Collegium Pharmaceutical Awarded Grant from the NIH to Advance Development of Oxymorphone DETERx®, an Abuse-Deterrent, Extended-Release Product for Chronic Pain

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NIH grant supports development of Collegium's second drug candidate utilizing the DETERx® technology platform

Canton, MA – August 7, 2014 – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company, today announced that it has been awarded a Phase I, Fast Track Small Business Innovation Research (SBIR) grant from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) to advance development of its Oxymorphone DETERx[®] program. Upon successful completion of the SBIR Phase I grant, Collegium will be eligible to receive additional funding for continuing support of the clinical development program through the SBIR Phase II grant.

Oxymorphone DETERx[®] has been granted Fast Track designation by the FDA and, in previous studies, demonstrated superior abuse-deterrent performance versus the marketed reference product. There are no formulations of oxymorphone on the market that have abuse-deterrent claims in the product label. DETERx[®] is a novel, patent-protected drug delivery technology that is designed to maintain the extended-release (ER) and safety profiles of highly abused drugs following various methods of abuse and tampering employed by drug abusers such as crushing, chewing, snorting, and IV injection.

"We are very pleased to receive this grant from NIDA. It is clear that NIDA is highly motivated to fund novel abuse-deterrent technologies that may have a meaningful impact in deterring prescription drug abuse and misuse," said Michael Heffernan, CEO of Collegium. "With the recently announced successful completion of our Phase 3 study with Oxycodone DETERx, and the progress we have made on additional product candidates, we are executing on our goal of developing a full suite of chronic pain products utilizing the DETERx® technology."

The project described was supported by Award Number R44DA037956 from the National Institutes of Health. The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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[®] 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.