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FOR IMMEDIATE RELEASE

## **Cancer Prevention Pharmaceuticals Receives Positive Scientific Advice from EMA for CPP-1X Phase III TRIAL in FAP**

**Tucson, Arizona, July 27, 2011**—Cancer Prevention Pharmaceuticals, Inc. (CPP) has received positive advice from the European Medicines Agency (EMA) regarding its Phase III trial in Familial Adenomatous Polyposis (FAP).

A request for Scientific Advice is a process offered by the EMA to provide guidance on conduct of studies. This process is helpful to ensure that the studies are appropriately designed to minimize the risk of major objections being raised during the regulatory review. Scientific advice received from the EMA represents the agreed EU regulators' position on issues relating to an evaluation of safety, quality and efficacy.

The EMA advice included agreement on key design features such as its clinically important endpoint, study duration, statistical analysis plan, and comparator arms. The EMA's advice is consistent with guidance received from the FDA earlier this year and the Company is now poised to begin a multinational study in FAP that will be used to support registration in both European Union (EU) and the United States.

Jeffrey Jacob, CEO of CPP said, "this is truly a breakthrough for our Company and the FAP Community. We have worked closely with global Key Opinion Leaders (KOLs) and regulatory authorities in Europe and the US to create a new registration pathway that will have both regulatory and commercial impact if our trial is successful."

The CPP study is a departure from previous and traditional trial designs that focused on "polyp counting." Celecoxib was previously approved for FAP using the polyp counting endpoint with only a ~28% reduction in polyp burden but unfortunately never translated into a standard of care or proven clinical benefit. The FAP indication was recently withdrawn from the Celecoxib label. In a departure from these endpoints, CPP will target a delay in FAP-related events such as surgical events, duodenal disease, cancer, and death which are now accepted by the regulators as "clinically meaningful."

Mr. Jacob added, "both the FDA and EMA made it clear that endpoints focused only on polyp counting will no longer be accepted for registration. In a previous Phase II/III sporadic adenoma trial with our drug combination, our Founders showed 92%-95% efficacy in preventing the recurrence of high risk polyps—i.e., those at high risk of transforming into cancer. We believe, along with many KOLs around the world, that these dramatic results may be replicated in the FAP population—with the added benefit of delaying surgical events, duodenal disease, cancer, and death. With agreement and guidance from the regulatory authorities, we are now ready to move this important pivotal trial forward."

## **About Familial Adenomatous Polyposis (FAP)**

Familial adenomatous polyposis (FAP) is an inherited disorder characterized by cancer of the large intestine (colon) and rectum. It is a significant orphan disease afflicting 1-in-10,000 people (roughly 30,000 in the United States and 40,000-50,000 in Europe). The classic type of FAP results in multiple noncancerous (benign) growths (polyps) in the colon that can appear in children and teenagers. Unless the colon is removed, these polyps will eventually become malignant (cancerous). In people with classic FAP, the number of polyps increases with age, and hundreds to thousands of polyps can develop in the colon. FAP patients are subjected to numerous surgical and endoscopic procedures throughout their lives and ultimately face life threatening duodenal disease, desmoids, and cancer. FAP has been designated as an orphan disease by the United States FDA and the European Commission.

## **About CPP**

Cancer Prevention Pharmaceuticals, Inc. (CPP) is developing therapeutics that reduce the risk of cancer. CPP's approach has been used with great success in other disease categories such as cardiovascular, neurovascular and infectious disease. Agents that target pre-disease states have helped reduce death rates from these conditions by 50%-70% over the past 30 years. Just as these other prevention therapies represent the largest-selling drug classes on the market today (>\$25 billion), CPP believes there is even more potential for therapies that reduce the risk of cancer. In addition to its Phase III FAP study, CPP is also co-sponsoring a large Phase III trial in colon cancer survivors (N-1350) expected to begin in the second half of 2011. Additional information on CPP is available at [www.canprevent.com](http://www.canprevent.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 planned Phase III trial of the CPP-1X/sul combination therapy in FAP as well as the company's focus, collaborative partners, and independent and partnered product candidates. 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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