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Tonix Pharmaceuticals Completes Enrollment in Phase 3 Clinical Trial of TNX-102 SL in Fibromyalgia

- Top-line Results on Track to be Reported 3Q 2016 for Pivotal Study in Flagship Program -

NEW YORK, May 02, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder, announced today that it has completed enrollment in its Phase 3 AFFIRM clinical trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia.

"We are developing a new medicine for fibromyalgia because there are still inadequate therapy options despite its prevalence as one of the most common chronic pain conditions. Many individuals with fibromyalgia cannot tolerate the existing medicines or achieve a durable therapeutic benefit from them according to the United States Food and Drug Administration (FDA) October 2014 Patient-Focused Drug Development Initiative Fibromyalgia Report[1]," said Seth Lederman, M.D., president and chief executive officer of Tonix. "The completion of patient enrollment in our flagship development program is an important clinical milestone, and we look forward to reporting top-line data from this trial in the third quarter of 2016," added Dr. Lederman.

The AFFIRM study is a randomized, double-blind, placebo-controlled, 12-week Phase 3 clinical trial, designed to evaluate the efficacy of TNX-102 SL for the management of patients with fibromyalgia. Participants are treated with TNX-102 SL 2.8 mg, sublingually once daily at bedtime for 12 weeks. The primary outcome assessment for the study will be an FDA-accepted pain responder analysis, defined as the proportion of patients who report at least a 30 percent reduction in pain from baseline at the end of the 12-week treatment period. The AFFIRM study is being conducted at approximately 35 U.S. clinical sites, and enrollment has achieved the 500-patient goal per protocol.

About Fibromyalgia

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life and frequently are disabled.

[1]*For more information, see the United States Food and Drug Administration's October 2014 Patient Focused Drug Development Initiative Fibromyalgia Report at* www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM422351.pdf.

About TNX-102 SL

TNX-102 SL is a proprietary sublingual (under the tongue) eutectic formulation of cyclobenzaprine (CBP) that efficiently delivers a low dose of cyclobenzaprine to the bloodstream through mucosal membrane absorption. TNX-102 SL is designed for use at bedtime and provides rapid drug exposure after administration. The active ingredient of TNX-102 SL, cyclobenzaprine, functions as an antagonist at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors. Because of sublingual transmucosal absorption, TNX-102 SL avoids first-pass metabolism and decreases exposure to the active metabolite norcyclobenzaprine, a less desirable molecule due to its long plasma half-life. Tonmya® has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia. TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder. 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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