Trial record **1 of 1** for: AM0010-301

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Study of AM0010 With FOLFOX Compared to FOLFOX Alone Second-line Tx in Pts With Metastatic Pancreatic Cancer (Sequoia)

ClinicalTrials.gov Identifier: NCT02923921

Recruitment Status: Recruiting
First Posted: October 5, 2016
Last Update Posted: June 28, 2018

See Contacts and Locations

Sponsor:
ARMO BioSciences

Information provided by (Responsible Party):
ARMO BioSciences

Study Description

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Brief Summary:
To compare the efficacy of AM0010 in combination with FOLFOX versus FOLFOX alone in patients with metastatic pancreatic cancer as measured by overall survival

Condition or disease	Intervention/treatment	Phase
Pancreatic Cancer	Biological: AM0010 Drug: FOLFOX	Phase 3

Detailed Description:
This is an open-label, multi-center, randomized, Phase 3 study designed to compare the efficacy and safety of AM0010 in combination with FOLFOX versus FOLFOX alone in patients with metastatic adenocarcinoma of the pancreas who have progressed on one prior gemcitabine containing regimen.

Study Design

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Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	566 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Randomized Study of AM0010 in Combination With FOLFOX Compared to FOLFOX Alone as Second-line Tx in Pts With Meta Pancreatic Cancer That Has Progressed During or Following a First-Line Gemcitabine Containing Regimen
Study Start Date:	November 2016
Estimated Primary Completion Date:	January 2019
Estimated Study Completion Date:	January 2020

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Pancreatic Cancer

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: ARM 1 AM0010 (5 µg/kg) dosed on Days 1-5 and Days 8-12 SQ plus FOLFOX (dl-LV 400 mg/m2 and oxaliplatin 85 mg/m2 followed by bolus 5-FU 400 mg/m2 and a 46-hour infusion of 5-FU 2400 mg/m2) initiated on Day 1 of a 14-day cycles or until disease progression.	Biological: AM0010 AM0010 plus FOLFOX Drug: FOLFOX FOLFOX Alone Other Names: • oxaliplatin • 5-FU • leucovorin
Active Comparator: ARM 2 FOLFOX (dl-LV 400 mg/m2 and oxaliplatin 85 mg/m2 followed by bolus 5-FU 400 mg/m2 and a 46-hour infusion of 5-FU 2400 mg/m2) initiated on Day 1 of a 14-day cycles or until disease progression.	Drug: FOLFOX FOLFOX Alone Other Names: • oxaliplatin • 5-FU • leucovorin

Outcome Measures

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Primary Outcome Measures :

1. Overall Survival [Time Frame: 36 months after the last patient randomized]

Secondary Outcome Measures :

1. Progression Free Survival [Time Frame: 36 months after the last patient randomized]
2. Objective Response Rate [Time Frame: 36 months after the last patient randomized]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. The presence of metastatic pancreatic adenocarcinoma
2. Measurable disease per RECIST v.1.1
3. Patient must have documented tumor progression during or following a gemcitabine containing regimen to treat metastatic disease as established by CT or MRI scan
4. Eastern Cooperative Oncology Group Performance Status of 0 - 1
5. Patient must have completed prior chemotherapy at least 2 weeks (washout period) prior to randomization and recovered from toxicity to Grade 1 or baseline
6. Patients must not have received previous radiation therapy or investigational therapy for the treatment of advanced metastatic disease.
7. Patients having received cytotoxic doses of gemcitabine or any other chemotherapy in the adjuvant setting are not eligible for this study
8. No peripheral neuropathy
9. No known history of dihydropyrimidine dehydrogenase deficiency

Exclusion Criteria:

1. Diagnosis of pancreatic islet neoplasm, acinar cell carcinoma, non- adenocarcinoma (i.e., lymphoma, sarcoma), adenocarcinoma originating from the biliary tree, or cystadenocarcinoma
2. Patient on Coumadin and not willing to change to LMWH or oral Factor II or Xa inhibitor with half-life of less than 24 hours.
3. Patient has received prior treatment with AM0010 or fluoropyrimidine/platinum containing regimen
4. Patients who were intolerant of a gemcitabine containing regimen.
5. History of positivity for human immunodeficiency virus

6. Chronic active or active viral hepatitis A, B, or C infection
7. Clinically significant bleeding within two weeks prior to randomization (e.g., gastrointestinal (GI) bleeding, intracranial hemorrhage)
8. Pregnant or lactating women
9. Patients with a history of immune-mediated neurological disorders such as multiple sclerosis, Guillain-Barré or inflammatory CNS/PNS disorders
10. Clinically significant ascites defined as requiring ≥ 1 paracentesis every 2- weeks
11. Major surgery, defined as any surgical procedure that involves general anesthesia and a significant incision (i.e., larger than what is required for placement of central venous access, percutaneous feeding tube, or biopsy),within 28 days prior to randomization or anticipated surgery during the study period
12. Prior history of receiving immune modulators including, but not limited to, anti-CTLA4, anti-PD1, anti-PD-L1

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02923921***

Contacts

Contact: Study Director 650-771-9325 **AM0010-301**@armobio.com

Show 153 Study Locations

Sponsors and Collaborators

ARMO BioSciences

More Information

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Responsible Party:	ARMO BioSciences
ClinicalTrials.gov Identifier:	NCT02923921 History of Changes
Other Study ID Numbers:	**AM0010-301**
First Posted:	October 5, 2016 Key Record Dates
Last Update Posted:	June 28, 2018
Last Verified:	June 2018

Additional relevant MeSH terms:

Pancreatic Neoplasms	Digestive System Diseases
Digestive System Neoplasms	Pancreatic Diseases
Neoplasms by Site	Endocrine System Diseases
Neoplasms	Oxaliplatin
Endocrine Gland Neoplasms	Antineoplastic Agents