



FOR IMMEDIATE RELEASE

Cancer Prevention Pharmaceuticals (CPP) Extends Agreement with Sanofi as Exclusive Supplier of CPP-1X/sul

CPP preparing NDA and MAA filings for US and EU

TUCSON, Arizona, January 8, 2020 – Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, announced today the extension of a long-term agreement with Sanofi, a French multinational pharmaceutical company, to continue as the exclusive supplier of its lead drug candidate, CPP-1X/sul, for adults with familial adenomatous polyposis (FAP).

The agreement extends the 10-year supplier relationship through the regulatory submission process and for at least six years after approval of the drug.

FAP is a rare genetic disease that if left untreated progresses to colorectal cancer in nearly 100% of patients. FAP patients have no approved pharmaceutical therapies.

CPP recently completed the CPP FAP-310 trial, a Phase 3 trial comparing the performance of the combination of CPP-1X/sul (eflornithine + sulindac) to each single agent alone in delaying progression to an FAP-related event, such as surgery.

The trial design included FAP patients with varying lower and upper GI disease. The combination did not demonstrate statistical significance in outperforming the single agents in the overall population. However, further analysis of the data showed key differential effects of the agents in the lower vs upper GI anatomy. Focusing on lower GI anatomy (patients with an intact colon, retained rectum or surgical pouch), the data showed statistically significant benefit for CPP-1X/sul vs both single agents ($p \leq 0.02$) in delaying surgical events in the lower GI.

Also, the safety profile of the CPP-1X/sul combination did not significantly differ from that demonstrated by the single agents and did not pose any concerns for long-term use of the product.

“Approval of CPP-1X/sul could mean the first effective treatment for FAP patients who now have limited therapeutic options,” said CPP CEO Jeff Jacob. “Having this supply agreement in place also will optimize potential commercial launch of the product for CPP and any collaborators. Sanofi has been an excellent and reliable supplier, and we are very pleased the relationship will continue.”



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 subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward looking statements include statements that the data suggests that in adults with FAP, CPP-1X/sul may delay colorectal surgery, approval of CPP-1X/sul could mean the first effective treatment for FAP patients who now have limited therapeutic options and having the supply agreement in place also will optimize potential commercial launch of the product for CPP and any collaborators. 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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