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# Newly Published Data Demonstrates 85% Eradication of Ulcer Causing Bacteria

## Study supports use of Omeclamox®-Pak as first-line treatment for H. pylori

NASHVILLE, Tenn., March 26, 2018 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a U.S. specialty pharmaceutical company announced today the publication of an open access article in *Infection and Drug Resistance*, with results demonstrating an 85% eradication rate of Helicobacter pylori (H. pylori) infection using clarithromycin-based triple therapy. Cumberland markets a branded clarithromycin-based triple therapy in the U.S. under the name Omeclamox®-Pak.

H. pylori has long been known as a common pathogen associated with gastric ulcers and related dyspeptic symptoms in many infected patients. If H. pylori is left untreated, it can damage the stomach and small intestine wall causing peptic ulcer disease, specifically duodenal ulcers. Symptoms of H. pylori-induced duodenal ulcers generally surface in adults and may include burning pain in the abdomen, nausea, vomiting, bloating, and weight loss.

Currently, the use of clarithromycin-based triple therapy has the support of organizational bodies in gastroenterology. Over the last 10 years, early recommendations to use clarithromycin-based triple therapy have been challenged by some sources and based on the premise that resistance is increasing.

This study, led by Devjit S. Nayar at Gastroenterology Associates of Central Jersey, evaluated the potential incidence of resistance in the New York Metropolitan region. The clinical success rate of clarithromycin-based triple therapy was evaluated by retrospectively reviewing patient data over six years. The cases of 151 patients, ranging in age from 21-76 years and receiving prescriptions for clarithromycin-based triple therapy between December 2011 and May 2017 were analyzed. The results of H. pylori eradication testing following completion of clarithromycin-based triple therapy revealed that 85%, or 130 of the 151, patients treated according to the standard protocol were negative for H. pylori.

Despite predictions from other sources in the last decade that clarithromycin-based treatments are becoming less effective, based on the results of this study, patients with a positive diagnosis of H. pylori could expect an 85% or better eradication rate when treated with clarithromycin-based triple therapy.

**About Omeclamox®-Pak (omeprazole, clarithromycin, amoxicillin)**

Omeclamox®-Pak is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori. Omeprazole is an antisecretory drug, which works by decreasing the amount of acid the stomach produces. Clarithromycin and amoxicillin are antibacterial drugs, which inhibit the growth of bacteria allowing the stomach lining to heal. Omeclamox-Pak is contraindicated in patients with a history of hypersensitivity to omeprazole, any macrolide antibiotic or penicillin. The safety and effectiveness of Omeclamox-Pak in the pediatric population has not yet been established. For full prescribing information, visit www.omeclamox.com.

**About Cumberland Pharmaceuticals**

**Cumberland Pharmaceuticals Inc.** is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. The Company develops, acquires, and commercializes brands for the hospital acute care, gastroenterology, and oncology market segments.

The Company's portfolio of FDA approved brands includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;

- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **Ethyol®** *(amifostine)* Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative radiation treatment for head and neck cancer and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer;
- **Totect®** *(dexrazoxane hydrochloride)* Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues).

Cumberland's pipeline of product candidates includes:

- **Hepatoren®** (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");
- **Boxaban®** *(ifetroban)* Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- **Vasculan®** *(ifetroban)* Oral Capsules, a Phase II candidate for the treatment of patients with systemic sclerosis (SSc) form of autoimmune disease;
- **Portaban®** *(ifetroban)* Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease;
- **RediTrex™** (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as severe disabling psoriasis.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com

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