

Collegium Pharmaceutical Announces Completion of Enrollment in Pivotal Phase 3 Clinical Study for Oxycodone DETERx®, its Lead Abuse-Deterrent Development Program

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Top-line results anticipated in second quarter 2014

Canton, MA – February 4, 2014 – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development of innovative treatments for chronic pain, today announced the completion of patient enrollment in the pivotal Phase 3 study for Oxycodone DETERx®, its lead development program.

The Phase 3 study is a multi-center, 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 achieve a stable and effective dose of Oxycodone DETERx® during the Titration Phase are randomized into a 12-week, Double-blind Maintenance Phase in which they either maintain their current dose regimen of Oxycodone DETERx® or are tapered to placebo. The primary efficacy endpoint of the study is the change in average pain intensity from baseline to week 12; pain was measured by the pain intensity numerical rating scale (PI-NRS). Secondary endpoints in the study include evaluation of safety and tolerability, quality of life, physical disability, and global impression of change.

“Completion of enrollment in the Phase 3 study marks our continued progress in advancing this novel treatment for patients with chronic pain. In previously completed studies, Oxycodone DETERx® demonstrated unique abuse-deterrent advantages when compared to currently marketed products. In addition, Oxycodone DETERx® would be the first abuse-deterrent, extended-release opioid suitable for administration via a sprinkle to patients with concurrent chronic pain with dysphagia (difficulty swallowing), a debilitating condition that affects approximately 11 million patients in the U.S.[\[1\]](#)”, said Michael Heffernan, CEO of Collegium.

Collegium has also completed abuse-deterrent studies that follow FDA’s “*Abuse-Deterrent Opioids – Evaluation and Labeling*” draft guidance published in January 2013. The Oxycodone DETERx® abuse-deterrent program consists of a battery of *in vitro* studies, three *in vivo* pharmacokinetic studies, and two 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, on food, or via feeding tubes, while maintaining the extended-release properties of the product.

Pending positive results of the Phase 3 study in the second quarter of 2014, Collegium expects to submit an NDA for Oxycodone DETERx® in the second half of 2014.

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 and abuse 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 on food, directly in the mouth, or via enteral tube, while maintaining the extended-release properties of the product. 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 extended-release delivery, unique abuse-deterrent properties, and flexible dose administration options. For more information, visit the Company's website at 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.