

Collegium Pharmaceutical Announces Publication of Abuse-Deterrent Data on Oxycodone DETERx® in Journal of Opioid Management

August 20, 2014 11:50 AM ET

Study results support the novel abuse-deterrent properties of Oxycodone DETERx®

Canton, MA – August 20, 2014 – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development of innovative treatments for chronic pain, today announced the publication of the following article, “Impact of physical manipulation on in vitro and in vivo release profiles of Oxycodone DETERx®: An extended-release, abuse-deterrent formulation,” in the *Journal of Opioid Management* (Volume 10, Number 4, July/August 2014.) a leading, peer-reviewed medical journal.

The publication included results from two studies conducted with Oxycodone DETERx®, which were designed per the FDA’s Draft Guidance issued in January 2013. The first study was a “Category 1” in vitro physical manipulation study assessing the effect of common crushing techniques on particle size reduction (PSR) and drug-release of Oxycodone DETERx® compared with reformulated OxyContin® as the comparator. The second study was a “Category 2” clinical study that evaluated the impact of the most aggressive physical manipulation methods (determined in the Category 1 study) and chewing on the pharmacokinetics (PK) of Oxycodone DETERx® relative to an immediate-release oxycodone solution.

Dr. Ernest Kopecky, Vice President, Clinical Development, stated “the in vitro and in vivo studies follow FDA’s guidance for the evaluation of abuse-deterrent opioids. Results from both studies, taken together, provide empirical data to show that manipulation by crushing or chewing did not alter the drug release or PK profile of Oxycodone DETERx.”

“Oxycodone DETERx® is intended to address both the misuse and abuse of opioid medications. Patients often inadvertently crush or grind their medication to facilitate swallowing, which can be very dangerous with currently marketed extended-release products. In addition, abusers will seek to crush, grind, or chew ER opioids to rapidly release the drug from the formulation. The results of these studies suggest that, if approved, Oxycodone DETERx® can be beneficial in addressing both of these issues,” said Michael Heffernan, CEO of Collegium.

Dr. Jeffrey Gudin, Director of the Pain Management Center at Englewood Hospital and Medical Center stated, “Abuse, misuse, and diversion of opioids, whether intentional or unintentional, is a major issue in every day medical practice. The fact that the PK profile of Oxycodone DETERx® does not change when crushed or chewed will likely not only deter abuse, but, equally as important, will offer a significant safety advantage to patients that may crush or chew their medication to facilitate swallowing.”

A copy of the publication is available at <http://www.ncbi.nlm.nih.gov/m/pubmed/25133909/?i=1&from=kopecky>.

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. 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. 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.