

“Evaluation of an Extended-Release, Abuse-Deterrent, Microsphere-in-Capsule Analgesic for the Management of Patients with Chronic Pain with Dysphagia (CPD),” Published in Pain Practice

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Clinical study demonstrates that the Xtampza ER™ ER (oxycodone extended-release) drug release profile is maintained when sprinkled onto food

Canton, MA – January 15, 2015 – Collegium Pharmaceutical, Inc., a specialty pharmaceutical company focused on the development of innovative treatments for chronic pain, today announced the publication of “*Evaluation of an Extended-Release, Abuse-Deterrent, Microsphere-in-Capsule Analgesic for the Management of Patients with Chronic Pain With Dysphagia (CPD)*,” in the peer-reviewed medical journal, *Pain Practice*.

The publication included results from multiple in vitro studies demonstrating that Xtampza ER (oxycodone extended-release), an abuse-deterrent, extended-release opioid, can be administered by sprinkling onto soft food or administering the capsule contents through enteral tubes (nasogastric and gastrostomy) without affecting the drug release profile of the formulation.

Dr. Bill McCarberg, a founding member of the Chronic Pain Management Program at Kaiser Permanente, stated, “Patients with chronic pain who have dysphagia – from mild difficulty swallowing to the need for an enteral tube – pose a significant treatment challenge. A major problem is with medication misuse, which can arise from patient or patient caregiver attempts to crush, chew, or dissolve oral opioid ER formulations in an effort to facilitate swallowing or passage of the analgesic through an enteral tube. In addition, for conditions in which dysphagia becomes progressively worse over time, continuous use of the same analgesic without the need to switch opioids due to formulation constraints, for example, is critical for adequate, uninterrupted pain relief. The results of these studies suggest that XTAMPZA ER could provide a valuable treatment option, especially in those patients who have dysphagia or an aversion to swallowing tablet formulations and for whom analgesic patches or other opioid formulations are not a viable, or practical, therapeutic option.”

Highlights from the in vitro studies include:

- The drug release profile of Xtampza ER microspheres sprinkled onto and mixed with various soft foods were similar to the control, intact Xtampza ER capsules.
- The drug release profile of Xtampza ER microspheres after passing through enteral feeding tubes (nasogastric and gastrostomy tubes) of varying sizes were similar to the control, intact Xtampza ER capsules.
- A comparative evaluation of Kadian® (morphine sulfate ER pellet formulation) demonstrated that Kadian® pellets clogged commonly used enteral tubes while Xtampza ER did not clog any of the studied enteral tubes.

Collegium also announced results from a recently completed clinical ‘sprinkle’ study with Xtampza ER. The objective of the study was to assess the safety and pharmacokinetics of Xtampza ER following administration of the capsule contents (microspheres) sprinkled onto applesauce compared with administration of intact Xtampza ER capsules. This single-dose, open-label, cross-over comparison study was conducted in 41 healthy subjects and achieved the primary endpoint. The study successfully demonstrated that the pharmacokinetic properties of Xtampza ER taken intact compared with opening the capsule and sprinkling the capsule contents – microspheres containing oxycodone – onto applesauce met the FDA bioequivalence guideline.

“The recently completed clinical study provides further evidence that, upon approval, Xtampza ER may provide a unique extended-release, abuse-deterrent treatment option for the large unmet need of patients with chronic pain and dysphagia,” said Michael Heffernan, CEO of Collegium.

A copy of the publication is available at: onlinelibrary.wiley.com/doi/10.1111/papr.12280/abstract.

Kadian[®] is a registered trademark of Actavis Elizabeth LLC.

About DETERx[®] Technology

The DETERx[®] 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[®] 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. Xtampza ER[™] (oxycodone extended-release) 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 ER delivery, unique abuse-deterrent properties, and flexible dose administration options. For more information, visit the Company's website at www.collegiumpharma.com.