Collegium Announces FDA Tentative Approval for Xtampza(TM) ER, a Novel Abuse-Deterrent Analgesic for Chronic Pain

November 9, 2015

CANTON, Mass., Nov. 9, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced that the United States Food and Drug Administration (FDA) has granted tentative approval to the Company's New Drug Application (NDA) for Xtampza™ ER (oxycodone) extended-release capsules 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 all of the 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 (Purdue) in March 2015. Purdue claims that Xtampza ER infringes three Orange Book listed patents that were recently found to be invalid by the United States District Court for the Southern District of New York and are currently under appeal. If Collegium receives a court order that the listed patents are invalid or not infringed, or if Collegium settles the Purdue litigation prior to the expiration of the 30-month period, the FDA can then provide final approval of Xtampza ER, at which point the product can be marketed.

"We are very pleased that the FDA has granted tentative approval for Xtampza ER. The FDA has recognized that Xtampza ER has abuse-deterrent properties consistent with FDA's final guidance titled, Guidance for Industry: Abuse-Deterrent Opioids - Evaluation and Labeling," stated Michael Heffernan, Collegium's Chairman and CEO. "We remain confident that Xtampza ER does not infringe the three patents that Purdue has asserted against us. We intend to vigorously defend ourselves against these claims."

Dr. Bill McCarberg, a founding member of the Chronic Pain Management Program at Kaiser Permanente and President of the Western Pain Society, stated,"Upon final approval, Xtampza ER may provide a unique extended-release, abuse-deterrent treatment option for the large unmet need of patients with chronic pain and dysphagia. Patients or their caregivers often inadvertently crush their medication to facilitate swallowing, which is 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 in order to achieve a 'high'. Xtampza ER could be beneficial in addressing both of these significant issues."

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.

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 U.S. Food and Drug Administration ("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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