



FOR IMMEDIATE RELEASE

**FDA Grants ‘Fast Track’ Status to  
Cancer Prevention Pharmaceuticals’ Lead Drug CPP-1X/sul  
for Treatment of Familial Adenomatous Polyposis**

*CPP-1X/sul aims to prevent disease progression  
in patients with Familial Adenomatous Polyposis*

TUCSON, Arizona, September 18, 2017 – Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted “Fast-Track” status for its lead drug CPP-1X/sul for adults with familial adenomatous polyposis (FAP), which is currently in a Phase 3 clinical trial. FAP is a rare genetic disease that if left untreated progresses to colorectal cancer in nearly 100% of patients. Currently there is no effective treatment for FAP.

The FDA’s Fast Track designation is intended to facilitate development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to patients earlier. Fast Track designation makes CPP’s drug eligible for Accelerated Approval and Priority review if relevant criteria are met. The FDA had previously also granted CPP-1X/sul orphan drug status for treatment of FAP.

“The FDA’s decision to grant Fast Track status for CPP-1X/sul is good news for FAP patients who currently have no approved therapies,” said Jeff Jacob, Chair and CEO of CPP. “It also means a potentially streamlined path to commercialization for CPP. The continuing support of our expert partner Sucampo Pharmaceuticals, Inc. in the US should help advance our FAP-310 clinical trial to completion and bring to market a first-in-class pharmaco-prevention therapeutic in FAP,” Jacob added.

CPP received \$8 million from Sucampo in January 2016 upon signing a collaboration agreement that grants Sucampo the sole option to acquire an exclusive license to commercialize CPP-1X/sul in North America. Sucampo, headquartered in Rockville, MD, also recently paid CPP another \$9.5 million (\$4.5 million in option fees and \$5 million in exchange for a convertible note).

The FAP-310 clinical trial is a randomized, double-blind, Phase 3 trial designed to determine if the combination of eflornithine plus sulindac is superior to eflornithine or sulindac as single agents in delaying time to the first occurrence of any FAP-related event. In June, an Independent Data Monitoring Committee conducted a futility analysis and recommended continuation of the Phase 3 trial, which is fully enrolled and expected to be completed in 2018 unless extensions are recommended. 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](http://www.canprevent.com).

### **About Sucampo Pharmaceuticals, Inc.**

Sucampo Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of highly specialized medicines. Sucampo has a late-stage pipeline of product candidates in clinical development for orphan disease areas, including VTS-270, a mixture of 2-hydroxypropyl-B-cyclodextrins with a specific compositional fingerprint that has been granted orphan designation in the U.S. and Europe and is in a pivotal Phase 2/3 clinical trial for the treatment of Niemann-Pick Disease Type C-1, a rare progressive genetic disorder. VTS-270 has also been granted breakthrough therapy designation in the U.S. Sucampo has an exclusive option for the North American rights to CPP-1X/sulindac, which is in Phase 3 development for the treatment of familial adenomatous polyposis and has been granted orphan drug designation in the U.S. The company has two marketed products – AMITIZA and RESCULA. For more information, please visit [www.sucampo.com](http://www.sucampo.com).

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*This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements about the benefits of Fast Track Status. These forward-looking statements represent the company's judgment as of the date of this release. The company disclaims, however, any intent or obligation to update these forward-looking statements.*

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