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Cumberland Pharmaceuticals Expands into Oncology Support

FDA-approved Ethyol® and Totect® address harmful effects of cancer treatments to help improve the quality of life for oncology patients

NASHVILLE, Tenn., April 9, 2018 /PRNewswire/ -- [Cumberland Pharmaceuticals](#) - announced today that it has expanded its medical specialties to include oncology-related medications. The company's entry into the oncology specialty includes two initial supportive care medications: Ethyol® (amifostine) injection and Totect® (dexrazoxane hydrochloride) injection.



"Since the company's founding, Cumberland has endeavored to deliver high quality medicines to improve patient care," said CEO AJ Kazimi. "Our strategy has been to focus on select medical specialties that we can support nationally and make a significant impact. Oncology is a particularly rewarding and valuable field, and we are delighted to be able to help patients as they undergo their cancer treatments."

There were 1,688,780 new cases of cancer diagnosed in the U.S. in 2017, and advances in treatment have resulted in the average patient now living longer after initial diagnosis. As a result, quality of life becomes of paramount concern - and Cumberland's focus is on supporting cancer patients during their treatment, with the goal of improving their ongoing quality of life.

"The overarching goal of supportive care is to help patients tolerate and continue their cancer treatments," said Kazimi. "Our oncology medications enable us to target the side effects of patients' cancer treatments and help address the psychological or social problems that might result from those complications. We're grateful for the opportunity to contribute to the welfare of cancer patients, and help improve their quality of life."

Cumberland entered into an exclusive U.S. license to distribute and market both Ethyol and Totect with the Clinigen Group plc, a British specialty pharmaceutical and services company following a Strategic Alliance established between the companies.

Ethyol® and Totect® can offer significant benefits to cancer patients as noted in the following:

ETHYOL® (AMIFOSTINE)

- 1 Ethyol, Cumberland's first oncology supportive care product, has two FDA-approved indications.
- 1 The product is used to protect kidneys in women who are receiving cisplatin, a chemotherapy treatment for ovarian cancer, as well as for the treatment of dry mouth (xerostomia) that can occur in patients receiving radiation treatment for head and neck cancer.
- 1 Due to the greater likelihood of positive survival outcomes and length of life, xerostomia is of great concern impacting the patient's ability to eat, chew, and swallow for the rest of their life. Xerostomia occurs in up to 80 percent of patients undergoing radiotherapy.

- More specifically, health care providers are concerned with toxicity levels in patients as a result of cumulative radiation and cisplatin. These toxicity levels can prevent treatment in the future, particularly toxicity to the kidneys (nephrotoxicity) caused by cisplatin. The use of Ethyol results in significantly fewer patients experiencing treatment-limiting nephrotoxicity when compared to patients who did not receive Ethyol treatment.

For more information, including full prescribing instructions, please visit www.ethyol.com

TOTECT® (DEXRAZOXANE)

- Totect, Cumberland's second oncology supportive care product, is an FDA-approved hospital-based emergency oncology intervention drug.
- The product is indicated to treat the toxic effects of extravasation which is the leakage associated with anthracycline chemotherapy. Extravasation occurs when an injected medicine escapes from the blood vessels and circulates into surrounding tissues in the body, causing severe damage and serious complications. Anthracyclines are a class of drugs that includes doxorubicin, epirubicin, and daunorubicin which are used to treat many cancers. The incidence of anthracycline extravasation has been reported to be up to 6.0 percent, although it is widely acknowledged to be both underreported and undertreated.
- Totect can limit the damage caused by extravasation without the need for surgery and enable patients to continue their essential anti-cancer treatment. It is the only FDA approved antidote to this dangerous and debilitating problem that can occur when administering anthracyclines. Even with advances in medicine, anthracyclines are still a first line treatment for most solid tumors. In clinical trials, Totect eliminated the need for surgery in 98 percent of patients with anthracycline extravasation.

For more information, including full prescribing instructions, please visit www.totect.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 the 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.

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



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