Collegium Announces FDA Acceptance of IND Application for Abuse-Deterrent, Hydrocodone DETERx®

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Second Clinical Candidate to Leverage DETERx Technology Platform

CANTON, Mass., Jan. 21, 2016 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's investigational new drug (IND) application to begin a clinical trial of Hydrocodone DETERx ®, an abuse-deterrent, extended-release analgesic for the treatment of chronic pain. This proof of concept clinical trial is intended to evaluate the safety, bioavailability, and abuse deterrence properties of Hydrocodone DETERx.

"Hydrocodone DETERx has met our in vitro screens for both abuse-deterrent and drug release characteristics" said Michael Heffernan, CEO of Collegium. "The commencement of this study marks another milestone for Collegium following the FDA tentative approval of our lead product candidate, Xtampza™ ER (Oxycodone DETERx). Upon successful completion of this clinical trial, we intend to accelerate development of this pipeline product."

"We believe that Hydrocodone DETERx has the potential to provide similar advantages and unique product characteristics as our lead product, Xtampza ER. These features include abuse-deterrent properties that may decrease oral abuse, intranasal abuse, and abuse by injection. Hydrocodone DETERx may provide physicians, once approved, with another abuse deterrent analgesic for the management of patients with chronic pain," said Dr. Ernest Kopecky, Vice President, Clinical Development. "In addition, the microsphere-in-capsule, oral formulation will be able to be sprinkled directly into the mouth, sprinkled onto soft foods, or delivered via feeding tubes."

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 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 the registration statement on Form S-1 (commission file number 333-208641), which was declared effective by the Securities and Exchange Commission ("SEC") on January 7, 2016, 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, Inc