# Collegium Provides Update on FDA Review of Xtampza(TM) ER, an Abuse-Deterrent Analgesic for the Treatment of Chronic Pain

October 12, 2015

CANTON, Mass., Oct. 12, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced that the U.S. Food and Drug Administration (FDA) has advised Collegium that it will not be able to complete its review of the New Drug Application (NDA) for Xtampza™ ER (oxycodone) extended-release capsules by the Prescription Drug User Fee Act (PDUFA) action date of October 12, 2015.

"We are confident in the Xtampza ER program and our NDA submission. We continue to work closely with the FDA as they complete their review," said Michael Heffernan, Collegium's Chairman and CEO. "We look forward to bringing Xtampza ER to market as a potential novel treatment option for patients in need of chronic pain therapy."

**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.

**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.

**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 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 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 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.

CONTACT: Douglas Carlson
Vice President, Corporate Development
dcarlson@collegiumpharma.com

Collegium Pharmaceutical Logo

Collegium Pharmaceutical