



FOR IMMEDIATE RELEASE

Marc L. Tokars Joins Cancer Prevention Pharmaceuticals as Vice President of Clinical and Regulatory Affairs

Company nearing completion of Phase 3 trial of lead drug, CPP-1X/sul, for Familial Adenomatous Polyposis

TUCSON, Arizona, October 22, 2018 – Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, announced today the appointment of Marc L. Tokars as Vice President for Clinical and Regulatory Affairs.

Tokars will lead all CPP's clinical, regulatory and quality assurance operations, including preparing a potential New Drug Application submission to the U.S. Food and Drug Administration (FDA) for CPP's lead drug CPP-1X/sul for adults with familial adenomatous polyposis (FAP). FAP is currently in a Phase 3 clinical trial, with final data expected early next year.

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. In 2017 the FDA granted "fast-track" status for CPP-1X/sul and previously also granted CPP-1X/sul orphan drug status.

"Marc brings decades of successful, strategic drug development experience to CPP as well as outstanding leadership skills in all facets of clinical, quality and compliance operations," said Jeff Jacob, chairman and CEO of CPP. "We believe that his deep knowledge of oncology and experience interacting with the FDA will be invaluable as we seek agency approval to bring this much-needed drug to patients who have no effective treatment options."

In April 2018, Mallinckrodt Pharmaceuticals exercised its option through the Mallinckrodt Plc Sucampo AG subsidiary and signed a license agreement for exclusive North American commercialization rights to CPP-1X/sul. Mallinckrodt paid CPP \$10 million to support the pivotal Phase 3 clinical trial.

"CPP has made significant progress advancing CPP-1X/sul through Phase 3 and is also building an impressive pipeline of multiple new therapies," said Tokars. "My immediate goal will be to help the CPP team bring CPP-1X/sul through the FDA approval process which will address a long overdue unmet medical need if the product is approved."

Tokars has 24 years' experience in clinical operations. He was most recently Vice President of Clinical Operations at Provepharm Pharmaceuticals where he had oversight of all preclinical and clinical trials conducted globally by the company as well as developing successful regulatory strategies and materials for FDA submission. Previously he was Vice President of Clinical



Operations at Luitpold Pharmaceuticals and Project Director of Omnicare. Tokars holds a BA in Biology from the University of Chicago.

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 sulindac or eflornithine as single agents in delaying time to the first occurrence of any FAP-related event. The final patient is expected to come off the trial in November 2018, with top-line results expected in 1H 2019. 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 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-IX/sul therapy and the contribution to the company by Marc L. Tokars. 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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