



Newly Published Data Demonstrates Amifostine Delayed The Onset Of Acute Esophagitis For Small Cell Lung Cancer Patients

September 27, 2018

NASHVILLE, Tenn., Sept. 27, 2018 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a U.S. specialty pharmaceutical company and **Clinigen Group plc (AIM: CLIN, 'Clinigen')**, the global pharmaceutical and services company, announce a new publication in *Lung Cancer: Targets and Therapy* of a contemporary retrospective series showing that subcutaneous amifostine administered before radiotherapy postponed the onset of acute esophagitis in stage 3 small cell lung cancer patients treated with concomitant doublet chemotherapy and hyperfractionated radiotherapy.



Cumberland markets branded amifostine in the U.S territory under the name Ethyol® on behalf of Clinigen Group plc who is the market authorization holder and owner of global rights.

Concurrent chemoradiotherapy, delivered every three weeks in conjunction with radiotherapy, is recognized as a standard treatment option in patients with stage 3 small cell lung carcinoma. Acute esophageal inflammation has been described as a dose-limiting effect and is observed in ~25% of patients undergoing such treatment. Studies have reported a relationship between the volume of the esophagus irradiated and the likelihood of an acute injury. Series have reported volumes of esophagus irradiated as most reflective of acute symptoms.

The study, led by Ariel E Pollock M.D, Icahn School of Medicine at Mt. Sinai, New York, evaluated the impact of amifostine on protecting the esophagus. Its aim was to determine if the amifostine group experienced less weight loss, less use of opiates during treatment, and/or allowed for a higher dose of radiotherapy to be delivered before opioids were needed for symptomatic relief of acute esophagitis. They assessed stage 3 small cell lung cancer patients treated at the Schiffler Cancer Center in Wheeling Hospital West Virginia between 2005 and 2016. Chemotherapy consisted of cisplatin and etoposide, with radiotherapy twice daily. In 32 patients (group 1), amifostine was delivered prior to the second daily radiotherapy treatment. The remaining 17 patients (group 2) did not receive amifostine.

The study investigators concluded, based on their observations and objective measurements, that subcutaneous amifostine may postpone the onset of acute esophagitis in a subset of patients with small cell lung carcinoma receiving concurrent chemoradiotherapy.

About Ethyol® (amifostine)

Ethyol is indicated to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. It is indicated to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands. Xerostomia, or diminished saliva production, can lead to difficulties eating, speaking, and swallowing. Ethyol is contraindicated in patients with known hypersensitivity to aminothiols compounds.

For full prescribing and important safety information, please visit www.ethyol.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.

For more information, please visit www.cumberlandpharma.com.

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time

through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

For more information, please visit www.clinigengroup.com



C View original content to download multimedia: <http://www.prnewswire.com/news-releases/newly-published-data-demonstrates-amifostine-delayed-the-onset-of-acute-esophagitis-for-small-cell-lung-cancer-patients-300720169.html>

SOURCE Cumberland Pharmaceuticals Inc.

Media Contact, Jeff Bradford, the Bradford Group, (615) 515-4880; Investor Contact, Erin Smith, Corporate Relations, (615) 255-0068; Clinigen Group plc, Shaun Chilton, Group Chief Executive Officer, Matt Parrish, Head of Investor Relations, +44 (0) 1283 495010