

## **Collegium Pharmaceutical Announces Successful Pre-NDA Meeting with FDA for Oxycodone DETERx®, its Extended-Release, Abuse-Deterrent Product for the Treatment of Chronic Pain**

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**Canton, MA – April 29, 2014** – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development of innovative treatments for chronic pain, today announced that it has successfully concluded its pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding Oxycodone DETERx®, its extended-release (ER), abuse-deterrent, oxycodone microsphere-in-capsule product. The purpose of the meeting was to discuss the non-clinical, clinical and Chemistry, Manufacturing and Controls (CMC) development of Oxycodone DETERx®, and to agree on the submission requirements for the NDA submission under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Following the meeting, Collegium intends to proceed with its NDA submission as previously announced.

“We continue to work closely with the FDA and appreciate its guidance as we prepare for our NDA submission,” said Michael Heffernan, CEO of Collegium. “The pre-NDA meeting reinforced our understanding of the Agency’s requirements for our submission and brings us one more important step closer to potentially gaining approval for Oxycodone DETERx®. We remain on track to file the NDA in Q4 2014 and due to our Fast Track Status anticipate a Priority Review.”

### **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 multi-particulate design is expected to enable patients with difficulty swallowing to open the capsule and to administer the contents sprinkled onto food, directly into the mouth, or via a 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 narrow therapeutic windows 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. Oxycodone DETERx® 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 ER 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).