



FOR IMMEDIATE RELEASE

**Cancer Prevention Pharmaceuticals Announces
Last Patient Completes Phase 3 Trial Protocol
of CPP-1X/sul for Familial Adenomatous Polyposis**

Analysis of data expected in early 2019

TUCSON, Arizona, December 10, 2018 – Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, announced today the last patient has completed the study protocol in its pivotal Phase 3 trial of CPP-1X/sul for adults with familial adenomatous polyposis (FAP), a rare genetic disease that, if left untreated, progresses to colorectal cancer in nearly 100% of patients.

Analysis of the results from the randomized, double-blind trial are expected to be complete in early 2019, followed by potential submission of a New Drug Application (NDA) with the US Food and Drug Administration (FDA), which has granted CPP-1X/sul for the treatment of FAP fast track and orphan drug designation.

“This is a significant milestone in our development of CPP-1X/sul,” said CPP Chairman and CEO Jeff Jacob. “It has taken five years across multiple sites in the United States, Canada and Europe to complete the trial. We look forward to bringing to FAP patients a pharmacoprevention therapeutic that, if approved, could change the treatment paradigm for their debilitating and life-threatening disease.”

FAP occurs in about 1 in 10,000 people. For most FAP patients, current medical practice recommends a lifetime of periodic monitoring as well as surgeries (FAP-related events). These FAP-related events include surgical removal of the colon, rectum, surgical pouch, duodenum and/or high-risk adenomas.

“Patients currently suffering from FAP have no effective treatments to delay or prevent progression of their disease,” said Carol A. Burke, MD, a gastroenterologist at the Cleveland Clinic and principal investigator for the FAP-310 clinical trial. “If the study results are favorable and CPP-1X/sul is approved by the FDA, clinicians will be able to offer their FAP patients a safe and effective drug treatment that may reduce or potentially avoid the need for complex endoscopic or surgical intervention.”

The FAP-310 clinical trial, which enrolled 171 patients at 17 research institutes in the United States, Canada and Europe, is the largest-ever FAP clinical trial and treated patients for longer than any other trial. It was designed to determine if CPP-1X (eflornithine) in combination with sulindac is superior to sulindac or eflornithine as single agents in delaying time to the first occurrence of any FAP-related event. For more information on the clinical trial visit:

<https://clinicaltrials.gov/ct2/show/NCT01483144>.



CPP has licensed North American development and commercialization rights for CPP-1X/sul to Mallinckrodt Pharmaceuticals, through its Sucampo AG subsidiary. CPP retains all rights elsewhere.

About Cancer Prevention Pharmaceuticals, Inc.

Cancer Prevention Pharmaceuticals, Inc. (CPP) is developing therapeutics designed to reduce the risk of cancer and other diseases. CPP's pharmaco-prevention approach has been used with success in other disease categories such as cardiovascular, neurovascular, and infectious disease. In addition to the CPP FAP-310 trial, CPP is co-sponsoring with the National Cancer Institute (NCI) and SWOG a large Phase 3 trial in colon cancer survivors. CPP is also working collaboratively with nonprofit groups to support their clinical trials in neuroblastoma, gastric cancer, and early-onset type 1 diabetes. CPP is located in Tucson, Arizona. For more information, please visit www.canprevent.com.

This press release contains forward-looking statements on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," and similar expressions. These statements are based upon our current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding the completion of the analysis of the results from the randomized, double-blind trial expected in early 2019, followed by potential submission of a NDA with FDA, bringing to FAP patients a pharmaco-prevention therapeutic that could change the treatment paradigm for their debilitating and life-threatening disease and clinicians being able to offer their FAP patients a safe and effective drug treatment that may reduce or potentially avoid the need for complex endoscopic or surgical intervention if the study results are favorable and CPP-1X/sul is approved by the FDA. The information in this release is provided only as of the date of this release.

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