



FOR IMMEDIATE RELEASE

Cancer Prevention Pharmaceuticals Completes North American Licensing Deal with Mallinckrodt

License includes 50/50 profit share and additional payments of up to \$185 million dependent on achieving clinical development and sales milestones, and subject to certain reductions

Phase 3 clinical trial results for CPP-1X/sul in patients with Familial Adenomatous Polyposis expected in 1H 2019

TUCSON, Arizona, Aug. 13, 2018 – Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, announced the signing of a license agreement with Mallinckrodt Pharmaceuticals, through its Sucampo AG subsidiary (“Mallinckrodt”), wherein Mallinckrodt obtained exclusive North American commercialization rights to CPP’s lead drug candidate, CPP-1X/sul.

In April 2018, UK-based Mallinckrodt had exercised its option to the license agreement, and paid CPP \$10 million to support the pivotal Phase 3 clinical trial of CPP-1X/sul in patients with the orphan disease familial adenomatous polyposis (FAP). Results from the FAP Phase 3 clinical trial are expected in the first half of 2019. FAP is a genetic disease that typically develops into colon cancer. There are no approved pharmaceutical treatments and no other drugs in late-stage clinical development.

Under the terms of the license agreement, Mallinckrodt paid CPP a \$5 million license fee. In addition, following commercialization of the product, CPP and Mallinckrodt will share profits equally on all North American sales of the drug. CPP is also eligible to receive up to an aggregate of \$185 million from Mallinckrodt, dependent upon achievement of other clinical development and sales milestones, subject to a reduction of up to \$15 million related to amounts provided by the company in advance of entering into this agreement. Each party will be reimbursed for its R&D expenses from future product profits. CPP maintains all global rights to CPP-1X/sul outside North America.

In connection with the transaction, CPP signed a service agreement with Mallinckrodt to assist with completing the FAP Phase 3 pivotal trial and certain activities supporting the preparation, filing and review of the NDA in the United States. CPP expects to be compensated for the services with additional R&D payments of up to approximately \$10 million.

“This is a significant milestone in our development of CPP-1X/sul,” said Jeff Jacob, Chair and CEO of CPP. “It will push this program across the finish line for NDA filing, assuming we hit our primary endpoint target. It also demonstrates Mallinckrodt’s support for this critically



important product, which could offer FAP patients their first real hope for treating this debilitating unmet medical need. We greatly appreciate Mallinckrodt's commitment and are very enthusiastic about our collaboration."

Steven Romano, M.D., Executive Vice President and Chief Scientific Officer of Mallinckrodt, said "In keeping with our focus on improving outcomes for patients with severe and critical conditions, Mallinckrodt looks forward to the opportunity of potentially bringing this therapy to patients with high unmet need."

The current standard of care for FAP requires patients to undergo the progressive removal of the colon and rectum, ongoing endoscopies of the gastrointestinal tract, and additional surgery throughout life. FAP has been designated an orphan indication in the U.S. and Europe, occurring in about 1 in 10,000 people, with an estimated 30,000 cases in the U.S. Last year the U.S. Food and Drug Administration granted CPP-1X/sul Fast Track designation, which provides a streamlined path to commercialization if approved.

The randomized, double-blind Phase 3 trial of CPP-1X/sul will determine if the combination of eflornithine plus sulindac is superior to either of the drugs as single agents in delaying time to the first occurrence of an FAP-related event. For more information on the clinical trial (CPP FAP-310) visit <https://clinicaltrials.gov/ct2/show/NCT01483144>.

About Cancer Prevention Pharmaceuticals, Inc.

Cancer Prevention Pharmaceuticals, Inc. (CPP), located in Tucson, AZ, is developing therapeutics designed to reduce the risk of cancer and other diseases. CPP's pharmacoprevention approach has been used with success in other disease categories such as cardiovascular, neurovascular, and infectious disease. In addition to the 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. For more information, please visit <http://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 about the continued Phase 3 trial of the CPP-1X/sul therapy. 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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