Collegium Announces Publication of Nasal Human Abuse Potential Study in American Academy of Pain Medicine

December 16, 2015

CANTON, Mass., Dec. 16, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced the publication of results from the intranasal human abuse potential of Xtampza™ ER (oxycodone) extended-release capsules. The publication is titled “A Randomized, Double-Blind, Double-Dummy Study to Evaluate the Intranasal Human Abuse Potential and Pharmacokinetics of a Novel Extended-Release Abuse-Deterrent Formulation of Oxycodone.”

In the published study, intranasal administration of crushed Xtampza ER was compared with oral administration of intact Xtampza ER and with intranasal administration of crushed immediate-release (IR) oxycodone in non-dependent, non-tolerant recreational opioid users (n=36). The primary endpoint for the study was Drug Liking at this moment from the Drug Effects Questionnaire, measured up to 24 hours after dosing using a bipolar visual analogue scale (VAS). Xtampza ER (both crushed intranasal and intact oral) had significantly lower maximum (peak) drug liking (Emax) when compared with intranasal crushed IR oxycodone ($p \leq 0.0001$). Furthermore, when comparing Xtampza ER treatments, Emax for drug liking after administration of crushed intranasal Xtampza ER was significantly lower than for intact oral administration of Xtampza ER ($p \leq 0.05$).

Dr. Lynn Webster, lead author on the publication and Vice President of Scientific Affairs, PRA Health Sciences (Raleigh, NC), stated, "This study presents the first pharmacokinetic and pharmacodynamic data showing that crushing Xtampza ER and administering it nasally is not associated with increased Drug Liking scores when compared with taking the drug as intended, via oral administration. The data from this study was included in the Xtampza ER NDA and is intended to support abuse-deterrent labeling upon final approval."

The following link will take you to the publication: Pain Medicine Access.

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.

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.

The United States Food and Drug Administration (FDA) has granted tentative approval to the Company's New Drug Application (NDA) for Xtampza ER 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. With a tentative approval, the FDA has determined that Xtampza ER meets required quality, safety and efficacy standards for approval but it is subject to an automatic stay of up to 30 months as a result of patent litigation filed by 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 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. Furthermore, we are subject to patent infringement litigation relating to Xtampza ER 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 ER 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, 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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