

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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 22, 2015

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**TONIX PHARMACEUTICALS HOLDING CORP.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or Other Jurisdiction  
of Incorporation)

**001-36019**  
(Commission  
File Number)

**26-1434750**  
(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

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New York, New York 10006  
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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))
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**Item 8.01 Other Events.**

On June 22, 2015, Tonix Pharmaceuticals Holding Corp. (the "Company") announced additional non-clinical data from its TNX-201 (dexisomethetene mucate) program presented in two posters entitled "(R)-Isomethetene (IMH) Binds to the Imidazoline-1 Receptor and (S)-IMH Increases Blood Pressure: Potentially Superior Benefit-to-Risk Ratio for (R)-IMH as an Analgesic for Headache" and "The (R)-isomer of isomethetene, decreases trigeminal sensitivity in the Inflammatory Soup and Spontaneous Trigeminal Allodynia rat models" (collectively, the "Posters") at the 57<sup>th</sup> Annual Scientific Meeting of the American Headache Society in Washington, DC.

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 22, 2015, the Company issued a press release announcing the presentation of additional non-clinical data from its TNX-201 (dexisomethetene mucate) program 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 (R)-Isomethetene (IMH) Binds to the Imidazoline-1 Receptor and (S)-IMH Increases Blood Pressure: Potentially Superior Benefit-to-Risk Ratio for (R)-IMH as an Analgesic for Headache Poster
- 99.02 The (R)-isomer of isomethetene, decreases trigeminal sensitivity in the Inflammatory Soup and Spontaneous Trigeminal Allodynia rat models Poster
- 99.03 Press Release, dated June 22, 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 22, 2015

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

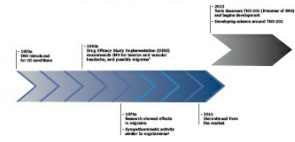
# (R)-Isometheptene\* (IMH) Binds to the Imidazoline-1 Receptor and (S)-IMH increases Blood Pressure: Potentially Superior Benefit-to-Risk Ratio for (R)-IMH as an Analgesic for Headache

Bruce Daugherty, Leland Gershall, Seth Lederman  
Tonix Pharmaceuticals, New York, NY

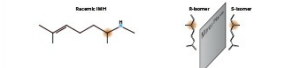
## Introduction

- Isometheptene (IMH) is a racemic drug that has been used clinically in the US for more than 70 years primarily as a treatment for headache. Yet its mechanism of action remains unknown.
- Racemic IMH has sympathomimetic effects that have been linked to cardiovascular effects reported in the product labeling.
- To elucidate the mechanism of action of IMH, we separated IMH into the individual isomers, (R)-IMH and (S)-IMH and studied their molecular and cardiovascular effects.

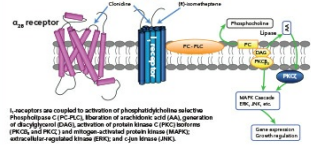
## Racemic isometheptene (IMH) has a long track record of use



## Previously marketed isometheptene drugs were a mixture containing equal amounts of two chemically distinct, mirror-image isomers



## Model of I<sub>1</sub>-imidazoline receptor signalling pathways



## Methods

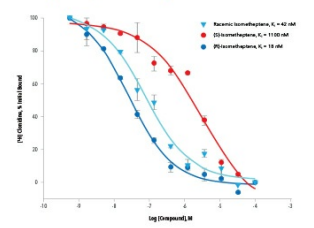
- Racemic IMH was screened on a broad panel of protein targets, which included enzymes, receptors (both GPCR and non-GPCR), ion channels and transporters.
- The effects on arterial blood pressure (AP) and heart rate (HR) of intravenous (IV) racemic IMH, (R)-IMH, and (S)-IMH in anesthetized male Wistar rats were studied (using consecutive doses of 0.03, 0.1, 0.3, 1, 3, and 10 mg/kg IV with 10 minute inter-dose intervals).
- The pharmacokinetics (PK) of racemic and (R)-IMH were studied in rats using stereospecific liquid chromatography-mass spectrometry.

## Results

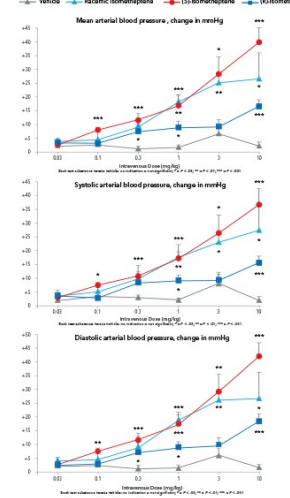
### Comparative Binding Affinities of (R)-Isometheptene versus (S)-Isometheptene to Receptors Expressed in the CNS

Compound	K <sub>i</sub> (nM)			Sigma-1 Receptor / Sigma-2 Receptor	
	IMH	(R)	(S)		
(R)-Isometheptene	18	42	50000	1800	5600
(S)-Isometheptene	1100	180	52000	2100	5200

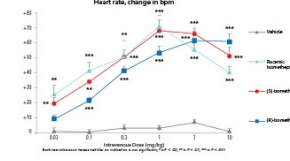
### Equilibrium Binding of (R)-Isometheptene, (S)-Isometheptene and Racemic Isometheptene to I<sub>1</sub>-Imidazoline Receptor



### (R)-Isometheptene Has Reduced Effects on Blood Pressure Compared to (S)-Isometheptene and Racemic Isometheptene



### (R)-Isometheptene Has Similar Effects on Heart Rate Compared to (S)-Isometheptene and Racemic Isometheptene



### Pharmacokinetics of Racemic Isometheptene Mixture and (R)-Isometheptene Mixture in Rats

Test Article	Dose (mg/kg)	C <sub>max</sub> (ng/mL)		AUC <sub>0-12h</sub> (ng·h/mL)		T <sub>1/2</sub> (h)		T <sub>max</sub> (h)	
		(R)-IMH	(S)-IMH	(R)-IMH	(S)-IMH	(R)-IMH	(S)-IMH	(R)-IMH	(S)-IMH
Racemic IMH	1	165	175	62	66	0.16	0.16	0.37	0.38
(R)-IMH	0.5	108	NC	74	NC	0.16	NC	0.47	NC

## Conclusions

- Our finding that (R)-IMH binds to I<sub>1</sub> with high affinity suggests that this receptor is the primary site of action for (R)-IMH's analgesic effects. This is confirmed by recent results in the rat brain, in which there is a decreased pain threshold.
- Our finding that (S)-IMH produces significantly higher increased BP suggests that this isomer is responsible for the cardiovascular liability observed with racemic IMH.
- These findings suggest that (R)-IMH is an agonist of I<sub>1</sub>, a receptor in the brain that regulates pain perception, and that it may have a superior benefit/risk ratio as an analgesic for headache compared to either the racemic or the (S) isomer.

## References

1. Mignen Two-Drug Migraine Prophylaxis. Clin Med. 2014.
2. Wang J, Smith KJ. Isometheptene: a review of the treatment of migraine. Headache. 1993;33(11):713.
3. Wang J, Smith KJ, et al. Generation and primary pharmacology of recombinant human imidazoline-1 (hI1) receptor. Mol Pharmacol. 2005;68(1):10-18.

\* (R)-IMH mixture is being investigated in the US for tension-type headache as TNOX-201 under US Investigational New Drug and it is not approved for any indication.

# The (R)- isomer of isometheptene\*, decreases trigeminal sensitivity in the Inflammatory Soup and Spontaneous Trigeminal Allodynia rat models.

Nathan T. Fried<sup>1</sup>, Michael L. Oshinsky<sup>1</sup>, Bruce Daugherty<sup>2</sup>, Seth Lederman<sup>2</sup> and Melanie B. Elliott<sup>1</sup>  
 1 Department of Neurosurgery, Thomas Jefferson University, Philadelphia, PA, USA  
 2 Tonix Pharmaceuticals Holding Corp, NYC, NY, USA



## Abstract

**Background:** Isometheptene, a racemic mixture of (R)- and (S)- enantiomers, is an active ingredient of the commonly known headache medication, Midrin. Although a previously untested mechanism of action related to the vascular hypothesis of migraine, the actual mechanism(s) remain elusive. Assessing the effect of each isomer individually in headache is essential in developing more efficacious treatment options for migraine patients. Two rat models of trigeminal pain which feature aspects of chronic migraine have been developed to allow for the testing of therapeutic compounds and investigation of the mechanisms behind migraine. The inflammatory soup (IS) model is developed by repeated dorsal infusion of an inflammatory soup (IS) for a month which results in chronic trigeminal sensitivity that outlasts the final infusion for months. The spontaneous trigeminal allodynia (STA) model is representative of primary headache since it is naturally expressed without experimental manipulation. Both these models chronic symptoms to human migraine patients such as episodic or chronic trigeminal sensitivity, phonophobia, responsiveness to abortive and prophylactic headache treatments, and sensitivity to migraine triggers.

**Objective:** The aim of this study was to test the effects of the (R)- and (S) isomers of isometheptene on trigeminal sensitivity in a rat model of the inflammatory soup and the spontaneous trigeminal allodynia rat models.

**Methods:** The pharmacokinetics (PK) of racemic and (R)-isometheptene were studied in rats using isomer-specific LC-MS. The effects of the (R)- and (S)- isometheptene on trigeminal sensitivity/allodynia in the IS and STA rats were analyzed. Animals for this study represent the 17th generation of an F1 rat colony. Periorbital thresholds, as measured with von Frey filaments were obtained to determine trigeminal sensitivity prior to and 0.5 hr., 1.5 hr., 2.5 hr., 3.5 hr., and 24 hr post-treatment with (S)-isometheptene, (R)-isometheptene, or saline vehicle. All treatments were administered intraperitoneally.

**Results:** Racemic and (R)-isometheptene had similar PK profiles (p.o.) with Tmax of 15-20 minutes and T1/2 of 0.5 h and no isomeric conversion between (R)- and (S)- isometheptene. Treatment with 30 mg/kg of the (R)-isomer of isometheptene significantly increased trigeminal thresholds at the 0.5 hr (2.3-fold), 1.5 hr (3.0-fold), 2.5 hr (2.5-fold), and 3.5 hr (1.7-fold) time points in IS rats (Fig. 3). Treatment with 30 mg/kg of the (R)-isomer of isometheptene significantly increased trigeminal thresholds at the 0.5 hr (1.8-fold), 1.5 hr (4.2-fold), 2.5 hr (4.5-fold), 3.5 hr (8.5-fold), and 24 hr (8.2-fold) time points in STA rats (Fig. 6). In contrast, treatment with 30 mg/kg of the (S)- isomer, had no effect on trigeminal sensitivity in either the IS or STA models (Fig. 3 & 6). 1mg/kg of the (R) or (S) isomer had no effect on trigeminal sensitivity (Fig. 2 & 5).

**Conclusions:** These data show (R)- isometheptene treatment relieved trigeminal sensitivity in the inflammatory soup and spontaneous trigeminal allodynia rat models, two models representative of the chronic nature of migraine. Additional dosing experiments are warranted to determine the dose response of this effect. These findings support development of the (R)-isomer of isometheptene as an abortive therapeutic for primary headache and other chronic pain indications.

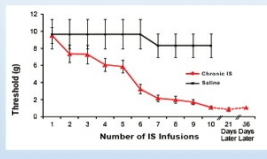
\* (R)-isometheptene is being investigated in the US for tension-type headache under a US IND and is not approved for any indication.

**Introduction**  
 Midrin, containing Isometheptene Muscate (50 mg), Dichloralphenazone (100 mg) and Acetaminophen (325 mg), is indicated for relief of migraine headache. It was initially believed that isometheptene's vasoactive effects were responsible for Midrin's efficacy in migraine. Isometheptene, however, is a racemic mixture of (R)- and (S)- enantiomers, each with its own very distinct receptor-interaction profile. The (R)- isomer has high specificity as an agonist for imidazoline receptor type 1 (1) while the (S)- isomer has no affinity for this receptor. 11 receptor knock-out mice feature reduced pain phenotypes, suggesting that this receptor may be involved in pain and that the (R)- isomer could be the effective component to isometheptene's role in migraine headache treatment via this receptor (Zhang, 2013).

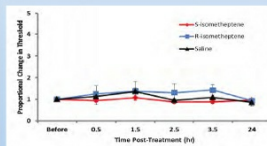
**Chronic Migraine Model**  
 Rats were fitted with a cannula for inflammatory soup infusions (Bradykinin, PGE2, 5-HT, Histamine). Von Frey testing was done in a plastic tube restraint in the periorbital region of the rat above the nostril part of the eye. Threshold was noted when rats quickly retracted their head away from the bending von Frey monofilament or performed a long brush of its face with the ipsilateral paw. Infusions were performed biweekly to simulate episodic activation of dural nociceptors in chronic migraine (Fig. 1) (Oshinsky, 2007).

**Spontaneous Trigeminal Allodynia Model**  
 Most animal headache models require manipulation of the animal, often with a stimulus to activate dural nociceptors or the trigeminal nerve. Using behavioral methods of monitoring trigeminal pain in rats, our group discovered a rat with spontaneous episodic trigeminal allodynia. Subsequent mating showed that the trait is inherited in 40-50% of offspring from affected animals crossed to unaffected animals, and in ~60-70% of offspring from crosses with 2 affected animals. A stable colony has been established through 18 generations of inbreeding. These rats exhibit episodic threshold decreases that are responsive to treatment by NSAIDs, triptans, and DHE. They also experience phonophobia (Oshinsky, 2012).

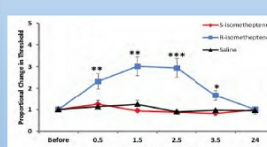
## Results - Inflammatory Soup Model



**Figure 1: Trigeminal sensitivity in the inflammatory soup model.**  
 To assess trigeminal allodynia, periorbital Von Frey Minofilament thresholds were measured throughout the treatment period in rats receiving infusions of saline (n=10) or IS (n=10), 3 days/week. Rats receiving infusions of IS "transitioned" to a more sensitive state, as seen as a decrease in their periorbital thresholds, whereas rats receiving saline infusions did not transition to a more sensitive state. Rats that have "transitioned" to chronic periorbital sensitivity have thresholds of < 2.0g. Naive or non-transitioned rats do not respond to any pressure less than 8-10g.

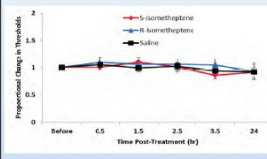


**Figure 2: Effects of 1mg/kg of R- & S-enantiomers of isometheptene on trigeminal sensitivity in the inflammatory soup model.**  
 No significant changes in trigeminal sensitivity were seen when IS rats were treated with 1mg/kg R- or S- isometheptene (i.p.) (n=8 rats/group).

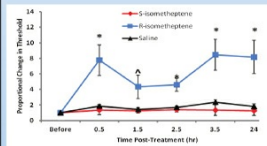


**Figure 3: Effects of 30mg/kg of R- & S-enantiomers of isometheptene on trigeminal sensitivity in the inflammatory soup model.**  
 30mg/kg of R-isometheptene decreased trigeminal sensitivity while 30mg/kg of S-isometheptene had no effect on sensory thresholds. Rats receiving saline treatment had no change in sensory thresholds over the course of the experimental timeline. (n=8 rats/group, \*P<0.05, \*\*P<0.01, \*\*\*P<0.001).

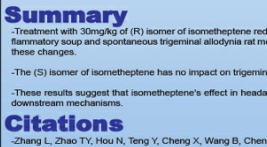
## Results - STA Model



**Figure 4: Trigeminal Sensitivity in the Spontaneous Trigeminal Allodynia rat model.**  
 Trigeminal threshold tracking for four individual rats in the 9th generation. The heterogenic pattern of periorbital von Frey threshold changes are seen in these rat. Tests were done 5 times per week for 4 weeks. Thresholds were obtained in the morning, within the 3 hours after the lights were turned on.



**Figure 5: Effects of 1mg/kg of R- & S-enantiomers of isometheptene on trigeminal sensitivity in the STA model.**  
 No significant changes in trigeminal sensitivity was seen when STA rats were treated with 1mg/kg R- or S- isometheptene. (n=8 rats/group).



**Figure 6: Effects of 30mg/kg of R- & S-enantiomers of isometheptene on trigeminal sensitivity in the STA model.**  
 30mg/kg of R-isometheptene decreased trigeminal sensitivity while 30mg/kg of S-isometheptene had no effect on sensory thresholds. Rats receiving saline treatment had no change in sensory thresholds over the course of the experimental timeline. (n=8 rats/group, \*P<0.01, \*\*P<0.05).

## Summary

Treatment with 30mg/kg of (R) isomer of isometheptene reduces trigeminal sensitivity in both the inflammatory soup and spontaneous trigeminal allodynia rat models. 1mg/kg is not sufficient to produce these changes.

The (S) isomer of isometheptene has no impact on trigeminal sensitivity.

These results suggest that isometheptene's effect in headache treatment is due (R) isomer-specific downstream mechanisms.

## Citations

Zhang L, Zhao TY, Hou N, Teng Y, Cheng X, Wang B, Chen Y, Jiang L, Wu N, Su RB, Yang X, Li J. Generation and primary phenotypes of imidazoline receptor antisense-selected (IRAS) knockout mice. *CNS Neurosci Ther.* (2013) 19(12):978-81.

Oshinsky ML, Gomochareonsiri S. Episodic dural stimulation in awake rats: a model for recurrent headache. *Headache.* (2007) 47(7):1026-36.

Oshinsky ML, Menka M, Sanghvi MS, Maxwell CR, Gonzalez D, Spangenberg R, Cooper M, and Silberstein S. Spontaneous Trigeminal Allodynia in Rats: A Model of Primary Headache. *Headache.* (2012) 52(9): 1336-1349.

## Funding

Tonix Pharmaceuticals Holding Corp, NYC, NY, USA  
 Mentoring Junior Investigators in Alcohol Research (T32 AA007463)

## Poster Citation

Fried, NT, Oshinsky, M, Daugherty, B, Lederman S and Elliott, MB. The (R) isomer of isometheptene decreases trigeminal sensitivity in a rat model of primary headache. *Headache.* 2015; June 55(53) Abstract P558. 184.

**Tonix Pharmaceuticals Presents Non-clinical Data on TNX-201 at the 57<sup>th</sup> Annual Scientific Meeting of the American Headache Society**

*- TNX-201 demonstrates significant analgesic effects in animal models of migraine and chronic pain -*

*- TNX-201 targets the imidazoline-1 receptor and may represent a novel approach to the treatment of pain -*

NEW YORK – June 22, 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, announced that it presented non-clinical data from its TNX-201 (dexisometheptene mucate) program in two posters at the 57<sup>th</sup> Annual Scientific Meeting of the American Headache Society in Washington, DC. Tonix is currently evaluating TNX-201 in a Phase 2 proof-of-concept (POC) study in episodic tension-type headache. To learn more, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02423408).

The active ingredient in TNX-201, dexisometheptene mucate, contains (R)-isometheptene, or (R)-IMH, a single optical isomer of isometheptene. Racemic IMH, a mixture of both the (R) and (S) isomers, had been widely used as a single-agent prescription medicine and as a component of combination drug products (e.g., Midrin<sup>®</sup>) for many decades in the U.S. for various indications including tension-type headache. IMH was introduced as a pharmaceutical prior to 1962, and no products containing IMH are currently approved by the U.S. Food and Drug Administration (FDA) for any indication. TNX-201 is being developed as a new chemical entity for the treatment of episodic tension-type headache, based on current FDA drug registration requirements.

The two posters are summarized below, and are available on Tonix’s website at [www.tonixpharma.com](http://www.tonixpharma.com).

Abstract PS29. “*(R)-Isometheptene (IMH) Binds to the Imidazoline-1 Receptor and (S)-IMH Increases Blood Pressure: Potentially Superior Benefit-to-Risk Ratio for (R)-IMH as an Analgesic for Headache*”<sup>(1)</sup>

Key points:

- Data from receptor binding studies, taken together with the recent description of a decreased pain threshold in imidazoline-1 receptor (I<sub>1</sub>R) knock-out mice<sup>(2)</sup>, suggest that I<sub>1</sub>R may be the primary site of action for racemic IMH’s analgesic effects. Since (R)-IMH, the active ingredient in TNX-201, binds I<sub>1</sub>R with approximately 60-fold greater affinity than (S)-IMH, TNX-201 may be responsible for the therapeutic effect of racemic IMH.
- In anesthetized rats, treatment with (S)-IMH resulted in dose-dependent and statistically-significant blood pressure increases that were higher relative to those produced by the (R)-isomer.

Abstract PS58. “*The (R)-isomer of isometheptene, decreases trigeminal sensitivity in the Inflammatory Soup and Spontaneous Trigeminal Allodynia rat models*”<sup>(3)</sup>

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## Key points:

- The effects of (R)-IMH and (S)-IMH were evaluated in two rat models of trigeminal pain which feature aspects of chronic migraine: the Inflammatory Soup (IS) model and the Spontaneous Trigeminal Allodynia (STA) model. <sup>(4,5)</sup> These models had been developed to allow for the testing of therapeutic compounds for migraine. Both of these models experience similar symptoms to human migraine patients such as episodic or chronic trigeminal hypersensitivity, phonophobia, responsiveness to abortive and prophylactic headache treatments, and sensitivity to migraine triggers.
- In the IS model, treatment with 30 mg/kg of (R)-IMH mucate significantly increased trigeminal thresholds at each of the 0.5 hour (hr) (2.3-fold, p<0.01), 1.5 hr (3.0-fold, p<0.01), 2.5 hr (2.9-fold, p<0.001), and 3.5 hr (1.7-fold, p<0.05) time points.
- In the STA model, treatment with 30 mg/kg of (R)-IMH mucate significantly increased trigeminal thresholds at the 0.5 hr (7.8-fold, p<0.01), 1.5 hr (4.3-fold, p<0.05), 2.5 hr (4.5-fold, p<0.01), 3.5 hr (8.5-fold, p<0.01), and 24 hr (8.2-fold, p<0.01) time points.
- Treatment with 30 mg/kg of (S)-IMH mucate had no effect on trigeminal sensitivity in either the IS or STA models.

“Our findings that TNX-201 selectively modulates a receptor in the central nervous system that appears to regulate pain perception and responses, together with positive data in two rodent models representative of migraine, support the development of TNX-201 as a therapeutic for headache and potentially other pain indications and one that may be differentiated from currently-approved products,” said Bruce Daugherty, Ph.D., Tonix’s chief scientific officer. “We look forward to reporting the results of our Phase 2 POC study in episodic tension-type headache in the fourth quarter of this year.”

## References

- (1) Daugherty BL, Gershell L, and Lederman S. (R)-isometheptene (IMH) binds to the imidazoline-1 receptor and (S)-isometheptene increases blood pressure: potentially superior benefit to risk ratio for (R)-IMH as an analgesic for headache. *Headache* 2015;June 55(53):Abstract PS29. 172.
- (2) Zhang L et al. *CNS Neurosci Ther* 2013;19:978-81.
- (3) Fried NT, Oshinsky MI, Daugherty BL, Lederman S and Elliott MB. The (R) isomer of isometheptene decreases trigeminal sensitivity in a rat model of primary headache. *Headache* 2015;June 55(53):Abstract PS58. 184.
- (4) Oshinsky ML and Gomomchareonsiri S. *Headache* 2007;47:1026-36.
- (5) Oshinsky ML et al. *Headache* 2012;52:1336-1349.

## About Episodic Tension-Type Headache

Episodic tension-type headache is the most common type of headache. It is estimated that approximately 30% of U.S. adults experience frequent episodic tension-type headaches (one to 15 headaches per month over a three-month period). Tension-type headache pain is often described as a constant pressure on both sides of the head, and typically lasts for several hours. All of the FDA-approved prescription options for tension-type headache contain barbiturates.

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## **About Tonix Pharmaceuticals Holding Corp.**

Tonix Pharmaceuticals 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 Tonmya™ is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

TNX-102 SL and TNX-201 are Investigational New Drugs and have not been 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.*

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