

RAMP 205: A Phase 1b/2a Study of Gemcitabine and Nab-paclitaxel in Combination with Avutometinib (VS-6766) and Defactinib in Patients with Previously Untreated Metastatic Adenocarcinoma of the Pancreas

Study Overview:

The purpose of the first part of the RAMP 205 study (or trial) is to see whether a combination of investigational drugs called avutometinib (VS-6766) and defactinib are safe when given in combination with standard chemotherapy drugs (gemcitabine and nab-paclitaxel) to patients with untreated metastatic PDAC. During the first part of the study, different doses of the four-drug combination will be tested to figure out the highest dose that can be tolerated. The second phase of the RAMP 205 study will assess how effective the four-drug combination is at preventing tumors from growing, reducing the size of tumors, and completely getting rid of tumors. It is possible that patients with a KRAS mutation, a genetic mutation that is common in PDAC, may have a different response to the drugs compared to patients who lack a KRAS mutation. For this reason, blood and tissue samples will be collected during the study to help researchers better understand the impact of KRAS mutations on treatment outcomes. The blood and tissue samples will also be used to answer other important research questions in the future.

Patients who are eligible and agree to participate in the study will be treated with a combination of avutometinib, defactinib, gemcitabine and nab-paclitaxel, with follow up appointments. This is an open-label trial. Every patient will be treated with active oral study drugs and standard of care chemotherapy, and their investigator will not be comparing it to a placebo. The study is being conducted by gastrointestinal cancer specialists.

Avutometinib and defactinib are investigational drugs that have not been approved by the U.S. Food and Drug Administration (FDA).

This study is being done in collaboration with the Pancreatic Cancer Action Network (PanCAN).

Protocol Title:

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Protocol Numbers:

VS-6766-205 (Verastem, Inc.)

Clinical Trial NCT05669482

Study Drugs or Compounds: Avutometinib (VS-6766) and Defactinib (VS-6063)

Study Phase: Phase 1b/2a

Total Enrollment: Estimated at 39 patients

