

## **Collegium Pharmaceutical Submits New Drug Application for Xtampza™ ER (oxycodone extended-release); Its Abuse-Deterrent, Extended-Release Analgesic for the Treatment of Chronic Pain**

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**Canton, MA – December 15, 2014** – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development of innovative treatments for chronic pain, today announced that it has filed a New Drug Application (NDA) with the U.S. Food & Drug Administration (FDA) seeking authorization to market Xtampza™ ER, its oxycodone extended-release (ER), abuse-deterrent analgesic utilizing the Company's proprietary DETERx® technology platform. The abuse-deterrent properties incorporated into the formulation are designed to make the product more difficult to manipulate for the purpose of abuse or misuse via common routes of administration including: oral after chewing or crushing; snorting; smoking; or injection.

The NDA filing includes Phase III data on 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, as well as 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abuse-deterrent development program that followed the FDA's "Abuse-Deterrent Opioids – Evaluation and Labeling" draft guidance published in January 2013.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 Xtampza™ ER abuse-deterrent program consisted of a battery of in vitro, pharmacokinetic, and human abuse potential (HAP) studies. In addition, Collegium has completed all of the necessary studies to support proposed product labeling, which will instruct patients with difficulty swallowing (dysphagia) to administer the capsule contents directly into their mouth; onto food; or via feeding tube.

If approved, Xtampza™ ER could be the only abuse-deterrent oxycodone product to offer patients with difficulty swallowing an administration option of sprinkling the capsule contents directly into the mouth or onto soft foods without compromising the integrity of the ER profile. Currently available abuse-deterrent opioid products instruct patients to swallow the medication intact due to the risk associated with crushing, breaking, or dissolving the product resulting in rapid release of the active ingredient, which may result in a potentially fatal dose.

"This FDA submission represents a major step toward offering the first extended-release, abuse-deterrent oxycodone product that not only resists common forms of abuse, but also provides an administration option for patients with concurrent chronic pain and difficulty swallowing pills," said Michael Heffernan, CEO of Collegium. "Filing the Xtampza™ ER NDA is an important milestone in our continued efforts to develop a portfolio of abuse-deterrent pain medications designed to address unmet societal needs."

### **About DETERx® Technology**

The DETERx® drug delivery 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 expected to enable patients with difficulty swallowing to open the capsule and administer the contents onto food or via feeding tube, while maintaining the 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 such as breaking, crushing, grinding, or dissolving the product. The formulation 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 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® formulation platform for the treatment of chronic pain. The DETERx® oral drug delivery technology provides 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).