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# **Tonix Pharmaceuticals Completes Enrollment in BESTFIT Trial of TNX-102 SL for Fibromyalgia**

## **Top Line Results Expected in the Fourth Quarter of 2014**

NEW YORK, May 12, 2014 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP), a clinical-stage pharmaceutical company, today announced that it has completed enrollment in the BESTFIT trial of TNX-102 SL for fibromyalgia, after having achieved the randomization goal of 200 subjects.

BESTFIT (BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy) is a 12-week, randomized, double-blind, placebo-controlled trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 2.8 mg taken at bedtime in patients diagnosed with fibromyalgia. The trial commenced in September 2013 and is being conducted at 17 U.S. clinical sites. The primary outcome measure of BESTFIT is the mean change in week 12 average daily pain intensity from baseline on the 11-point Numeric Rating Scale, using a daily telephonic diary. The safety and tolerability of TNX-102 SL are also being assessed in this trial. An ongoing 52-week open-label safety extension study, which will evaluate the long-term safety and tolerability of TNX-102 SL, continues to enroll subjects who have completed BESTFIT.

"The rate of patient recruitment into BESTFIT exceeded expectations," said Seth Lederman, M.D., president and chief executive officer of Tonix. "If successful, BESTFIT will serve as the first of two pivotal trials to support the marketing approval of TNX-102 SL for the management of fibromyalgia. Fibromyalgia is a debilitating syndrome and many patients are not satisfied with the existing treatment options. With enrollment completed in BESTFIT, we look forward to reporting top line data in the fourth quarter of 2014."

### **About Fibromyalgia**

Fibromyalgia is a chronic syndrome characterized by widespread pain, sleep disturbances, fatigue, cognitive dysfunction, depressed mood, and other symptoms. Fibromyalgia can be debilitating and interfere with daily activities. According to the National Institutes of Health, fibromyalgia affects five million adult Americans. It is not known what causes fibromyalgia.

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

Tonix is developing innovative prescription medications to treat fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, all characterized by inadequate treatment options, dissatisfaction expressed among patients and physicians, and significant expense burden. Tonix is developing first-in-class prescription products for approval by the Food and Drug Administration (FDA) to address important clinical problems that affect large

numbers of patients. Tonix is currently conducting the first anticipated pivotal trial of TNX-102 SL in fibromyalgia, the BESTFIT trial. Tonix expects to begin clinical development of TNX-102 SL in post-traumatic stress disorder in the third quarter of 2014. With TNX-102 SL, Tonix approaches the treatment of people suffering from fibromyalgia and PTSD by targeting their inability to obtain restorative sleep. TNX-201 is in development for episodic tension-type headache, and Tonix expects to begin clinical studies of TNX-201 in the fourth quarter of 2014. To learn more, please visit [www.tonixpharma.com](http://www.tonixpharma.com).

### **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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 March 28, 2014 and future periodic reports filed with the Securities and Exchange Commission. All of the Company'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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