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Newly Published Data Demonstrates Amifostine Reduces Gastro-Intestinal Toxicity For Multiple Myeloma Patients

Amifostine may prevent gastro-intestinal toxicities in certain cancer patients.

NASHVILLE, Tenn., Jan. 30, 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 *Leukemia & Lymphoma*, with study results showing that amifostine decreases gastro-intestinal (GI) toxicity in patients who receive treatment for their multiple myeloma. Cumberland markets branded amifostine in the U.S. under the name Ethyol®.

Multiple myeloma remains incurable, despite the significant improvement in treatment over the past 10 years. Data predicts that there will be over a 57% increase in the number of multiple myeloma patients by 2030 as a result of achieving longer survival for these patients and the population aging. Gastrointestinal (GI) toxicities such as nausea, vomiting, diarrhea and ulcers in mouth are a major limitation to the use of autologous hematopoietic cell transplantation (auto-HTC), especially in the elderly population which constitutes a significant proportion of multiple myeloma patients. Preventing GI toxicities for these patients without compromising efficacy of transplant is an important goal that could lead to an expansion of transplant eligibility criteria to older patients.

The study, led by Ehsan Malek, MD at Case Western Reserve University, assessed multiple myeloma patients receiving high dose melphalan followed by auto-HTC. It consisted of patients at University Hospitals Seidman Cancer Center in Cleveland, OH and the MD Anderson Cancer Center in Houston, TX. It evaluated the impact of amifostine on reducing GI toxicities among multiple myeloma patients undergoing transplant.

Amifostine is used to reduce the side effects of certain chemotherapy agents and radiation treatment. It is known as a cytoprotective agent, protecting the body from some of the potentially serious side effects of treatment. One hundred and seven patients participated in this study. Amifostine 740?mg was administered at 24?hours and 15?min before high-dose melphalan. The study concluded that amifostine therapy decreased GI toxicity without any significant adverse effects while preserving the anti-myeloma efficacy of high-dose melphalan and auto-HTC.

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.

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.

About Clinigen Group
Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing 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

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