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# **Tonix Pharmaceuticals Announces the Enrollment of Completers From the BESTFIT Trial Into a 12-Month Open-Label Extension Study**

NEW YORK, Dec. 10, 2013 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP), a development stage specialty pharmaceutical company, announced today that it is enrolling subjects into an open-label extension (OLE) study to the BESTFIT trial of TNX-102 2.8 mg sublingual tablet (SL) in fibromyalgia (FM).

The primary objective of the 12-month OLE study is to evaluate the long-term safety and tolerability of TNX-102 SL taken sublingually at bedtime once-daily in patients with FM. The secondary objective is to evaluate the long term efficacy of TNX-102 SL on the symptoms of FM. Subjects who complete the BESTFIT trial have the option to enroll into the OLE study, in which all participants will receive TNX-102 SL. Accepted by the Food and Drug Administration (FDA) as an abbreviated long-term safety exposure evaluation, this OLE study is being conducted to support a 505(b)(2) New Drug Application for TNX-102 SL as a chronic medication for the management of FM. The ongoing BESTFIT trial is the first of two anticipated placebo-controlled pivotal trials to support the efficacy and safety of TNX-102 SL in fibromyalgia.

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

Tonix is developing innovative prescription medications for challenging disorders of the central nervous system. Tonix seeks to address conditions characterized by significant unmet medical need, inadequate existing treatment options, and high dissatisfaction among patients and physicians. Tonix is advancing its lead therapeutic candidate TNX-102 SL for the management of fibromyalgia and PTSD. Tonix is currently enrolling patients into the first anticipated pivotal trial of TNX-102 SL in fibromyalgia, the BESTFIT trial (BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy). Tonix applies its core technology toward the treatment of people suffering from fibromyalgia and PTSD by targeting their inability to obtain restorative sleep. To learn more, please visit [www.tonixpharma.com](http://www.tonixpharma.com).

*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 amended Annual Report on Form 10-K/A filed with the SEC on November 22, 2013 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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