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Phase I Trial Data for Cornerstone Pharmaceuticals' CPI-613 in Combination with Modified Fluorouracil, Leucovorin, Irinotecan, and Oxaliplatin (mFOLFIRINOX) in Metastatic Pancreatic Adenocarcinoma to Be Presented at the Annual Gastrointestinal Cancers Symposium

Combination may be More Active than FOLFIRINOX Alone

CRANBURY, NEW JERSEY (January 22, 2016) – Cornerstone Pharmaceuticals, Inc., a leader in the growing field of cancer metabolism-based therapeutics, today announced that data from the Phase I clinical trial evaluating CPI-613 in combination with modified fluorouracil, leucovorin, irinotecan, and oxaliplatin (mFOLFIRINOX) to treat metastatic pancreatic adenocarcinoma to Be Presented at the Annual Gastrointestinal Cancers Symposium, held by the American Society of Clinical Oncology (ASCO) in San Francisco, California on Friday, January 22, 2016. CPI-613 is the company's lead Altered Energy Metabolism Directed (AEMD) drug candidate, a first-in-class anticancer compound designed to disrupt the altered energy production pathways in cancer cells by targeting mitochondrial metabolism.

The trial was performed at Wake Forest Baptist Medical Center. Dr. Angela T. Alistar is the Principal Investigator for the trial as well as the lead author of the poster presentation.

"We are very pleased that Dr. Alistar's results have been accepted for presentation by ASCO at this prestigious event," said Steve Carchedi, Chief Executive Officer of Cornerstone Pharmaceuticals. "We look forward to working with Wake Forest Baptist on continuing clinical trials in this patient population to further investigate this combination therapeutic approach."

The open-label, dose-escalation Phase I trial was designed to determine the maximum tolerated dose (MTD), safety, and efficacy of CPI-613 given intravenously in combination with mFOLFIRINOX. A total of 20 patients presenting with Stage IV pancreatic adenocarcinoma were enrolled in the trial. The MTD for CPI 613 was identified at 500mg/m2. The treatment combination was determined to be feasible and well-tolerated, with no Grade 5 adverse events reported, and the combination treatment was further found not to have higher toxicity than FOLFIRINOX alone. The objective response rate for the treatment combination was 56 %, higher than that for FOLFIRINOX alone, which was reported in published Phase 3 trial results as 31.6%. One patient demonstrated a complete radiologic and clinical response, while two other patients showed near-complete responses. The preliminary efficacy data of this Phase I trial shall inform a multi-institutional randomized phase II study of FOLFIRINOX vs. m FOLFIRINOX + CPI613 in the near future.

About CPI-613

CPI-613 is the lead drug candidate from Cornerstone's proprietary AEMD platform. Cornerstone's AEMD drug platform disrupts the essential "bioenergetic" differences that support the growth and development of many types of cancer cells. In the case of CPI-613, the compound has been shown to selectively induce inhibition of pyruvate dehydrogenase (PDH) and alpha ketoglutarate dehydrogenase (KGDH), key mitochondrial enzymes involved in cancer cell metabolism in vitro. Disruption of PDH and KGDH function cuts off the tumor's energy supply, culminating in cell death. CPI-613 is currently being evaluated in Phase I, I/II, and II human clinical trials in solid tumors and hematological malignancies.

About Cornerstone Pharmaceuticals

Cornerstone Pharmaceuticals, Inc. is a clinical stage, oncology-focused pharmaceutical company committed to the development and commercialization of therapies that exploit the metabolic differences between normal cells and cancer cells. The company's primary objective is to develop highly selective and effective agents with minimal toxic effects on normal cells and tissues. The company's unique approach to targeting cancer metabolism has led to two distinct technology platforms: altered energy metabolism directed, or AEMD, compounds and an Emulsiphan lipid nanoemulsion based drug delivery system. www.cornerstonepharma.com.

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This release contains forward-looking statements. These statements relate to future events or the company's future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential" or "continue", the negative of such terms, or other comparable terminology. These statements are only predictions. Actual events or results may differ materially from those in the forward-looking statements as a result of various important factors. Although we believe that the expectations reflected in the forward-looking statements are reasonable, such statements should not be regarded as a representation by the company, or any other person, that such forward looking statements will be achieved. The business and operations of the company are subject to substantial risks which increase the uncertainty inherent in forward-looking statements. We undertake no duty to update any of the forward-looking statements, whether as a result of new information, future events or otherwise. In light of the foregoing, readers are cautioned not to place undue reliance on such forward-looking statements.