

## **Collegium Pharmaceutical Releases Positive Top-Line Results of Oral Human Abuse Potential (HAP) Study with Oxycodone DETERx®, an Abuse-Deterrent, Extended-Release Product**

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*Primary endpoint met in oral abuse potential study*

**Canton, MA – November 17, 2014** – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development of innovative treatments for chronic pain, today announced positive top-line results from its second human abuse potential (HAP) study for Oxycodone DETERx®, its extended-release (ER), abuse-deterrent, oxycodone microsphere-in-capsule product. Oxycodone DETERx®, utilizing Collegium's DETERx® technology, is designed to be more resistant to tampering and abuse than traditional formulations of the drug. All of Collegium's abuse-deterrent studies, both in vitro and in vivo, are consistent with FDA's Guidance "Abuse-Deterrent Opioids - Evaluation and Labeling."

The Oral HAP study, demonstrated that chewed Oxycodone DETERx®, had significantly lower peak "drug liking" (Emax) when compared with crushed immediate release (IR) oxycodone ( $p < 0.0001$ ). Furthermore, there was no difference in the pharmacokinetics when Oxycodone DETERx® was chewed or taken intact as determined by bioequivalence measures (Cmax and AUC).

Statistically significant differences in peak effects (Emax) between chewed Oxycodone DETERx® treatments and crushed IR oxycodone were also demonstrated for secondary endpoints such as "feeling high," "any drug effects," "good drug effects," and the Addiction Research Center Inventory – Morphine Benzedrine Group (ARCI-MBG) score (a measure of euphoria and positive mood).

Oxycodone DETERx® has been developed to provide clinicians and patients with a novel abuse-deterrent formulation of oxycodone utilizing the DETERx® technology. HAP studies are clinical studies that determine the intrinsic potential for abuse of a drug formulation. These studies are conducted in a non-dependent, recreational drug abuser population and are designed to predict how probable it is that a particular drug formulation will be attractive to abusers (i.e., "liked"). The primary measure in this study, drug liking (Emax), is recommended by the FDA in the Guidance for pre-marketing evaluation of abuse-deterrent opioid formulations. This measure is known to correlate most directly with a drug's potential for abuse.

Dr. Lynn Webster, Principal Investigator of the study and Vice President Scientific Affairs, PRA International, stated, "These study results were consistent with the results generated from Collegium's intranasal HAP study. The positive study results from both the oral and intranasal HAP studies demonstrate that Oxycodone DETERx® may provide an option to address the significant societal need for safer and more abuse-deterrent opioid formulations."

In an intranasal HAP study completed in Q1 2014, Oxycodone DETERx® (both crushed intranasal and intact oral) had significantly lower peak "drug liking" (Emax) when compared with intranasal crushed IR oxycodone ( $p < 0.0001$ ). Furthermore, when comparing Oxycodone DETERx treatments, Emax for "drug liking" after administration of crushed intranasal Oxycodone DETERx® was significantly lower than for intact oral administration of DETERx® ( $p=0.0343$ ).

"We are pleased with the results of this study, as they are consistent with prior findings that demonstrate that Oxycodone DETERx® may provide unique advantages when compared with currently marketed products as well as those in development," said Michael Heffernan, CEO of Collegium. "Following an earlier announced successful Pre-NDA meeting and completion of our Phase 3 clinical study, we remain on track to file the NDA for Oxycodone DETERx® by the end of this year."

**About DETERx® Technology**

The DETERx<sup>®</sup> 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 an enteral tube, while maintaining the ER properties of the product. The DETERx<sup>®</sup> 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. 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 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).

<sup>1</sup> Butler, et al. 2012; NAVIPPRO 2nd Annual Scientific Meeting; March 28, 2012.