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Cancer Prevention Pharmaceuticals (CPP) and Mallinckrodt Announce Results from Pivotal Phase 3 Trial of CPP-1X/Sulindac in Patients with Familial Adenomatous Polyposis

May 7, 2019

-- Full data to be presented in detail by CPP at Digestive Disease Week (DDW) conference on May 19, 2019 at 5:19 pm Pacific Time --

TUCSON, Ariz. and STAINES-UPON-THAMES, United Kingdom, May 7, 2019 /PRNewswire/ -- Cancer Prevention Pharmaceuticals, Inc. (CPP), a private biotech company developing novel therapeutics to prevent cancer and other diseases, and its partner Mallinckrodt Plc (NYSE: MNK), a leading global specialty pharmaceutical company, today announced that CPP's pivotal phase 3 clinical trial, CPP FAP-310, of the investigational drug CPP-1X/sulindac in patients with familial adenomatous polyposis (FAP), did not meet its primary endpoint. Specifically, the reduction of time to the first occurrence of an FAP-related event for the combination of CPP-1X (eflornithine) and sulindac (a nonsteroidal anti-inflammatory drug) did not reach statistical significance compared to the two control arms. CPP FAP-310 included only active comparator arms and was the largest and longest study ever conducted in patients with FAP.

CANCER PREVENTION PHARMACEUTICALS

"While we are disappointed that the CPP FAP-310 clinical trial did not achieve its primary endpoint, we are encouraged by the data that relate to important outcome measures," said CPP CEO Jeff Jacob. "The results showed CPP-1X/sul was well tolerated and activity was observed in some patients, including strong signals for delaying the need for colon surgery."

Jacob continued: "We are analyzing the data and trial design to better understand the outcome, and look forward to presenting the data in detail at the upcoming DDW meeting. CPP will continue to explore all options with principal investigators as well as US and EU regulators in our commitment to seek a path forward."

Steven Romano, M.D., Chief Scientific Officer and Executive Vice President of Mallinckrodt, said, "We thank the physicians and patients who participated in the clinical trial, and are hopeful there is useful information to be gleaned from the study by clinicians treating patients with this very challenging disease."

Based on the topline results, Mallinckrodt does not plan to pursue the commercialization of the CPP-1X/sulindac program. Jacob added: "CPP is grateful to Mallinckrodt for their support of this program and the FAP patient community. We remain committed to FAP patients, for whom no approved pharmaceutical therapy exists, as well as our additional pipeline projects."

ABOUT CPP FAP-310

The CPP FAP-310 clinical trial, which enrolled 171 patients at 17 research institutes in the United States, Canada and Europe, is the largest-ever FAP clinical trial and treated patients for longer than any other trial. It was designed to determine if CPP-1X (eflornithine) in combination with sulindac is superior to sulindac or eflornithine as single agents in delaying time to the first occurrence of any FAP-related event. For more information on the clinical trial 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 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 Cancer Research Network 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.

ABOUT MALLINCKRODT
Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics. Its Specialty Generics and Amitiza® reportable segment includes specialty generic drugs, active pharmaceutical ingredients and AMITIZA (lubiprostone). To learn more about Mallinckrodt, visit www.mallinckrodt.com.

FORWARD-LOOKING STATEMENTS *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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