



Collegium Announces Positive Topline Results for Hydrocodone DETERx® Clinical Study

June 22, 2016

Results demonstrate utility of the DETERx technology platform for hydrocodone as a second abuse-deterrent opioid candidate

CANTON, Mass., June 22, 2016 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced positive topline results from a clinical study evaluating Hydrocodone DETERx® as a second product candidate using its proprietary DETERx drug delivery technology platform. The objective of this pharmacokinetic proof of concept study was to assess two prospective formulations of Hydrocodone DETERx in a bioavailability clinical study. The primary goals were to assess the extended-release profile and the resistance to a common method of physical manipulation used by drug abusers – crushing. The drug release profile of the two formulations was characterized when taken intact after oral administration compared with opening the capsule and crushing the capsule contents (microspheres) prior to oral administration.

The results of the study demonstrated that both Hydrocodone DETERx product candidates were bioequivalent when comparing crushed and intact dosing, demonstrating resistance to physical manipulation. One of the product candidates achieved the targeted pharmacokinetic profile for 12-hour dosing interval.

"There is a significant market opportunity and unmet need for a differentiated, abuse-deterrent formulation of extended-release hydrocodone. Based upon the results of this study and our in vitro characterization, we expect Hydrocodone DETERx to provide similar advantages and unique product characteristics as Xtampza™ ER, our first FDA approved product to utilize the DETERx technology platform," said Michael Heffernan, CEO of Collegium.

Based on the positive results of this study, Collegium plans to accelerate development of the lead Hydrocodone DETERx formulation candidate.

About Collegium Pharmaceutical, Inc.

Collegium is a specialty pharmaceutical company focused on developing a portfolio of products that incorporate its proprietary DETERx® technology platform for the treatment of chronic pain and other diseases. The DETERx technology platform is designed to provide extended-release delivery, unique abuse-deterrent properties, and flexible dose administration options.

About Xtampza ER

Xtampza ER is Collegium's first product utilizing the DETERx technology platform. Xtampza ER is an abuse-deterrent, extended-release, oral formulation of oxycodone approved by the FDA 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.

For Important Safety Information Visit, <http://www.xtampzaer.com/>.

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," "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. 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 products and 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 and 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 and 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 our Annual Report on Form 10-K for the year ended December 31, 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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Collegium Pharmaceutical, Inc