement" (collectively, the "Posters") at the 16th Annual European Congress of Rheumatology, to be hosted by the European League Against Rheumatism. The Posters were presented by Dr. Seth Lederman, M.D., President and Chief Executive Officer of the Company and Dr. R. Michael Gendreau, M.D., Ph.D., Principal of Gendreau Consulting and a member of the Company's scientific advisory board.

The foregoing description of the Posters is qualified in its entirety by reference to the Posters, copies of which are filed as Exhibits 99.01 and 99.02 to, and are incorporated by reference in, this report.

On June 11, 2015, the Company issued a press release announcing the presentation of additional data from the Phase 2b BESTFIT study through the Posters. A copy of the press release that discusses this matter is filed as Exhibit 99.03 to, and incorporated by reference in, this report.

The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01	TNX-102 SL for the Treatment of Fibromyalgia: Role of Nonrestorative Sleep on Pain Centralization Poster
99.02	TNX-102 SL for Treatment of Fibromyalgia: Approaches to Pain Measurement Poster
99.03	Press Release, dated June 11, 2015, issued by Tonix Pharmaceuticals Holding Corp.

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: June 11, 2015

By: */s/ LELAND GERSHELL*
Leland Gershell
Chief Financial Officer

THU0325

TNX-102 SL* for the Treatment of Fibromyalgia: Role of Nonrestorative Sleep on Pain Centralization

Seth Lederman[1], Daniel Clauw[2], Judy Gendreau[3], Lesley Arnold[4], Harvey Moldofsky[5], Philip Mease[6], Bruce Daugherty[1], R. Michael Gendreau[3]

[1]Tonix Pharmaceuticals, New York, New York. [2]University of Michigan, Ann Arbor, Michigan. [3]Gendreau Consulting, LLC, Poway, California. [4]Psychiatry, University of Cincinnati College of Medicine, Cincinnati, Ohio. [5]University of Toronto, Toronto, Canada. [6]University of Washington, Seattle, Washington.

Introduction

- In patients with fibromyalgia (FM), sleep quality has been shown to correlate to symptoms: when sleep is perceived as restful, patients report substantial improvement in their daytime symptoms
- Unfortunately, poor nighttime sleep has been considered as a predictor of a more painful day, and a more painful day in turn tends to be followed by poorer sleep at night, creating a vicious cycle
- The importance of nonrestorative sleep in the pathophysiology of FM suggests that treatments that improve sleep quality may improve FM globally by a mechanism distinct from that of centrally acting analgesics
- TNX-102 SL is an eutectic sublingual formulation of cyclobenzaprine (CBP) designed for rapid transmucosal absorption and bedtime use
- Phase 1 comparative pharmacokinetic study supports the advantage of the proprietary CBP eutectic formulation
- The current study was designed to evaluate the safety and efficacy of TNX-102 SL in the treatment of FM

Methods

BESTFIT Study Characteristics and Endpoint Measures

BESTFIT = Bedtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy

- 12 week randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by 2010 ACR criteria
- 205 participants in 17 centers in the United States
  - Placebo (n=102)
  - TNX-102 SL 2.8 mg (n=103)

Entry Criteria

- The patient had a diagnosis of primary fibromyalgia as defined by the 2010 ACR Preliminary Diagnostic Criteria for fibromyalgia defined as all of the following:
  a) WPI ≥ 7 and SS scale score ≥ 5; OR WPI 3-6 and SS scale score ≥ 9; and
  b) Symptoms present at a similar level for at least 3 months; and
  c) Patients did not have a disorder that would have otherwise explained their pain.

Primary efficacy endpoint

- Mean change from baseline in the daily diary pain score during week 12
- 11-point (0-10) Numerical Rating Scale (NRS) to assess prior 24-hour average pain intensity

Key secondary efficacy endpoints

- Patient Global Impression of Change (PGIC)
- Fibromyalgia Impact Questionnaire-Revised (FIQ-R)
- Daily Sleep Diary
- PROMIS Sleep Disturbance Instrument

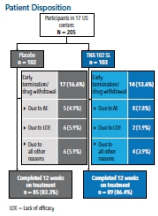
Safety Evaluation

- Adverse events (AEs)
- Administration site reactions/local oral adverse events

Baseline Characteristics

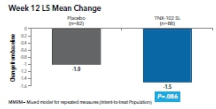
Characteristic	Placebo N=101	TNX-102 SL N=103
Age (SD)	49.7 (11.7)	50.7 (9.9)
Males (%)	3 (3%)	7 (6.8%)
Caucasian (%)	88 (87%)	91 (88%)
Weight, kg (SD)	80.9 (17.2)	80.6 (16.7)
BMI (SD)	30.0 (5.5)	30.0 (5.7)
Never smoked	68%	60%
Currently employed	55%	48%
College level or higher education	77%	85%

Patient Disposition

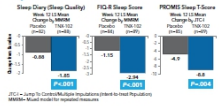


LOE = Lack of efficacy

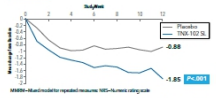
TNX-102 SL Daily Pain Scores at Week 12 (MMRM)



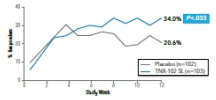
All sleep secondary endpoints improved on TNX-102 SL



Change from Baseline in NRS Weekly Average of Daily Sleep Quality Scores (MMRM)

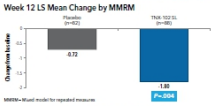


30% Responder Rate on Daily Diary Pain Score Was Higher for TNX-102 SL

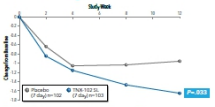


TNX-102 SL Improved FIQ-R Pain Scores

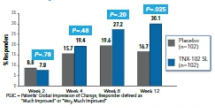
Week 12 LS Mean Change by MMRM



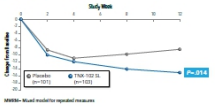
TNX-102 SL Showed Significant Improvement on the Clinic-Reported Numeric Rating Scale Pain Measure



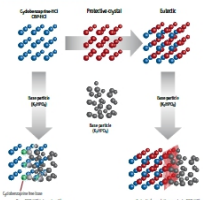
PGIC Response Rate Over Time



TNX-102 SL Demonstrated a Significant Improvement in FIQ-R Total Score (MMRM)

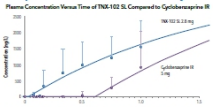


Proprietary Cyclobenzaprine Hydrochloride Eutectic Mixture Stabilizes Tablet Formulation



Cyclobenzaprine Is Detected in Plasma Within 20 Minutes Following Sublingual Administration of TNX-102 SL in Phase 1 Comparative Pharmacokinetic Study

Plasma Concentration Versus Time of TNX-102 SL Compared to Cyclobenzaprine IR



Pharmacokinetics of Cyclobenzaprine Formulations and Active Metabolite

Parameter	TNX-102 2.8 mg SL	Oral IR CBP	Comparison
Dose	2.8 mg sublingual tablet	5 mg oral tablet	44% lower dose for SL
Absorption Lag Time	0.083 h (<15 min)	0.423 h (~27 min)	12 x faster for SL
Relative Bioavailability	114%		14% greater for SL
T_{max}	0.33 h	4.00 h	Similar
C_{max}	3.41 ng/mL	4.26 ng/mL	20% lower for SL
$AUC_{0-\infty}$	33.4 ng•h/mL	29.5 ng•h/mL	13% lower for SL
Active Metabolite	nCBP	nCBP	
C_{max}	0.81 ng/mL	1.71 ng/mL	53% lower for SL
$AUC_{0-\infty}$	39.5 ng•h/mL	68.6 ng•h/mL	43% lower for SL

TNX-102 SL Adverse Events

Systemic Adverse Events (≥2 subjects in either group)

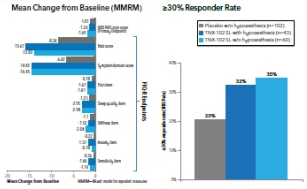
System Organ Class	Adverse Event Term	Placebo (n=101)	TNX-102 SL (n=103)
	Total n (%)	47 (46.5%)	68 (66.0%)
Gastrointestinal Disorders	Dysmenorrhoea	7 (6.9%)	10 (9.7%)
	Nausea	7 (6.9%)	8 (7.8%)
	Diarrhoea	4 (3.9%)	5 (4.9%)
	Constipation	2 (2.0%)	2 (1.9%)
	Dyspepsia	1 (1.0%)	2 (1.9%)
	Vomiting	0 (0.0%)	2 (1.9%)
Infections and Infestations	Nasopharyngitis	4 (3.9%)	3 (2.9%)
	Upper respiratory tract infection	3 (3.0%)	3 (2.9%)
	Sinusitis	1 (1.0%)	2 (1.9%)
	Influenza	1 (1.0%)	2 (1.9%)
	Urinary tract infection	1 (1.0%)	2 (1.9%)
Nervous system disorders	Dizziness	2 (2.0%)	3 (2.9%)
Musculoskeletal and connective tissue disorders	Back pain	3 (3.0%)	5 (4.9%)
General disorders and administration site conditions	Product taste abnormal	0	9 (7.8%)
	Fatigue	2 (2.0%)	3 (2.9%)
Psychiatric disorders	Insomnia	2 (2.0%)	3 (2.9%)
	Anxiety	0 (0.0%)	3 (2.9%)
	Nervousness	0 (0.0%)	2 (1.9%)
Investigations	Weight	2 (2.0%)	0

Oral Adverse Events (≥2 subjects in either group)

Adverse Event Term	Placebo (n=101)	TNX-102 SL (n=103)
Total n (%)	47 (46.5%)	68 (66.0%)
Dysmenorrhoea	7 (6.9%)	10 (9.7%)
Product taste abnormal	-	9 (7.8%)
Nausea	7 (6.9%)	8 (7.8%)
Diarrhoea	4 (3.9%)	5 (4.9%)
Sinusitis	1 (1.0%)	2 (1.9%)
Dizziness	2 (2.0%)	3 (2.9%)
Nasopharyngitis	4 (3.9%)	3 (2.9%)
Upper respiratory tract infection	3 (3.0%)	3 (2.9%)
Insomnia	2 (2.0%)	3 (2.9%)
Fatigue	2 (2.0%)	3 (2.9%)
Back pain	3 (3.0%)	5 (4.9%)
Influenza	1 (1.0%)	2 (1.9%)
Urinary tract infection	1 (1.0%)	2 (1.9%)
Anxiety	-	3 (2.9%)
Nervousness	-	2 (1.9%)
Paraesthesia (or Dysgeusia)	-	2 (1.9%)
Swollen tongue	1 (1.0%)	2 (1.9%)
Erythema chronicum migrans	1 (1.0%)	1 (1.0%)
Eye swelling	-	2 (1.9%)
Tongue ulceration	-	2 (1.9%)

Presence of Oral Adverse Events Did Not Lead to Significant Differences in Outcome Measures

Mean Change from Baseline (MMRM) ≥30% Responder Rate



Conclusions

- TNX-102 SL, an eutectic sublingual formulation of CBP, administered at bedtime improved sleep quality by multiple measures
- Nonrestorative sleep has been linked to central sensitization, which is a process in which regional chronic pain leads to changes in central pain processing and interpretation
- Treatment with TNX-102 SL demonstrated improvement in sleep quality, which in turn led to a broad range of FM symptom improvements including PGIC, FIQ-R total score, as well as pain reduction (30% response)
- A Phase 3 study has been initiated based on this outcome

References

1. Data on file, Tonix Pharmaceuticals.

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

Lederman S, Clauw D, Gendreau J, et al. TNX-102 SL for the treatment of fibromyalgia: role of nonrestorative sleep on pain centralization. Poster presented at: 16th EULAR Annual European Congress of Rheumatology; June 10-13, 2015; Rome, Italy.

Annual European Congress of Rheumatology, Fiera di Roma, Roma, Italy, 10 - 13 June 2015

THU0322

TNX-102 SL* for Treatment of Fibromyalgia: Approaches to Pain Measurement

R. Michael Gendreau[1], Daniel Clauw[2], Judy Gendreau[1], Bruce Daugherty[3], Seth Lederman[3]

[1]Gendreau Consulting, LLC, Poway, California, [2]University of Michigan, Ann Arbor, Michigan, [3]Tonix Pharmaceuticals, New York, New York

Introduction

- TNX-102 SL is a novel sublingual investigational formulation of low dose (2.8 mg) cyclobenzaprine designed for rapid absorption and routine bedtime use
- We recently completed a Phase 2b trial (BESTFIT) of TNX-102 SL, which was the first large scale evaluation of this therapeutic approach in fibromyalgia patients
- In addition to assessments of the efficacy of TNX-102 SL in reducing symptoms of fibromyalgia, we explored various methodological approaches to evaluation of changes in patient reported symptoms

Methods

BESTFIT Study Characteristics and Endpoint Measures

BESTFIT – Bedtime Sublingual TNX-102 SL as Fibromyalgia

Intervention Therapy

- 12-week, randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by 2010 ACR criteria
- 205 participants in 17 centers in the United States
  - Placebo (n=102)
  - TNX-102 SL 2.8 mg (n=103)

Primary efficacy endpoint

- Mean change from baseline in the daily diary pain score during week 12
- 11-point (0-10) Numerical Rating Scale (NRS) to assess prior 24-hour average pain intensity

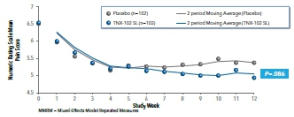
Key secondary efficacy endpoints

- Patient Global Impression of Change (PGIC)
- Fibromyalgia Impact Questionnaire-Revised (FIQ-R)
- Daily Sleep Diary
- PROMIS Sleep Disturbance Instrument

Safety Evaluation[1]

- Adverse events
- Oral adverse events

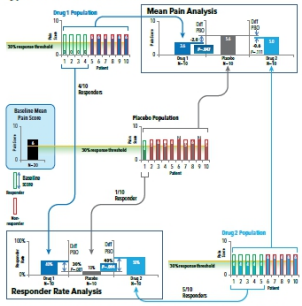
Change from Baseline (CFB) in Mean Pain over 12 Weeks Was Numerically Lower for TNX-102 SL Than for Placebo (MMRM)



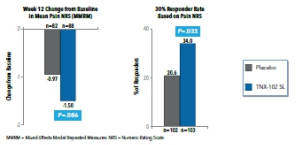
MMRM = Mixed-Effects Model Repeated Measures

Responder Analysis versus Mean Pain Analysis Has More Clinical Relevance and Greater Statistical Significance in Certain Cases

Hypothetical Clinical Trial Result

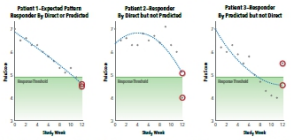


In BESTFIT, TNX-102 SL Had a Significant Effect on 30% Responder Rate but Not Mean Pain



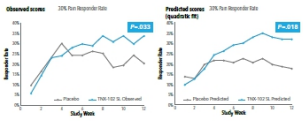
MMRM = Mixed-Effects Model Repeated Measures; NRS = Numeric Rating Scale

Quadratic Fitting Normalizes Anomalies That May Occur in Individual Pain Scores at Study Endpoint

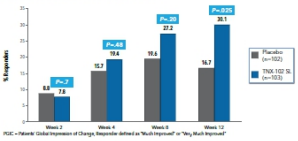


- Predicted values obtained by 2nd order line fitting normalizes anomalous results that may occur at individual study visits
- Because a patient's response is based on the week 12 score, anomalous results at week 12 can skew the response rate
- Response rates based on predicted pain scores can compensate for anomalous scores, leading to reduced variation and lower P-values

30% Responder Rate Predicted Scores Were More Significant than Observed Scores

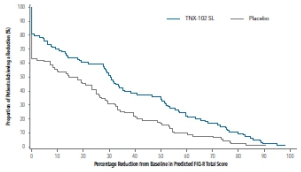


PGIC Response Rate Over Time



PGIC = Patients' Global Impression of Change, Responder defined as "Much Improved" or "Very Much Improved"

Continuous Responder Analysis on FIQ-R Total Score at Week 12



Conclusions

- To convey the benefits of a pain medication to patients and physicians, responder analysis is more clinically relevant and comprehensible than change from baseline
- Change from baseline analysis is often preferred because it generally has more power to detect a treatment effect, thus necessitating fewer patients in the study
- Using predicted pain score values for response categorization of individual patients may improve the statistical significance of the response rates
- TNX-102 was significantly better than placebo on the pain responder rates determined using the pain numeric rating scale
- The most common local adverse event was transient tongue or mouth numbness occurring in 42% of treated patients. No systemic adverse events were noted in >5% of treated patients.
- Regulators have recognized that responder analyses have face validity and are a viable alternative to mean change analyses to determine therapeutic efficacy

References

1. Lederman S, Clauw D, Gendreau J, et al. TNX-102 SL for the treatment of fibromyalgia: role of nonrestorative sleep on pain normalization. Annual European Congress of Rheumatology, Rome, Italy, 10-13 June 2015; Abstract THU0295.
2. Moore RA, Moore OA, Derry S, Peloso PM, Gammaitoni AR, Wang H. Responder analysis for pain relief and function: an approach to deriving a clinically important outcem from four chronic osteoarthritis trials. Arthritis Res Ther. 2010;12(2):R73. doi: 10.1186/ar2985. Epub 2010 Apr 20. Review. PubMed PMID: 20406467; PubMed Central PMCID: PMC2888189.
3. Data on file. Tonix Pharmaceuticals.

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

Gendreau RM, Clauw D, Gendreau J, Daugherty B, Lederman S. TNX-102 SL for treatment of fibromyalgia: approaches to pain measurement. Poster presented at: 16th EULAR Annual European Congress of Rheumatology; June 10-13, 2015; Rome, Italy.

Exhibit 99.03

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 – 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.

Contacts:

Tonix Pharmaceuticals Holding Corp.
Leland Gershell
Chief Financial Officer
(212) 980-9155 x104
leland.gershell@tonixpharma.com

Martini Communications
Amy Martini (investors)
amartini@martinicommunications.com

Dian Griesel Int'l.
Susan Forman/Laura Radocaj (media)
(212) 825-3210
sforman@dgicomm.com
lradocaj@dgicomm.com