# CUMBERLAND PHARMACEUTICALS ANNOUNCES FDA CLEARANCE OF IND FOR NEW TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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*Cumberland initiating Phase II FIGHTING FIBROSIS ™ clinical trial,*

*Newest program in Cumberland's ifetroban pipeline*

NASHVILLE, Tenn., May 23, 2023 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq:CPIX) today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug Application (IND) for a Phase II study in patients with Idiopathic Pulmonary Fibrosis, the most common form of progressive fibrosing interstitial lung disease. As a result, Cumberland will launch its FIGHTING FIBROSIS trial designed to enroll 128 patients in over 20 medical centers of excellence across the U.S.

**Idiopathic Pulmonary Fibrosis (IPF)** is the newest clinical program in the pipeline for Cumberland's first new chemical entity: ifetroban – a potent and selective thromboxane receptor antagonist. The Company has designed a Phase II clinical trial to study the safety, tolerability, and efficacy of oral ifetroban in patients with IPF. Recent studies have shown ifetroban can both prevent and enhance resolution of lung fibrosis in multiple preclinical models.

Cumberland previously received IND clearance from the FDA for several indications including Systemic Sclerosis and Duchenne Muscular Dystrophy. Phase II clinical studies in patients with those conditions are well underway.

"We are pleased that the FDA has cleared this new clinical program as we work to develop new medicines for the future – especially those that address unmet medical needs," said A.J. Kazimi, Cumberland Pharmaceuticals Chief Executive Officer. "Given the exciting preclinical data demonstrating ifetroban can prevent lung fibrosis, we are very excited to advance directly to a Phase II study for IPF patients."

**About the new Phase II Clinical Trial**

The FIGHTING FIBROSIS ™ clinical trial is a multicenter, double-blind, placebo-controlled Phase II study in patients with IPF. The study will investigate the safety and efficacy of once daily oral ifetroban for 52 weeks. Subjects will be block randomized by background therapy (pirfenidone or nintedanib) and assigned to one of two treatment groups, ifetroban or placebo, at a dose of 250 mg daily. Approximately 128 subjects with IPF will be enrolled in the U.S. The primary objective is to improve lung function, as measured by the FVC in IPF patients on ifetroban compared to placebo over 52 weeks.

**About Idiopathic Pulmonary Fibrosis**

Idiopathic pulmonary fibrosis (IPF) is a progressive interstitial lung disease marked by inflammation and fibrosis of the lungs, resulting in rapidly declining lung function and reduced survival within 5 years of diagnosis. IPF is the most common form of interstitial lung disease and is estimated to affect up to 2 million individuals globally.

While FDA-approved antifibrotic therapies have shown efficacy to slow progression of the disease, there is no approved treatment which effectively halts disease progression and improves patients' symptoms. Therefore, an unmet need exists to identify additional treatments which add benefit and provide alternatives to existing therapies.

**About Ifetroban**

Ifetroban is a potent and selective thromboxane-prostanoid receptor (TPr) antagonist. Ifetroban exhibits high affinity for TPr on many cell types including platelets, vascular and airway smooth muscle, and fibroblasts, and lacks agonistic activity. Ifetroban also displays anti-platelet, antivasospastic, antifibrotic, and antibronchospastic activities and is effective in certain preclinical models of vasospasm, thrombosis, reperfusion injury, cardiac fibrosis, lung fibrosis and endothelial dysfunction, including models that are insensitive to aspirin.

Cumberland previously announced the acquisition of the ifetroban program in collaboration with Vanderbilt University and Cumberland Emerging Technologies (CET).

Cumberland is also sponsoring the FIGHT DMD™ trial a multicenter, randomized, placebo-controlled Phase II study evaluating two doses of oral ifetroban for the treatment of the cardiomyopathy associated with Duchenne muscular dystrophy, a rare and fatal genetic disorder. The FDA awarded Cumberland $1 million in funding under its orphan products grants program to support this trial. This was the first DMD trial awarded such funding.

Cumberland recently completed a Phase II study investigating ifetroban in patients with aspirin-exacerbated respiratory disease (AERD), a rare and severe form of asthma. While the Phase II AERD study showed ifetroban improved patient symptoms, and significantly in some cases, there was not a statistically significant difference with the comparator arm of the study.

The Company plans to complete each of these sponsored studies, analyze data, announce top-line results, and then decide on the best development path for the registration of ifetroban, which has the potential to benefit many patients with orphan diseases that represent unmet medical needs.

**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 rheumatology 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;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **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;
- **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; and
- **Sancuso®** (*granisetron)* transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment.

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**

Cumberland Emerging Technologies, Inc. is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, Launch Tennessee and WinHealth Pharma. The mission of CET is to bring biomedical technologies and products conceived at Vanderbilt and other regional research centers to 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, located in Nashville, Tennessee, provides laboratory space, equipment and infrastructure to early-stage life sciences companies.

**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. 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, natural disasters, public health epidemics, and other events beyond our control, as more fully discussed in the Company's most recent Form 10-K and subsequent 10-Qs 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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