



Collegium Announces Favorable Judgment by the District Court of Massachusetts

February 11, 2016

CANTON, Mass., Feb. 11, 2016 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) announced that the District Court of Massachusetts issued an order for final judgment in favor of Collegium and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies. The judgment relates to Purdue's three Orange Book-listed patents asserted against Collegium that were the cause of the 30 month stay imposed on our New Drug Application for Xtampza™ ER.

"We are excited to have resolved this litigation of the patents that was delaying the potential final approval of Xtampza. The termination of the 30 month stay is a significant milestone for the Company," said Michael Heffernan, CEO of Collegium. "We intend to move forward with our request for the U.S. Food and Drug Administration to convert our Tentative Approval to a Final Approval."

"This judgment provides additional clarity on the timing for the potential commercial launch of Xtampza. Our commercial leadership team has developed our commercialization strategy over the last 12 months," said Barry Duke, Chief Commercial Officer of Collegium. "Over the next few months, we will complete the hiring and training of our sales organization, as we prepare for a late second quarter launch."

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. 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 existence of any patent infringement or similar litigation relating to any of our products or product candidates, and costs and delays associated with such litigation; 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.

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Collegium Pharmaceutical, Inc