Collegium Publishes Data From Xtampza(TM) ER Phase 3 Clinical Trial in the Journal PAIN

August 24, 2015

CANTON, Mass., Aug. 24, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today announced the publication of results from the Phase 3 clinical trial of Xtampza™ ER (oxycodone extended-release capsules). The study is titled "A phase 3, multi-center, randomized, double-blind, placebo-controlled, safety, tolerability, and efficacy study of Xtampza ER in patients with moderate-to-severe chronic low back pain" and was published online in the August issue of the peer-reviewed journal *PAIN*. The study will be published in print at a later date.

The Phase 3 study was a multicenter, double-blind, enriched enrollment, randomized withdrawal, placebo-controlled, safety, tolerability, and efficacy study of Xtampza ER versus placebo in opioid-experienced and opioid-naïve subjects with moderate-to-severe chronic low back pain. The study met its primary endpoint which showed a statistically significant difference in average pain intensity from Randomization Baseline to Week 12 between the Xtampza ER and placebo groups ($p<0.0001$). All sensitivity analyses of the primary endpoint were also statistically significant. Xtampza ER had an adverse event profile consistent with other opioids, was well tolerated, and no new safety concerns were identified.

"The Phase 3 clinical trial results, coupled with the results from Collegium's abuse-deterrent development program, suggest that Xtampza ER not only represents an efficacious alternative opioid with abuse-deterrent properties, but could also benefit patients with dysphagia [difficulty swallowing], and mitigates the risk of overdose if inadvertently crushed or chewed," said Dr. Nathaniel Katz, lead author and President of Analgesic Solutions, and Former Chair of the Advisory Committee, Anesthesia, Critical Care, and Addiction Products Division, FDA.

"The positive Phase 3 study results demonstrate that Xtampza ER is effective in treating patients with moderate-to-severe chronic pain, was well-tolerated, and has a safety profile consistent with other ER/LA opioids. Collectively, with its abuse-deterrent characteristics, flexible dosing options, and its efficacy and safety profile, Xtampza ER upon FDA approval will provide clinicians and patients with a unique treatment option for the treatment of chronic pain," said Dr. Ernest Kopecky, Vice President, Clinical Development and Head of Neuroscience at Collegium.

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 ER 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.

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 new drug application, or NDA, submission for Xtampza ER, the Company's lead product candidate, was accepted for review by the FDA on February 10, 2015. 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 NDA.

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 Securities and Exchange Commission. 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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