



Cumberland Pharmaceuticals Announces Strategic Review

March 29, 2019



- Review follows rapid growth in product portfolio

- Will also include review of expanded group of international partners

NASHVILLE, Tenn., March 29, 2019 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company, today announced that it has commenced a strategic review of its branded product portfolio, as well as its roster of international partners. The Company expects to communicate results from the review during its upcoming report on the first quarter of 2019.

The strategic review follows an accelerated business development initiative that has resulted in a series of transactions over the last thirty six months. Following the Company's acquisition of Vibativ[®] in late 2018, its commercial portfolio now includes eight FDA-approved brands. The product line encompass three medical specialties – hospital acute care, gastroenterology and oncology. The brands are supported by Cumberland's two national sales divisions, one of which covers key hospital accounts across the United States, and the other targets gastroenterologists and other select office-based physicians. This strategic review will consider the status of each brand in its product life cycle, its profitability, synergies with other products in the Company's portfolio and assurance of ongoing supply.

In addition to the product review, Cumberland will also evaluate the appropriate level of sales and medical support for its line of products. The strategic review will seek to ensure national coverage of a majority of each brand's current business, as well as its potential. Both the expansion of the Company's internal sales organization and augmented support from co-promotion partners will be considered during the review.

Cumberland's strategy is to focus on the U.S., which is the largest market for its biopharmaceutical products. The Company has established a network of partners based outside the U.S. to bring its products to patients in other countries. As a result of the Vibativ[®] acquisition, Cumberland inherited a new group of firms who have licenses to that brand for international markets. The total number of the Company's existing international partners now numbers seventeen. The group includes those with rights to Cumberland products in other countries, as well as those partners who have licensed products to the Company for the U.S. market. The capabilities, status and potential of each partner will be evaluated during the review.

"We have successfully executed on our strategy to expand our commercial product line through a series of transactions," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We expect to deliver on our goal of three planned product launches within a twelve month period. Because of this progress, we believe it's important to take a fresh look at our portfolio, partners and organization to ensure we have the proper focus and capabilities to make the most of our new opportunities."

Recap of Recent Developments

Cumberland expanded its commercial product line in 2018 with the acquisition of Vibativ[®] from Theravance Biopharma.

Vibativ[®] is a patented, FDA-approved anti-infective injectable product, designed to treat certain serious bacterial infections - including hospital-acquired pneumonia and complicated skin infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multi-drug resistant such as MRSA. Wide-spread use of generic anti-infective products has led to a sharp increase in the number of patients experiencing resistance to certain products, resulting in a shift in the clinical standard of care for antibiotic treatments.

Early in 2018, Cumberland submitted an application to the FDA for the approval of its Next Generation Caldolor[®] product. After a series of interactions with the FDA and amendments to the application, Cumberland was subsequently notified of the product's FDA approval in early 2019. The Company is now preparing for the launch of this patented product which features both an improved package and formulation.

In late 2018, Cumberland closed on an agreement with Gastro-Entero Logic, LLC ("GEL") to acquire the assets associated with

Omeclamox®-Pak. With the closing of the agreement, Cumberland no longer provides GEL with royalties on sales and is now responsible for maintaining the FDA approval and overseeing the product's packaging, trademarks and other assets.

During late 2018, Cumberland completed the submission and then filed with the FDA a New Drug Application for the approval of its methotrexate product line. This line of methotrexate products is designed for the treatment of adult and pediatric patients with rheumatoid arthritis as well as adults with psoriasis. In January 2019, the FDA accepted the submission as complete and ready for review, providing a target approval decision date for September 2019.

Meanwhile, Cumberland continued to advance its clinical programs in 2018, which feature several new product candidates in Phase II studies. The Company completed study enrollment for Portaban®, its Portal Hypertension clinical program. Initial review of the data from the study shows ifetroban to be safe and well tolerated with no unexpected safety findings. Cumberland also continued to advance its Vasculan® and Boxaban® clinical programs, with patient enrollment progressing in each of those Phase II studies.

Through Cumberland Emerging Technologies (CET), the Company is establishing a pipeline of new product candidates and fostering innovation by partnering with academic centers. During 2018, CET expanded its network of institutional collaboration by entering into agreements with Louisiana State University and the Medical College of South Carolina. These two new arrangements expanded CET's roster of academic affiliations which also includes: Vanderbilt University, the University of Mississippi School of Pharmacy, and the University of Tennessee Research Foundation.

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. These medical specialties are categorized by moderately concentrated prescriber bases that we believe can be penetrated effectively by targeted sales forces. 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;
- **EthyoI®** (*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); and
- **Vibativ®** (*telavancin*) Injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections.

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) a 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; and
- **RediTrex™** (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as 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 Cumberland Emerging Technologies (CET)

Cumberland Emerging Technologies, Inc., or CET, (www.cet-fund.com) is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, LaunchTN, and Gloria Pharmaceuticals. The mission of CET is to advance biomedical technologies and products conceived at Vanderbilt University and other regional research centers towards the marketplace.

CET helps manage the development and commercialization process for select projects, and provides expertise on intellectual

property, regulatory, manufacturing and marketing issues that are critical to successful new biomedical products. CET's Life Sciences Center, provides laboratory space, equipment and infrastructure for CET's activities and other early-stage life sciences ventures.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. Forward-looking statements include, among other things, statements regarding our intent, belief or expectations. As with any business, all phases of Cumberland's operations are subject to factors outside of its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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