

Drug Development

Trial to Evaluate High-Risk Gastric Cancer Treatment Underway

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Cancer Prevention Pharmaceuticals in collaboration with the NCI and Vanderbilt University Medical Center

initiates Phase 2 trial to evaluate CPP-1X in patients with high risk of gastric cancer.

Cancer Prevention Pharmaceuticals, Inc. (CPP) announced the launch of a Phase 2 clinical trial at Vanderbilt University Medical Center to evaluate CPP-1X in patients with precancerous gastric lesions who are at high risk for gastric cancer.

The trial is funded by the National Cancer Institute (NCI) and run in collaboration with Keith T. Wilson, M.D., and Douglas R. Morgan, M.D., MPH, of Vanderbilt University School of Medicine, Vanderbilt University Medical Center, and the Vanderbilt-Ingram Cancer Center.

This randomized, double-blind, placebo-controlled pharmaco-prevention trial will enroll 300 patients. Each patient will receive daily treatment for 18 months to determine the drug's effectiveness in ameliorating DNA damage in patients with premalignant atrophic gastritis or intestinal metaplasia. This trial is an initial step in a program to determine if CPP-1X can prevent gastric cancer.

In 2015, CPP received Orphan Drug Designation for CPP-1X for the treatment of gastric cancer including cancer of the gastroesophageal junction from the U.S. Food and Drug Administration (FDA). CPP was also granted orphan designation in familial adenomatous polyposis and neuroblastoma in the United States and European Union.

"Our mission is to develop new therapeutics that focus on the prevention of cancer and its recurrence," said Jeffrey Jacob, CEO of CPP. "We are pleased to collaborate with the NCI and leaders in gastric cancer

prevention at Vanderbilt University to evaluate the potential of CPP-1X in reducing the progression of precancerous lesions in high-risk patients, and thereby help prevent gastric cancer.”

“Currently there are no agents for the prevention of gastric cancer in patients with precancerous conditions of the stomach,” said Dr. Wilson. “Gastric cancer, which is also known as stomach cancer, is the third leading cause of cancer-related deaths in the world, and we need prevention options for these patients,” added Dr. Morgan.

The American Cancer Society estimates the incidence of stomach cancer in the United States in 2015 to be about 24,590 cases, and about 10,720 people will die from this type of cancer this year.

CPP’s pharma partners have certain rights to CPP’s combination product CPP-1X/sulindac. CPP-1X as a standalone therapy is owned exclusively by CPP.

(Source: [Business Wire](#))

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