

## **Collegium Pharmaceutical Announces FDA Acceptance for Filing of NDA for Xtampza ER™ (oxycodone extended-release capsules), an Abuse-Deterrent Analgesic for Chronic Pain**

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**Canton, MA – February 12, 2015** – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development and commercialization of innovative abuse-deterrent treatments for chronic pain and other diseases, today announced that the U.S. Food & Drug Administration (FDA) has accepted for filing the Company's New Drug Application (NDA) for Xtampza ER, its novel, abuse-deterrent, extended-release oxycodone formulation for the treatment of chronic pain.

Xtampza ER is Collegium's lead product candidate utilizing its proprietary DETERx® technology platform, and is designed to maintain its extended-release profile after being subjected to common methods of tampering. The abuse-deterrent properties incorporated into the Xtampza ER formulation are designed to make it more difficult to manipulate for the purpose of abuse or misuse via common routes of administration including chewing, crushing and/or dissolving, and then taking orally, snorting, smoking, or injecting.

"Collegium is committed to developing and commercializing a portfolio of products that address the epidemic of chronic pain and the growing problems associated with non-medical use, abuse, and misuse of prescription products by leveraging our proprietary DETERx technology platform," stated Michael Heffernan, CEO of Collegium. "Upon approval, Xtampza ER has the potential to provide a novel treatment option to patients in need of chronic pain therapy."

The NDA submission is based on a comprehensive development program including a pivotal Phase III clinical trial and data from an extensive abuse-deterrent development program that followed the FDA's "Abuse-Deterrent Opioids – Evaluation and Labeling" draft guidance published in January 2013. The Phase III clinical trial evaluated the safety, tolerability, and efficacy of Xtampza ER compared with placebo in opioid-experienced and opioid-naïve subjects with moderate-to-severe chronic low back pain. The Xtampza ER abuse-deterrent program consisted of a battery of in vitro (laboratory-based), pharmacokinetic, and human abuse potential studies. In addition, the NDA submission includes data from head-to-head abuse-deterrent studies (in vitro and pharmacokinetic) comparing Xtampza ER to OxyContin® OP. Furthermore, Collegium has completed all of the studies that we believe are necessary to support proposed product labeling, which will instruct patients with chronic pain with difficulty swallowing to administer the capsule contents directly into their mouth; sprinkled onto soft food; or via feeding tubes.

### **About DETERx Technology**

The DETERx technology platform consists of a microsphere-in-capsule formulation. While developed primarily to provide abuse-deterrent properties to protect against common methods of tampering such as chewing, crushing, insufflation, and extraction for IV injection, the microsphere design is intended to enable patients with difficulty swallowing to open the capsule and administer the contents onto food or via feeding tube, while maintaining the extended-release (ER) properties of the product. The DETERx technology can be used with drugs that are commonly abused such as opioids and amphetamines, as well as drugs that have a narrow therapeutic index that would benefit from protection against misuse. The DETERx technology platform is covered by U.S. and international patents and patent applications. Xtampza ER (oxycodone extended-release capsules) is the first of a number of Collegium product candidates using the DETERx platform.

### **About Collegium Pharmaceutical, Inc.**

Collegium Pharmaceutical, Inc. 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. The DETERx oral drug delivery technology is designed to provide extended-release delivery, unique abuse-deterrent properties, and flexible dose

administration options. For more information, visit the Company's website at [www.collegiumpharma.com](http://www.collegiumpharma.com).

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