



## **Collegium Announces Publication of "Comparing the Effect of Tampering on the Oral Pharmacokinetic Profiles of Two Extended-Release Oxycodone Formulations With Abuse-Deterrent Properties," in Pain Medicine**

June 25, 2015

CANTON, Mass., June 25, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced the publication of a comparative clinical trial titled "Comparing the Effect of Tampering on the Oral Pharmacokinetic Profiles of Two Extended-Release Oxycodone Formulations with Abuse-Deterrent Properties," in the peer-reviewed medical journal, *Pain Medicine*.

The objective of the clinical trial was to assess the safety and pharmacokinetics of Xtampza ER when the capsule was taken intact after oral administration compared with opening the capsule and crushing the capsule contents (microspheres) prior to oral administration. These treatments were compared with reformulated OxyContin® ("OxyContin") intact, OxyContin crushed, and an immediate-release (IR) oxycodone tablet formulation crushed in naltrexone-blocked, healthy subjects (n=42). The clinical trial was an open label, randomized, active-controlled, 5 treatment, 5 period, cross-over comparison design. The selected crushing techniques were previously identified in the laboratory as the most effective methods of reducing the particle size for each respective product. These crushing methods are also commonly employed by abusers to destroy the time-release mechanism of extended-release (ER) opioid formulations to make the drug more abusable.

### **Key publication highlights:**

- Crushing Xtampza ER demonstrated no increase in C<sub>max</sub>, T<sub>max</sub>, or AUC and was bioequivalent to taking Xtampza ER intact capsules.
- Crushing reformulated OxyContin demonstrated an increase in C<sub>max</sub> and a decrease in T<sub>max</sub>, and was bioequivalent to crushed IR oxycodone tablets.
- Crushing Xtampza ER demonstrated no increase in Abuse Quotient ("AQ" = C<sub>max</sub>/T<sub>max</sub>) while crushing reformulated OxyContin increased the AQ four times, which was similar to the AQ for crushed IR oxycodone tablets.

Dr. Jeffrey Gudin, lead author on the publication and Director of Pain Management and Palliative Care at Englewood Hospital and Medical Center, stated "Patients or their caregivers often inadvertently crush their medication to facilitate swallowing, which can be very dangerous with currently marketed ER products. In addition, abusers will seek to crush or chew ER opioids to rapidly release the drug from the formulation. The results of these studies suggest that, if approved, Xtampza ER can be beneficial in addressing both of these issues."

A copy of the publication is available at: <http://onlinelibrary.wiley.com/doi/10.1111/pme.12834/abstract>

### **About Collegium Pharmaceutical, Inc.**

Collegium is a specialty pharmaceutical company focused on developing a portfolio of products that incorporate its patent-protected DETERx® 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. The new drug application, or NDA, filing for Xtampza ER, the Company's lead product candidate, was accepted by the FDA on February 10, 2015. The FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of October 12, 2015 for completion of its review of the Xtampza ER NDA.

OxyContin® is a registered trademark of Purdue Pharma, L.P.

### **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 approval for Xtampza or any of our other product candidates from the U.S. Food and Drug Administration ("FDA") or foreign regulatory authorities; even if Xtampza is approved, we may not be able to obtain the label claims that we are seeking from the FDA. Furthermore, we are subject to patent infringement litigation relating to Xtampza and may, in the future, be subject to additional litigation relating to our other product candidates, which may be expensive to defend and delay the commercialization of Xtampza or our other product candidates. 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 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 a Current Report on Form 8-K, which was filed with the Securities and Exchange Commission ("SEC") on June 19, 2015. 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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