



## Collegium Notified that the FDA Will Not Meet PDUFA Goal Date for sNDA for Xtampza® ER

November 6, 2017

CANTON, Mass., Nov. 06, 2017 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) announced today that the U.S. Food and Drug Administration (FDA) will not meet the prescription drug user fee act (PDUFA) date for its Supplemental New Drug Application (sNDA) to enhance the label for Xtampza® ER (oxycodone extended-release), an abuse-deterrent, extended-release opioid, 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 FDA hasn't requested any additional scientific information or data," said Michael Heffernan, CEO of Collegium. "We will continue to work closely with the FDA on our sNDA".

Management will discuss the sNDA on its Third Quarter Conference call on Wednesday, November 8, 2017 at 4:30 p.m. Eastern Time.

### Conference Call Information:

To access the conference call, please dial (888)698-6931 (U.S.) or (805)905-2993 (International) and refer to Conference ID: 668-9689. An audio webcast will be accessible from the Investor Relations section of the Company's website: <http://www.collegiumpharma.com/>. An archived webcast will be available on the Company's website approximately two hours after the event.

### 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.

### LIMITATIONS OF USE

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Xtampza ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

Xtampza ER is not indicated as an as-needed (prn) analgesic.

The Full Prescribing Information for Xtampza ER contains the following Boxed Warning:

### **WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION**

#### **Addiction, Abuse, and Misuse**

Xtampza ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing Xtampza ER and monitor all patients regularly for the development of these behaviors or conditions.

#### **Life-Threatening Respiratory Depression**

Serious, life-threatening, or fatal respiratory depression may occur with use of Xtampza ER. Monitor for respiratory depression, especially during initiation of Xtampza ER or following a dose increase.

#### **Accidental Ingestion**

Accidental ingestion of even one dose of Xtampza ER, especially by children, can result in a fatal overdose of oxycodone.

#### **Neonatal Opioid Withdrawal Syndrome**

Prolonged use of Xtampza ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

#### **Cytochrome P450 3A4 Interaction**

The concomitant use of Xtampza ER with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving Xtampza ER and any CYP3A4 inhibitor or inducer.

#### **Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants**

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of Xtampza ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

#### **IMPORTANT SAFETY INFORMATION**

Xtampza ER is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity (e.g., anaphylaxis) to oxycodone.

Xtampza ER contains oxycodone, a Schedule II controlled substance. As an opioid, Xtampza ER exposes users to the risks of addiction, abuse, and misuse. As extended-release products, such as Xtampza ER, deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of oxycodone present.

Potential serious adverse events caused by opioids include addiction, abuse, and misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, risks of concomitant use or discontinuation of cytochrome P450 3A4 inhibitors and inducers, risks from concomitant use with benzodiazepines or other CNS depressants, risk of life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients, adrenal insufficiency, severe hypotension, risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness, risks of use in patients with gastrointestinal conditions, risk of use in patients with seizure disorders, withdrawal, risks of driving and operating machinery, and laboratory monitoring.

The most common AEs (>5%) reported by patients in the Phase 3 clinical trial during the titration phase were: nausea (16.6%), headache (13.9%), constipation (13.0%), somnolence (8.8%), pruritus (7.4%), vomiting (6.4%), and dizziness (5.7%).

For Important Safety Information including full prescribing 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 obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product; our plans to commercialize our product candidates and grow sales of our products; the size and growth potential of the markets for our products and product candidates, and our ability to service those markets; the success of competing products that are or become available; our ability to obtain reimbursement and third-party payor contracts for our products; the costs of commercialization activities, including marketing, sales and distribution; our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of our products and product candidates; changing market conditions for our products and product candidates; the outcome of any patent infringement or other litigation that may be brought against us, including litigation with Purdue Pharma, L.P.; our ability to attract collaborators with development, regulatory and commercialization expertise; the success, cost and timing of our product development activities, studies and clinical trials; our ability to obtain funding for our operations; regulatory developments in the United States and foreign countries; our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our products and product candidates; our ability to operate our business without infringing the intellectual property rights of others; the performance of our third-party suppliers and manufacturers; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency compliance; our ability to retain key and management personnel; our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. 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, 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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