



Cumberland Pharmaceuticals Announces

ASSIST-SSc Trial Top-Line Results

Ifetroban was well tolerated in patients with systemic sclerosis

NASHVILLE, Tenn. (October 23, 2026) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), an innovation-driven biopharmaceutical company advancing new therapies that address significant unmet medical needs, announces top-line results from its Phase 2a ASSIST-SSc trial evaluating oral ifetroban for patients with systemic sclerosis ("SSc"). These results support the safety and tolerability of ifetroban in this rare disease population. Cumberland will next complete correlative biomarker studies using specimens collected during the trial, along with an evaluation of cardiac imaging from patients continuing on the open-label extension.

SSc is a rare autoimmune disease characterized by excess collagen deposition resulting in skin thickening, cardiovascular disease, gastrointestinal problems, and more, and affects approximately 100,000 individuals in the U.S. Current therapies target specific manifestations of SSc, and approved options are available for SSc-associated interstitial lung disease. However, there is no approved therapy directed at the primary cardiac issues associated with SSc. Both cardiac and pulmonary manifestations remain among the leading causes of mortality for patients with the disease.

Ifetroban is a once-daily oral medication that works by blocking the thromboxane receptor, which plays a key role in inflammation, vascular dysfunction and fibrosis. In preclinical models of pulmonary arterial hypertension and heart disease, ifetroban treatment was associated with a reduction in fibrosis and provided cardioprotective effects (West 2016). A delay or inhibition of tissue fibrosis and improved cardiac function could provide significant improvement in quality of life for SSc patients. These preclinical results were foundational to the development of this Phase 2a clinical trial.

The 12-month Phase 2a ASSIST-SSc trial ([NCT02682511](#)) was a pilot trial to evaluate the safety of oral ifetroban in patients with SSc. Patients with either diffuse cutaneous (dcSSc) or pulmonary arterial hypertension (SSc-PAH) manifestations were randomized to receive ifetroban or matching placebo. A total of 31 subjects received ifetroban (22 dcSSc and 9 SSc-PAH) and 10 subjects received placebo (9 dcSSc and 1 SSc-PAH). Safety was evaluated by the frequency of treatment emergent adverse events between treatment groups. Exploratory efficacy endpoints were evaluated by SSc cohort to assess the effect of ifetroban on multiple aspects of SSc disease, including cardiovascular, pulmonary, skin, activity and quality of life.

Ifetroban was generally well tolerated, with a safety profile consistent with prior experience. As in prior ifetroban studies, gastrointestinal adverse events were more frequent in the ifetroban group than in the placebo group; the majority were mild and resolved. A modest increase in bleeding-related adverse events was also observed with ifetroban, in keeping with its mechanism as a thromboxane prostanoid receptor antagonist, and these events were predominantly mild. No serious adverse event during the 12-month treatment period was assessed by the medical monitor as related to study drug.

The majority of subjects in both treatment groups showed limited disease progression during the study, which reduced the ability of a trial of this size to detect a treatment difference. This Phase 2a trial was not designed or powered to evaluate efficacy, and the sample size and exploratory analytic approach preclude efficacy conclusions.

Cumberland has reviewed the results from both the dcSSc and SSc-PAH cohorts with clinical experts in SSc. As next steps, the Company plans to submit the clinical study report to the U.S. Food and Drug Administration (“FDA”) and to also complete correlative biomarker studies using specimens collected during the trial, along with an evaluation of cardiac imaging from patients continuing on the open-label extension. Those findings will inform Cumberland's decision on the further development of ifetroban in SSc.

About Systemic Sclerosis (SSc)

SSc is a rare autoimmune connective tissue disease which is characterized by rapidly progressing fibrosis and atrophy in the musculoskeletal system and internal organs including the lungs, heart, gastrointestinal tract and kidneys. While approved therapies exist for certain pulmonary manifestations, no therapy is currently approved to treat or prevent the primary cardiac involvement of SSc.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is an innovation-focused biopharmaceutical company developing new therapies to address significant unmet medical needs and improve the quality of patient care. 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 Duchenne Muscular Dystrophy, Idiopathic Pulmonary Fibrosis and Cancer Metastasis.

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. 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, the risks inherent in clinical development, regulatory review and the commercialization of ifetroban and other pipeline or CET-supported assets, 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 U.S. Securities and Exchange Commission (“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.

SOURCE: Cumberland Pharmaceuticals Inc.

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