Collegium Announces FDA Advisory Committees Unanimously Recommend Approval of Xtampza ER(TM), an Abuse-Deterrent Analgesic for Chronic Pain

September 12, 2015

CANTON, Mass., Sept. 11, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (NASDAQ:COLL) today announced that the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted unanimously to support the approval of 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.

Xtampza ER, Collegium's lead product candidate, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. The FDA will consider the advisory committees' recommendation as it continues its review of Xtampza ER. 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 New Drug Application (NDA).

"We are very pleased that the FDA advisory committees recommended approval for Xtampza ER," said Michael Heffernan, Collegium's Chairman and CEO. "We look forward to working with the FDA as it finalizes its review."

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 NDA filing for Xtampza ER, the Company's lead product candidate, was accepted by the FDA on February 10, 2015. The FDA set a PDUFA goal date of October 12, 2015 for completion of its review of the Xtampza ER NDA.

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. The active ingredient in Xtampza is oxycodone, which is approved by the FDA and other regulators around the world in a number of both immediate-release and extended-release drug products. Collegium developed Xtampza using its proprietary DETERx abuse-deterrent technology to address common methods of abuse, including chewing, crushing and/or dissolving, and then taking it orally or snorting or injecting Xtampza ER.

Collegium's preclinical studies and clinical trials have shown that the contents of the Xtampza capsule can be removed from the capsule and sprinkled on food, directly into the mouth or administered through feeding tubes, without compromising their drug release profile, safety or abuse-deterrent characteristics. By contrast, OxyContin OP, which is formulated in hard tablets, has a black box warning label stating that crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active ingredient. Collegium believes that Xtampza, if approved, can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

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 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 and in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, which was filed with the SEC on August 12, 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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