Cumberland Pharmaceuticals and Vanderbilt Health Announce Potential New Therapy to Prevent Cancer Metastasis

Positive Results from Phase 2a Clinical Trial

Study met its primary endpoint demonstrating safety and tolerability of ifetroban in patients with high-risk solid tumors

Trial revealed promising efficacy signals with fewer deaths due to metastasis in the ifetroban arm, than in the placebo arm (p=0.037)

Results support development of ifetroban as a candidate for metastasis prevention

NASHVILLE, Tenn. (June 2, 2026) - Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company focused on developing new products for rare diseases, and Vanderbilt Health today announce data from a Phase 2a clinical trial of ifetroban to prevent metastasis in high-risk solid tumors. The study's primary safety endpoint was achieved, along with favorable trends in decreased metastasis recurrence and metastasis-free survival. A safe and effective medication that reduces distant metastatic recurrence could transform cancer management and improve the lives of millions of cancer survivors and their families.

The randomized, double-blind, placebo-controlled Phase 2a trial evaluated the safety of ifetroban, an investigational thromboxane A2 receptor antagonist, in patients with solid tumors at high risk of early metastatic recurrence. Cancer types included breast, lung, pancreatic, soft tissue, bladder, and renal cancers.

The study met its primary endpoint, demonstrating that ifetroban was safe and well-tolerated in this patient population. Rates for adverse events related to treatment were similar between placebo and ifetroban. No serious adverse events (> grade 3) in either group were identified as being related to study treatment. Treatment discontinuation rates were not statistically different between placebo and ifetroban.

Although primarily a safety study and intentionally not powered for efficacy, the study compared the percentage of patients with distant metastatic recurrence 12 months after completion of therapy in both groups (10 placebo-treated and 18 ifetroban-treated participants) as a prespecified secondary endpoint. While 50% of participants experienced distant metastatic recurrence in the placebo arm, only 17% of participants experienced distant metastatic recurrence in the ifetroban arm (p=0.091). Three deaths due to distant metastatic disease occurred in the placebo arm, and none occurred in the ifetroban arm (p=0.037).

Though metastasis is a primary driver of cancer lethality, most current therapies act on tumor cells directly. Approaches targeting the mechanisms underlying the metastatic process are lacking. Even during clinical remission, microscopic metastases can remain present, leaving many patients at serious risk for metastatic recurrence. The premise of this novel therapy is that antagonizing the thromboxane A2 receptor and blocking platelet activation and aggregation lessens tumor cells' ability to migrate, spread, cluster, invade distal organs, and evade immune detection.

This was the first trial evaluating the effects of ifetroban in people with solid tumors with high risk for early recurrence, defined as ≥ 50% chance of recurrence within 5 years of diagnosis. The intervention was given after all cancer-related therapies and surgical procedures had been completed; participants received the intervention for 12 months and were then followed for an additional 12 months. Among 29 participants, 10 received placebo and 19 received ifetroban.

“A therapeutic intervention aimed at metastasis prevention for cancer patients with high risk of recurrence that is given during the period of “watchful waiting” could be groundbreaking if proven beneficial in larger scale investigations,” said Dr. Ben Ho Park of the Vanderbilt-Ingram Cancer Center. “We look forward to pursuing those pivotal studies as we relentlessly look for treatments to benefit patients living with cancer.”

This clinical trial translated robust in silico and preclinical data to humans, confirming safety of ifetroban in patients with solid tumors and preliminarily suggesting that ifetroban may target biologic mechanisms involved in distant metastatic recurrence. A phenome-wide association study (PheWAS) was conducted by Vanderbilt Health investigators using the BioVU biorepository, which linked a naturally occurring genetic variant in the thromboxane receptor gene (TBXA2R) to an increased risk of metastatic disease across multiple cancer types.

Preclinical studies subsequently published in *Molecular Cancer Therapeutics* demonstrated that ifetroban reduced metastasis in several animal models without affecting tumor growth, and that the drug's effects appeared to involve strengthening of the vascular endothelial barrier and inhibiting the ability of tumor cells to migrate across blood vessel walls.

“The favorable safety profile of ifetroban in this patient population, combined with the efficacy signals observed in this study, supports continued investigation of ifetroban as a candidate for metastasis prevention," said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals. "The contributions of the Vanderbilt Health team have been essential to advancing this program."

Results of this Phase 2a clinical trial will be used to guide the further clinical development verifying efficacy and further demonstrating safety.

About Ifetroban

Ifetroban is a potent and selective thromboxane-prostanoid receptor (TPr) antagonist. It exhibits high affinity for TPr on many cell types including platelets, cardiomyocytes, vascular and airway smooth muscle, and fibroblasts, and lacks agonistic activity. Cumberland is also evaluating ifetroban in Phase 2 clinical programs for patients with Duchenne Muscular Dystrophy, Systemic Sclerosis and Idiopathic Pulmonary Fibrosis. Ifetroban has a favorable safety profile as evidenced by multiple completed clinical trials collectively enrolling over 1,400 people.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Nashville-based specialty pharmaceutical company focused on developing new therapies for rare diseases. The company is advancing a clinical pipeline of investigational candidates, including ifetroban and IV guanfacine, across multiple therapeutic areas with significant unmet medical need.

Cumberland's Phase 2 clinical programs are evaluating ifetroban in patients with Duchenne Muscular Dystrophy, Systemic Sclerosis, and Idiopathic Pulmonary Fibrosis, in addition to the oncology program described in this release.

For more information, please visit 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," "goal", "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 risks and uncertainties related to the strategic transaction, risks related to our ability to develop our pipeline of new product candidates, macroeconomic conditions, including changes in interest rates, inflation, tariffs, 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.

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