



Independent Data Monitoring Committee Recommends Continuation of Cancer Prevention Pharmaceuticals' Phase 3 Trial for Familial Adenomatous Polyposis Patients

CPP-1X/sulindac aims to prevent disease progression

TUCSON, Arizona, June 12, 2017 – Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, announced today that an Independent Data Monitoring Committee (IDMC), following a planned interim futility analysis, recommended continuation of the company's pivotal Phase 3 trial, CPP FAP-310, evaluating CPP-1X/sulindac for adults with familial adenomatous polyposis (FAP).

FAP is a rare genetic disease that if left untreated progresses to colorectal cancer in nearly 100% of patients. 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.

"The IDMC's recommendation to continue this ongoing pivotal Phase 3 clinical trial is an important win for FAP patients and an important clinical milestone for CPP," said Jeff Jacob, Chair and CEO of the company. "We look forward to completing the trial and bringing to market a first-in-class pharmaco-prevention therapeutic."

The purpose of this randomized, double-blind, Phase III trial is to determine if the combination of eflornithine plus sulindac is superior to sulindac or eflornithine as single agents in delaying time to the first occurrence of any FAP-related event. The ongoing trial has enrolled 171 patients at 17 research institutes in the United States, Canada, and Europe. Patients receive daily treatments of CPP-1X/sulindac or one of the single agents for at least two years, during which the time to the first occurrence of any FAP-related event is evaluated. The US Food and Drug Administration (FDA) has granted CPP orphan drug designation for CPP-1X/sulindac for the treatment of FAP.

The IDMC is an independent group of experts that monitors patient safety and other data and makes recommendations on continuation of the clinical trial based on its findings.

For more information on the clinical trial (CPP FAP-310), please visit: <https://clinicaltrials.gov/ct2/show/NCT01483144>.

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,” “looks forward to,” 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 expected completion of the Phase 3 trial and our intent to bring to market a first-in-class pharmaco-prevention therapeutic. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those set forth or implied by any forward-looking statements including, among others, our ability to obtain the necessary regulatory approvals for commercialization of our therapeutics, our ability to commence or complete our clinical trials and those of our investigators on time or to achieve desired results, our ability to receive anticipated funding, our ability to successfully develop, market or sell our products, or our ability to maintain our material licensing agreements. The information in this release is provided only as of the date of this release, and we undertake no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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