



**CUMBERLAND PHARMACEUTICALS ANNOUNCES
PLANS TO FILE NEW DRUG APPLICATION FOR
IFETROBAN DMD PROGRAM**

NASHVILLE, Tenn. (Oct. 26, 2026) – Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), (“Cumberland” or the “Company”) an innovation-focused biopharmaceutical company developing new products for rare diseases, today provided an update on its ifetroban product candidate in development as a potential treatment for the cardiomyopathy associated with Duchenne muscular dystrophy (“DMD”). The Company announced plans to submit a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for ifetroban as a potential treatment for the cardiomyopathy associated with DMD.

Cumberland requested a pre-NDA meeting with FDA, which was held this fall. During the pre-NDA meeting, the discussions involved the format and content and of the planned submission including the needed reports and requested analysis. Cumberland is proposing the FIGHT DMD™ trial as the pivotal study to be combined with comparison data from two natural history databases to support product approval. Following the meeting FDA granted the Company's request for a rolling review of the NDA, which allows completed sections of the application to be provided to the FDA for review, prior to the submission of the entire application.

Cumberland’s decision to submit the NDA followed an End-of-Phase 2 meeting with FDA in September 2025 and a follow-up Type C meeting in January 2026. FDA suggested a Phase 3 trial and raised several issues regarding the Phase 2 study results including the suitability of the LVEF endpoint, comparator related questions and the development of the statistical analysis plan. In response, the Company provided additional data supporting its efficacy findings, natural history data from a second DMD registry, and documentation of how the statistical analysis plan was developed.

“Our natural history study demonstrated that heart function declines steadily in boys and young men with Duchenne muscular dystrophy and that a lower ejection fraction is associated with higher mortality.” said Jonathan Soslow, MD, MSCI, Professor of Pediatric Cardiology, Director of Clinical Research, Pediatric Cardiology at the Vanderbilt University Medical Center. “That trajectory is the benchmark against which any cardiac therapy in Duchenne has to be judged.”

“We decided to file our application for approval given the urgency in addressing the unmet medical need for patients suffering from this devastating disease,” said A.J. Kazimi, CEO of Cumberland. “With a favorable safety profile and the encouraging dose response findings in our FIGHT DMD™ trial, we want to make this treatment available for these DMD patients who have no approved treatment specifically for their cardiomyopathy.”

The planned submission for Traditional Approval will include data from the Company's FIGHT DMD™ clinical study and its ongoing open-label extension, data from two natural history databases of DMD patients, preclinical data published in the *Journal of the American Heart Association*, manufacturing information and a safety database that includes more than 1,400 subjects across approximately 30 clinical studies. The FDA raised concerns regarding the needed substantial evidence of efficacy and requested additional analysis, particularly regarding missing data, and other supporting information, which the Company will also provide in the NDA.

“For years, families have told us that heart disease is one of their greatest concerns as their sons grow older, said Pat Furlong, Founding President, Parent Project Muscular Dystrophy (PPMD). PPMD has supported the FIGHT DMD™ trial from its earliest days because this is the kind of research our community asked for. Heart function continues to decline as these young men grow older, and families tell us they need treatment options for the heart as soon as possible.”

The 12-month FIGHT DMD™ trial ([NCT03340675](https://clinicaltrials.gov/ct2/show/study/NCT03340675)) demonstrated that high-dose ifetroban treatment resulted in a significant 5.4% absolute improvement in left ventricular ejection fraction (LVEF) ($p=0.002$) compared to a control group composed of placebo-treated patients combined with propensity score-matched natural history patients. The study findings also included reductions in cardiac damage markers (NT-proBNP and cardiac troponin I) in the high-dose group. All patients who completed the 12-month study opted to continue in the open-label extension. Long-term cardiac MRI data from Months 24 and 36 of the open-label extension are being analyzed for inclusion in the NDA.

“When we designed the FIGHT DMD™ clinical trial, we chose cardiac MRI as the modality to evaluate heart function because it has the ability to detect subtle changes in heart function years before heart failure symptoms appear said Larry Markham, MD, Division Director of Pediatric Cardiology, Co-Executive Director, Golisano Pediatric Heart Institute at Monroe Carell Jr Children's Hospital. “I have been part of this work since the early preclinical studies at Vanderbilt, when our colleagues first studied ifetroban in models of muscular dystrophy heart disease. It has been rewarding to see this research carried forward for our patients. Cardiomyopathy is now the leading cause of death in Duchenne, and to date, there are no approved Duchenne cardiomyopathy-specific treatment options.”

Findings from the Phase 2 FIGHT DMD™ trial, supported by long-term safety data from the ongoing open-label extension, further characterize the cardioprotective effect exerted by ifetroban in DMD cardiomyopathy. Through 36 months of treatment across both the Phase 2 trial and the open-label extension, ifetroban maintained a favorable safety profile in DMD patients with no treatment-related serious adverse events or new safety concerns.

Evaluation of novel blood biomarkers identified a 30% reduction in MYL3 and a 50% reduction in MYOD1 (circulating markers of heart muscle and cell damage), alongside a 2.4-fold increase in FGF16 and a 2.1-fold increase in TSPAN7 (cardioprotective and tissue repair proteins) with ifetroban treatment compared with placebo. These findings further support the potential therapeutic mechanisms for ifetroban in DMD cardiomyopathy.

Ifetroban is proposed as a once-daily oral medication that works by blocking the thromboxane receptor, which plays a key role in inflammation and fibrosis. The drug has received Orphan Drug Designation, Rare Pediatric Disease Designation and Fast Track Designation from FDA for the indication of cardiomyopathy associated with DMD. There is currently no approved treatment specifically targeting DMD heart disease, highlighting the critical unmet medical need in this patient population where cardiac complications are typical and represent the leading cause of death.

Cumberland has secured a growing portfolio of patents protecting ifetroban for the DMD heart disease indication. FDA has also conditionally accepted DYSCORBAN® as the proprietary name for the product.

More information regarding the FIGHT DMD™ trial is available at www.fightdmdtrial.com

For additional information on Cumberland's plans to file an NDA with FDA for ifetroban as a potential treatment for the cardiomyopathy associated with DMD, please see the Company's filings with the Securities and Exchange Commission.

Cumberland is also developing ifetroban for a series of other indications. The Company has completed a Phase 2 study of ifetroban in patients with systemic sclerosis and is conducting a Phase 2 study in idiopathic pulmonary fibrosis. In addition, researchers at Vanderbilt Health completed a Phase 2a clinical trial of ifetroban to prevent metastasis in high-risk solid tumors. The study's primary safety endpoint was achieved, and favorable trends in decreased metastasis recurrence and metastasis-free survival were identified.

About Duchenne Muscular Dystrophy (DMD)

DMD is a rare and incurable pediatric disease 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.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is an innovation-focused biopharmaceutical company developing new therapies to address significant unmet medical needs and improve the patient outcomes. The Company is advancing a clinical pipeline of late-stage product candidates across multiple therapeutic areas with significant unmet medical needs.

Cumberland's Phase 2 clinical programs are also evaluating ifetroban in patients with Idiopathic Pulmonary Fibrosis and Cancer Metastasis. Top-line results from a Phase 2 study in patients with Systemic Sclerosis were recently announced.

For more information, please visit www.cumberlandpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as “may,” “will,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “potential,” “continue,” “could,” “should,” “would” and similar expressions, although not all forward-looking statements contain these words. These statements include, among others, statements regarding the timing, content and completion of the NDA submission, including the rolling review; Cumberland's plan to seek approval based on the FIGHT DMD™ trial and natural history data without conducting additional trials; the results of the ongoing open-label extension analyses; regulatory review, approval and labeling; the potential benefits of Orphan Drug, Rare Pediatric Disease, including eligibility for a priority review voucher, and Fast Track designations, which may not be realized; the proprietary name; patent protection and exclusivity; manufacturing; commercialization and market acceptance; the need for additional capital; competition; reliance on third parties; and other ifetroban programs. These statements are based on current assumptions and plans of Cumberland's management and are subject to risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. Important factors that could cause such differences include, among others, the risk that FDA will refuse to file the NDA or will not approve ifetroban; the risk that FDA will not agree with Cumberland's interpretation of the minutes or outcomes of its meetings with FDA; the risk that FDA will require additional trials and data, which could significantly delay or prevent approval and require substantial additional capital; the risk that additional data may not be favorable; Cumberland's ability to meet FDA's other approval requirements, including chemistry, manufacturing and controls requirements; the risk that rolling review will not shorten the review timeline; restrictions that may be placed on the label, if approved; changes in FDA requirements, policies or regulatory pathways; and the risks described under the heading "Risk Factors" in Cumberland's most recent Form 10-K and subsequent Form 10-Q filings, as well as other reports filed with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Cumberland undertakes no obligation to update any forward-looking statement except as required by law.

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