

## **Collegium Pharmaceutical Announces Positive Top-Line Data from Phase III Study of Oxycodone DETERx®, its Abuse-Deterrent, Extended-Release Product for Chronic Pain**

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*Data Supports 2014 NDA Filing*

**Canton, MA – August 6, 2014** – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company, today announced positive top-line results from its pivotal Phase 3 study of the company's investigational analgesic Oxycodone DETERx® that studied the treatment of patients with moderate-to-severe chronic low back pain. The study successfully met the primary efficacy endpoint by showing that patients with chronic low back pain treated with Oxycodone DETERx® experienced a statistically significant reduction in pain compared with placebo ( $p < 0.0001$ ). In addition, sensitivity analyses of the primary endpoint also achieved statistically significant differences between Oxycodone DETERx® and placebo.

The Phase 3 study was a multicenter, double-blind, enriched enrollment, randomized withdrawal, placebo-controlled, safety, tolerability and efficacy study of Oxycodone DETERx® versus placebo in opioid-experienced and opioid-naïve subjects with moderate-to-severe chronic low back pain. Patients who achieved a stable and effective dose of Oxycodone DETERx® during the open-label Titration Phase were randomized ( $n=389$ ) into the 12-week, Double-blind Maintenance (treatment) Phase in which they were either maintained on their current dose regimen of Oxycodone DETERx® or were tapered to placebo. The primary efficacy endpoint of the study was the change in average pain intensity from baseline to week 12; pain was measured using an 11-point pain intensity numerical rating scale (PI-NRS). Secondary endpoints in the study included evaluation of safety and tolerability, quality of life, physical disability, and global impression of change.

“These positive clinical study results represent a major milestone for the DETERx® technology, which has the potential to serve as a platform for multiple drugs that require extended-release administration in an abuse-deterrent formulation. Completion of this Phase 3 study and our Pre-NDA meeting with the FDA positions us for filing an NDA for Oxycodone DETERx® by the end of 2014,” stated Michael Heffernan, CEO of Collegium.

“In previously completed studies, Oxycodone DETERx® demonstrated unique abuse-deterrent advantages when compared to the currently marketed, abuse-deterrent oxycodone product. In addition, Oxycodone DETERx® would be the first abuse-deterrent, extended-release opioid suitable for administration via sprinkling onto soft foods, directly into the mouth or via enteral tube administration to patients with concurrent chronic pain and dysphagia (difficulty swallowing), a debilitating condition that affects approximately 11 million patients in the U.S.[1],” said Dr. Ernest Kopecky, Vice President, Clinical Development at Collegium.

Collegium has also completed an extensive program of abuse-deterrent studies that follow FDA's “Abuse-Deterrent Opioids – Evaluation and Labelling” draft guidance published in January 2013. The Oxycodone DETERx® abuse-deterrent program consists of a battery of *in vitro* studies, *in vivo* pharmacokinetic studies, and clinical human abuse potential (“HAP”) studies. In addition, Collegium has completed all necessary studies to support product labelling, which will instruct patients with difficulty swallowing to open the capsule and administer the contents directly into their mouth, onto food, or via feeding tube, while maintaining the extended-release properties of the product.

### **About DETERx® Technology**

The DETERx® drug delivery platform consists of a multi-particulate, matrix formulation in a capsule. 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 administer the contents onto food or via a gastrostomy tube, while

maintaining the extended-release properties of the product. DETERx<sup>®</sup> 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<sup>®</sup> is the first of a number of product candidates using the DETERx<sup>®</sup> 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<sup>®</sup> formulation platform for the treatment of chronic pain. The DETERx<sup>®</sup> 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).

[1] Pergolizzi, J, et al. "Challenges of treating patients with chronic pain with dysphagia (CPD): Physician and patient perspectives". Current Medical Research and Opinion, Online October 2013; In press- Volume 30, Issue 2, February 2014.