Cumberland Pharmaceuticals Receives FDA Fast Track Designation for its Ifetroban Duchenne Muscular Dystrophy Program

NASHVILLE, Tenn. (February 4, 2026) - Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company focused on developing new products for rare diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted **Fast Track Designation** for its novel oral therapy targeting a fatal form of heart disease in Duchenne muscular dystrophy (DMD) patients.

The FDA's Fast Track program facilitates the development and expedites the review of a drug designed to treat a serious or life-threatening condition and unmet medical need. This designation provides an opportunity for more frequent communication with the FDA, enabling Cumberland, as the sponsor, to obtain early feedback and guidance. Under Fast Track, Cumberland can also submit portions of an application for marketing approval on a rolling basis.

Cumberland requested Fast Track Designation to streamline the regulatory pathway for ifetroban for DMD heart disease. This Fast Track Designation follows the drug's receipt of both **Orphan Drug Designation** and **Rare Pediatric Disease Designation**, confirming both the urgency and the significant impact of the product for this indication.

Cumberland previously announced positive results from its Phase 2 FIGHT DMD trial evaluating oral thromboxane receptor antagonist ifetroban in DMD heart disease, demonstrating a 5.4% improvement in left ventricular ejection fraction (LVEF) over 12 months of treatment.

"The FDA's Fast Track Designation for ifetroban underscores the urgent and critical unmet medical need in DMD heart disease," said A.J. Kazimi, Cumberland founder and CEO. "This designation, combined with our breakthrough Phase 2 results, positions us to work closely with the FDA through more frequent interactions and expedited review processes to advance this promising heart-targeted therapy for DMD patients as efficiently as possible. We look forward to engaging with the Agency and our patient advocacy partners to bring this much-needed therapy to DMD patients and their families."

About Duchenne Muscular Dystrophy (DMD)

DMD is a rare and incurable pediatric disease affecting approximately 1 in 3,500-5,000 male births caused by mutations in the gene encoding dystrophin, a protein critical for muscle function, including the heart. Patients with DMD slowly lose muscle function, resulting in the inability to walk, difficulty breathing, and heart failure. While current treatments can help manage some DMD symptoms, there are no approved therapies specifically targeting DMD-related heart disease, highlighting a critical unmet medical need.

Heart disease is the leading cause of death in DMD patients, with heart damage beginning early and progressing at different rates for each patient. Despite this, no treatments are currently approved specifically for DMD heart disease. The current treatment options include the use of corticosteroids to reduce inflammation and traditional heart disease medications to manage blood pressure and heart rate, reducing strain on the heart. While these therapies slow the onset and progression of DMD heart disease, none of them provides a lasting benefit for this unique form of heart disease or improves patient survival. Additionally, exon-skipping and gene therapies approved for DMD have shown no cardiac benefit to date.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is the largest biopharmaceutical company founded and headquartered in Tennessee and is focused on providing unique products that improve the quality of patient care. The company develops, acquires, and commercializes products 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*) oral, a prescription laxative, for the treatment of constipation;
- **Sancuso®** (*granisetron*) transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **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; and
- **Talicia®** (*omeprazole, amoxicillin and rifabutin*) oral capsule, for the treatment of *H. pylori* infection.

The company also has a series of Phase 2 clinical programs underway evaluating its ifetroban product candidate in patients with Systemic Sclerosis and Idiopathic Pulmonary Fibrosis, in addition to Duchenne muscular dystrophy.

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

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 the company's intent, belief or expectations, and can be identified by the use of terminology such as "may," "will," "expect," "believe," "intend," "plan," "estimate," "should," "seek," "anticipate," "look forward" and other comparable terms or the negative thereof. 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 operation results. These factors include macroeconomic conditions, including rising interest rates and inflation, competition, an inability of manufacturers to produce Cumberland's products on a timely basis, failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, natural disasters, public health epidemics, maintaining an effective sales and marketing infrastructure, and other events beyond the company's control as more fully discussed in its most recent annual report on Form 10-K as filed with the U.S. Securities and Exchange Commission ("SEC"), as well as the company's other filings with the SEC from time to time. 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.

SOURCE: Cumberland Pharmaceuticals Inc.

Investor Contact:
Shayla Simpson
Cumberland Pharmaceuticals
(615) 255-0068

Media Contact:
Emily Kent
Dalton Agency
(540) 621-5448