

# Collegium Announces Publication of Data on the Durability of Pain Relief with Xtampza ER

# April 7, 2016

CANTON, Mass., April 07, 2016 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced the publication of an analysis of the duration of effect of Xtampza<sup>™</sup> ER administered every 12 hours during the Double-blind Maintenance Phase of a multicenter, 12-week clinical study. The publication is titled, "Evaluation of the Durability of Pain Relief Throughout a 12-Hour Dosing Interval of a Novel, Extended-Release, Abuse-Deterrent Formulation of Oxycodone – Oxycodone DETERx<sup>®</sup>, and is published in the peer-reviewed journal, Current Medical Research and Opinion.

The analysis of the data from the Phase 3 randomized withdrawal, double-blind, placebo-controlled, enriched-enrollment, parallel-group, multicenter, 12-week clinical study in patients with chronic low back pain showed limited use of acetaminophen, the only rescue medication used in the study. In addition, the analysis showed no increase in rescue medication consumption from 8 to 12 hours after dosing, which is the time interval commonly associated with end-of-dose failure leading to inadequate analgesic effect; these data suggest that subjects maintained pain relief over the entire dosing interval with twice daily administration of Xtampza ER.

"The results of this analysis suggest that Xtampza ER may provide clinicians an effective 12-hour, twice daily, formulation of oxycodone for their patients with chronic pain who require continuous, around-the-clock opioid analgesia for an extended period of time," stated Dr. Sri Nalamachu, lead author on the publication and President and Medical Director for the International Clinical Research Institute, Inc. "It is also encouraging that patients were able to achieve adequate and sustained pain relief with minimal use of rescue medications."

The following link will take you to the publication: Current Medical Research and Opinion.

## About Collegium Pharmaceutical, Inc.

Collegium is a specialty pharmaceutical company focused on developing a portfolio of products that incorporate its patent-protected DETERx<sup>®</sup> technology platform for the treatment of chronic pain and other diseases. The DETERx oral drug delivery technology is designed to provide extended-release delivery, unique abuse-deterrent properties, and flexible dose administration options.

## About Xtampza™ ER

Collegium's lead product candidate, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone, in development for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Collegium developed Xtampza using its proprietary DETERx technology platform to address common methods of abuse, including chewing, crushing and/or dissolving, and then taking it orally or snorting or injecting.

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's current expectations. For example, there can be no guarantee that we will obtain final approval for Xtampza ER or any of our other product candidates from the FDA or foreign regulatory authorities; even if Xtampza ER obtains final approval, we may not be able to obtain the label claims that we are seeking from the FDA. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: our ability to commercialize our product candidates; the existence of any patent infringement or similar litigation relating to any of our products or product candidates, and costs and delays associated with such litigation; the size and growth potential of the markets for our product candidates, and our ability to service those markets; our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of our product candidates; the success, cost and timing of our product development activities, studies and clinical trials; the success of competing products that are or become available; and our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our product candidates. These and other risks are described under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015, and those risks described from time to time in other reports which we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Collegium Pharmaceutical, Inc