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Tonix Pharmaceuticals Presents Non-clinical Data on TNX-201 at the 57th 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 (GLOBE NEWSWIRE) -- 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 57th 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 (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®) 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.

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*"(1)

Key points:

- Data from receptor binding studies, taken together with the recent description of a

decreased pain threshold in imidazoline-1 receptor (I_1R) knock-out mice[2], suggest that I_1R may be the primary site of action for racemic IMH's analgesic effects. Since (R)-IMH, the active ingredient in TNX-201, binds I_1R 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"*[3]

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.[4,5] 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 Gomonchareonsiri 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.

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.

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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